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42 CFR Parts 402 and 403

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 402 and 403

[CMS–5060–F]

RIN 0938–AR33

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will require 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 Web site.

DATES: *Effective date:* These regulations are effective on April 9, 2013.

Compliance date: Applicable manufacturers and applicable group purchasing organizations must begin to collect the required data on August 1, 2013 and report the data to CMS by March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Erica Breese, (202) 260–6079.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary for This Final Rule

1. Purpose

This final rule is necessary to implement the requirements in section 6002 of the Affordable Care Act, which added section 1128G to the Social Security Act (the Act). That provision requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children's Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other

transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

We believe that these provisions of the Act were modeled largely on the recommendations of the Medicare Payment Advisory Commission (MedPAC), which voted in 2009 to recommend Congressional enactment of a new regulatory program. In addition, the Institute of Medicine (IOM) recommended implementing a national disclosure program for payments to health care providers and prescribers in the 2009 report titled, "Conflict of Interest in Medical Research, Education and Practice." Given these recommendations and other information on conflicts of interest that could affect treatment decisions, Congress enacted legislation establishing a national disclosure program with section 6002 of the Affordable Care Act. This final rule provides the implementing requirements for this program.

2. Summary of the Major Provisions

a. Transparency Reports

This rule finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients. The rule provides definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply. In addition, the rule also 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. The rule also finalizes which payments or other transfers of value are excluded from the reporting requirements.

In addition, the rule 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. The rule details what constitutes an ownership or investment interest for purposes of the reporting requirements, and defines for whom they must be reported. The rule also clarifies the content for the ownership or investment interest report.

b. Report Submission, Correction, and Publication

The 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. The rule also 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. In addition, the rule clarifies the information to be included on the publicly available Web site, as well as the usability of the public Web site. Finally, the rule includes details on the processes for reporting and publishing payments or other transfers of value which are eligible for delayed publication.

c. Penalties

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.

d. Annual Report

The rule finalizes the details of the annual reports to Congress and the States.

e. Relation to State Laws

The rule clarifies the statutory requirements for the pre-emption of State laws.

3. Summary of Costs and Benefits

Based on the comments submitted, we anticipate that much of the total estimated burden of this final rule will fall on applicable manufacturers and applicable GPOs. We have estimated that the total cost of these provisions will be approximately \$269 million in the first year and \$180 million annually thereafter. We have no empirical ability to estimate the monetary benefits of this provision; however, there are nonmonetary benefits, which are difficult to quantify. 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.

B. Background

1. Legislative Overview (Statutory Background)

Section 6002 of the Affordable Care Act added section 1128G to the Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a State plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities.

Specifically, manufacturers of covered drugs, devices, biologicals, and medical supplies (applicable manufacturers) are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to the Secretary of the Department of Health and Human Services (HHS) (the Secretary) in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to the Secretary the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. The Secretary is required

by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each State summarizing the data reported. Finally, section 1128G of the Act generally preempts State laws that require disclosure of the same type of information by manufacturers.

2. Transparency Overview

We recognize that collaboration among physicians, teaching hospitals, and industry manufacturers contributes to the design and delivery of life-saving drugs and devices and we received many comments supporting this statement. However, as discussed in the proposed rule and in the public comments submitted, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interest that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.

We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts. Given the intricacies of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones, we have worked closely with stakeholders to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers. In addition to this feedback, we consulted with the HHS Inspector General, as required by the statute. Our conclusions and interpretations in the preamble are solely for purposes of this regulation and do not apply in other contexts.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the December 19, 2011 proposed rule (76 FR 78742), we solicited public comment on a number of proposals regarding transparency reports and the reporting of physician ownership or investment interests. In response to our solicitation, we received approximately

373 timely public comments. Most of the public comments addressed provisions included in the proposed rule. We received some comments that were outside the scope of the proposed rule and, therefore, will not be addressed in this final rule. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this final rule, we have organized the document by presenting our proposals, summarizing and responding to the public comments for the proposal(s), and describing our final policy.

The following sections outline the agency's directives concerning implementation of section 1128G of the Act, including clarification of the terms and definitions used in the statute, as well as procedures for the submission, review, and publication of the reported data. For terms undefined by the statute, we have provided definitions where appropriate to provide additional clarity, as well as explanations of how we interpret such terms. During the public comment period, we received numerous comments on how to approach and structure the final rule, such as providing additional examples and memorializing intentions in the regulatory text. We appreciate the comments and have endeavored to develop a final rule that allows for reporting flexibility while also providing sufficient detail, clarity, and standardized processes, in order to better ensure the accuracy of the published data. Throughout the final rule, time periods referenced in days are considered to be calendar days, unless otherwise noted.

A. Timing

This final rule has not been published in time for applicable manufacturers and applicable GPOs to begin collecting the information required in section 1128G of the Act on January 1, 2012, as provided in the statute. In the proposed rule, we indicated that we would not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of this final rule. We proposed a preparation period of 90 days. Additionally, we considered requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013. We also stated that we were considering requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013, and requested comments on the feasibility of a partial year collection.

Comment: Many 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.

A number of these commenters suggested that the reporting requirements begin as quickly as possible following the publication of the final rule, in order to ensure that there is sufficient time for data to be collected for a partial year of 2012. These commenters recommended a 30-day preparation period. Conversely, many other commenters requested that the data collection requirement not begin until January 1, 2013, stating that the data collection requirement for collecting a partial year of data would be difficult and overly burdensome. Other commenters did not address the beginning date for data collection, but instead advocated for a longer preparation period than the proposed 90 days. The majority of these commenters requested an 180-day preparation period, but a few suggested longer, with the longest being 15 months. Some commenters also requested that regardless of the timing, data collection should begin at the beginning of a quarter and also explained that making systems changes during the last quarter of a year would be difficult.

Response: We appreciate these comments and agree that data collection needs to begin as soon as reasonably possible; however, to allow us time to address the important input we received from stakeholders during the rulemaking process, we announced in May 2012 that we would not require the collection of any data before January 1, 2013. We are finalizing that the data collection requirement will begin on August 1, 2013, allowing about an 180-day preparation period. We believe that this is a sufficient amount of time for applicable manufacturers and applicable GPOs to prepare.

Comment: A few commenters requested that CMS modify the reporting requirements for the first year. Some suggested easing the initial burden by phasing in reporting with a higher minimum dollar threshold, while others recommended collecting more data for 2012 by requiring retroactive reporting.

Response: We appreciate these comments, but we do not believe that we have authority to amend the reporting requirements for the first year. In addition, we believe that changing the reporting requirements for a single year would be operationally difficult, since both CMS and applicable

manufacturers and applicable GPOs would have to develop systems and then change them after the first year. The statute sets forth the minimum threshold for reportable payments and does not appear to provide any authority for us to change it. We believe that because the threshold is provided in the statute itself, applicable manufacturers were given adequate notice of the threshold amount and should be able to prepare for it. We are also concerned that changing the threshold for 1 year would be confusing to users. With regard to retroactive reporting, we similarly believe that we do not have the authority to require this and will not adopt that approach.

After consideration of the public comments received and given the timing of the final rule, we are establishing that data collection will begin on August 1, 2013 and must be reported to us by March 31, 2014. There will be no retroactive reporting.

B. Transparency Reports

Section 1128G(a) of the Act outlines the transparency reporting requirements and consists of two paragraphs. The first, section 1128G(a)(1) of the Act, outlines the required reports from applicable manufacturers on payments or other transfers of value to covered recipients. The second, section 1128G(a)(2) of the Act, outlines the reporting requirements for 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. While there is some overlap between these submissions, we proposed that these two types of information be reported separately to ensure that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. We solicited comment on this general approach, but received no comments, so we are finalizing this provision as proposed.

Additionally, we also want to emphasize that compliance with the reporting requirements of section 1128G of the Act does not exempt applicable manufacturers, applicable GPOs, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act). However, we also want to make clear that the inclusion of

a payment or other transfer of value, or ownership or investment interest on the public database does not mean that any of the parties involved were engaged in any wrongdoing or illegal conduct.

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

a. Applicable Manufacturers

While the term applicable manufacturer was defined in section 1128G of the Act, we provided additional clarification in the proposed rule. In this section, we aim to even more clearly define the entities that will be required to report.

(1) Definition of Applicable Manufacturer

In the proposed rule we defined “applicable manufacturer” for the purposes of this regulation as an entity that is—

- 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 defining applicable manufacturer, we interpreted the statutory phrase “operating” in the United States, or in a territory, possession, or commonwealth of the United States in section 1128G(e)(2) of the Act, as “for sale or distribution” in the United States, or in a territory, possession, or commonwealth of the United States.

Comment: Many commenters expressed concern with CMS’s interpretation of the phrase “applicable manufacturer.” Specifically, many commenters suggested that the phrase “for sale or distribution” is overly broad and would apply to nearly any entity in the world involved in the manufacturing chain or marketing of a covered drug, device, biological, or medical supply (referred to generally for purposes of this rule as a “covered product”) that is ultimately sold or distributed in the United States, even if such entity has no operations in the United States. These commenters

recommended that CMS retain the statutory language and define the phrase “operating” in the United States as having a physical location in the United States or conducting business activities in the United States. Several commenters agreed with and supported the proposed definition.

Response: We appreciate the comments and agree that the proposed definition may have inadvertently captured entities that operate wholly outside the United States, many of which may have little or no interaction with U.S. health care providers. We did not intend to capture foreign entities that may contribute to the manufacturing process of a covered product, but have no business presence in the United States. Accordingly, we have decided to revise the definition by retaining the statutory phrase operating in the United States, which we defined as having a physical location within the United States, or otherwise conducting activities within the United States or in a territory, possession, or commonwealth of the United States. We believe that any manufacturer, foreign or not, which operates in the United States (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured. Therefore, under this final rule, entities based outside the United States that *do* have operations in the United States are subject to the reporting requirements. Additionally, we note that entities that have operations in the United States 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 United States. Such payments are considered to be made by the entity that is operating in the United States as an indirect payment or other transfer of value and must be reported as such, so long as the entity operating in the United States is aware of the identity of the covered recipients receiving the payments as required for all indirect payments or other transfers of value.

Comment: Many commenters recommended additional limitations on the scope of the definition of applicable manufacturer. A few commenters suggested CMS limit the definition to manufacturers directly involved in manufacturing of the final products, and not entities that supply components and raw materials. In addition, many commenters stated that the definition should not include hospitals or other entities that produce covered products for sale to or use by their own patients only. A few commenters provided

similar comments that entities that produce or compound products or tests should be exempt from the definition. For example, many pharmacies compound medications in small batches for individual patients at the direction of a prescribing physician.

Response: We recognize that entities that only manufacture raw materials or components may differ from manufacturers of the final product, and we believe that the statutory framework already treats them differently. The definition of “applicable manufacturer” is dependent on the definition of “covered drug, device, biological or medical supply.” Raw materials and components often do not meet the definition of covered drug, device, biological, or medical supply because payment is not available for them in their component form under Medicare, Medicaid or CHIP. 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. In the event a supplier of raw materials is under common ownership with an applicable manufacturer, it will be subject to the reporting requirements for entities under common ownership, including options for consolidated reporting with the applicable manufacturer.

In addition, we agree with the comments regarding hospitals, pharmacies, and laboratories that produce or manufacture materials and products solely for their own use or use by their patients. We believe that it was not the intent of the statute to include these entities as applicable manufacturers, since they are not listed in the statute as manufacturers. Given these considerations, we have revised the definition of applicable manufacturer to exclude 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. In addition, 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.

Comment: Many commenters addressed whether distributors and wholesalers, including repackagers, relabelers, and kit assemblers, met the definition of applicable manufacturer. These entities were not specifically addressed in the proposed rule other than the recognition that there are other definitions of “manufacture,” “manufacturer” and “manufacturing” with which industry may be familiar (such as those in 21 CFR 207.3, 21 CFR 210.3(b)(12), 21 CFR 820.3(o), and 42 U.S.C. 1396r–8(k)(5)). The commenters represented both sides—some advocated that these types of entities meet the definition, while others advocated that they do not. Some commenters noted that distributors and wholesalers purchase and often take the title to covered products and then sell them to providers. The distributor may or may not rebrand or repackage the product before resale. Commenters on both sides referred to other definitions of “manufacturer” and “manufacture” both in the Affordable Care Act and elsewhere, some of which specifically reference distributors and some of which did not, similar to the statutory definition in section 1128G(e)(9) of the Act. The advocates for including distributors and wholesalers state that because these entities are involved in “preparation” and “propagation” of covered products, they should be included based on the statutory definition. Conversely, other commenters stated that distributors and wholesalers stock multiple competing products, so they do not try to sway purchasing decisions in the same way as a manufacturer.

Response: We agree that distributors and wholesalers (which include repackagers, relabelers, 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. We believe that distributors that hold the title to a covered product are similar to applicable manufacturers since both hold title to the product at some point in the production and distribution cycle. These entities will be subject to the same requirements as all other applicable manufacturers, as described in more detail in this section. 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. Finally, 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.

(2) Limitations to the Definition of Applicable Manufacturer

In the preamble to the proposed rule, we clarified that the applicable manufacturer definition included entities that hold Food and Drug Administration (FDA) approval, licensure, or clearance for a covered drug, device, biological, or medical supply, even if they contract out the actual physical manufacturing of the product to another entity. We interpreted these entities as being “engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply.” However, we did not address whether the entity manufacturing the product under contract is an applicable manufacturer. We also proposed that any manufacturer that meets the definition of applicable manufacturer by manufacturing at least one covered drug, device, biological or medical supply (as defined later in this section) would be considered an applicable manufacturer, even though it may also manufacture products that do not fall within that category.

Comment: A few commenters requested clarification on the reporting requirements for situations when the license-holder is not the manufacturer or the manufacturing process is contracted out. These commenters recommended that if an entity, which manufactures a covered product under contract, but does not market or distribute the product and is not an applicable manufacturer otherwise, then the entity does not meet the definition and does not need to report.

Response: We agree that additional clarification is necessary, although we recognize that it is difficult to anticipate all potential manufacturing arrangements. In general, we believe that our proposed position to require reporting by an entity that holds an FDA approval, licensure, or clearance for a covered product is appropriate. Such entities are clearly “engaged in the production, preparation, propagation, compounding, or conversion” of a covered product. We did not receive any comments on this and are finalizing it as proposed. For the contracted entity conducting the actual manufacturing, we believe 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, we are finalizing that entities that manufacture any covered product are applicable manufacturers, even if the manufacturer does not hold the FDA approval, licensure, or clearance. While we recognize that such entities do not necessarily market the product, we believe it is clear that they do manufacture it. However, we also understand that these manufacturers’ business model may not be focused on covered products. Therefore, 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*. This is described in the regulatory text at § 403.904(b)(4). 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. We believe that this is consistent with our treatment of other manufacturers with business models that are not focused on covered products, as discussed in more detail in this section. Finally, no payment or other transfer of value should be reported more than one time by a single entity.

Comment: Several commenters also discussed CMS’s proposed decision to require applicable manufacturers to

report all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies. While a few commenters supported this proposal, others did not. Entities and organizations with only a small number of covered products believed that reporting all payments would be overly burdensome and recommended limiting the definition to manufacturers that obtain a certain percentage (generally 5 or 10 percent) of their sales or revenues from covered products.

Response: We stand by our decision to require reporting of all payments or transfers of value to covered recipients rather than only payments related to covered drugs, devices, biologicals, and medical supplies and discuss this decision more fully in section II.B.1.b of this final rule. We do not believe that all payments or other transfers of value are related to particular covered products, so we do not want an applicable manufacturer to avoid reporting by representing certain payments or other transfers of value to covered recipients as being unrelated to covered products.

However, we are sensitive to applicable manufacturers whose primary business focus is not the production of covered drugs, devices, biological or medical supplies, but may still produce one or a few covered products. We recognize that since so few of their products are covered, many of their competitors will not be subject to the reporting requirements, providing the competitors with a potential competitive advantage. Despite this recognition, we also do not believe that these entities should be exempt from all reporting, since other manufacturers of the same covered products with a different business model would be subject to reporting. We recognize that these applicable manufacturers could also classify payments or other transfers of value as unrelated to a covered drug, device, biological or medical supply in order to try to avoid the reporting requirements; however, we believe the burden on these applicable manufacturers of reporting all interactions related to all products (not just covered drugs, devices, biologicals, or medical supplies) outweighs this concern. Therefore, we have 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. We selected a 10-percent threshold based on the public comments that we received suggesting a range from 5 to 10 percent; we chose the higher percentage in order to reduce the reporting burden on a greater number of entities.

Comment: A few commenters also requested additional clarification on when an entity with no covered products becomes an applicable manufacturer because payment becomes available for one of the company's products under Medicare, Medicaid or CHIP (for example, because a manufacturer's only product received FDA approval). Most of the commenters simply requested clarification, since this was not addressed in the proposed rule. However, a commenter suggested that CMS should allow new applicable manufacturers a grace period (for example, 180 days) to allow the manufacturer time to prepare to comply with the data collection requirements.

Response: We agree that we should provide clarification on when a product becomes "covered" and, thus, when an applicable manufacturer who did not previously have any other covered products becomes subject to the data collection and reporting requirements under this rule. We will allow the applicable manufacturer a grace period of 180 days following a product becoming "covered" to begin complying with the data collection and reporting requirements. We believe this is appropriate because it is the same preparation period allowed after the publication of the final rule, allowing all new applicable manufacturers the same time to prepare for complying with the data collection and reporting requirements.

(3) Common Ownership

The definition of applicable manufacturer includes entities under common ownership with an applicable manufacturer. We proposed to define "common ownership" as when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. This would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries

and brother/sister corporations. In addition, we also included an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. This would be subject to the same requirements as the definition described previously, but would only apply to common interests of 5 percent or more.

Regarding how applicable manufacturers under common ownership will submit reports, we proposed that if two or more entities individually met the proposed definition of an applicable manufacturer under paragraph (1) of the definition, the entities should report separately under section 1128G of the Act. However, if only one company under common ownership met the proposed definition of applicable manufacturer under paragraph (1) of the proposed definition, and the other company is required to report under paragraph (2) of the definition, then the affected entities can choose whether or not to report together. Additionally, we proposed that a payment or other transfer of value provided to a covered recipient in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers must be reported in the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers.

Comment: Many commenters did not support the agency's definition of common ownership. These commenters generally recommended that a threshold greater than the proposed alternative of 5 percent be applied to determine common ownership. The commenters that support a higher threshold generally advocated for a "common control" standard, which is traditionally a greater ownership percentage of 50 to 80 percent, rather than an affiliate status, which is generally around 5 percent. Conversely, some commenters supported the proposed definition, as well as the 5 percent alternative.

Response: We appreciate the comments and have decided to finalize the 5-percent ownership threshold for common ownership. We recognize that this is a lower threshold than many of the commenters recommended; however, we believe this is appropriate.

We believe that had Congress intended to establish a "common control" standard, it would have used that term, rather than "common ownership." Similarly, a 5-percent threshold for common ownership is used elsewhere in the Act, in other CMS regulations, and is one with which entities are familiar. For example, section 1124(a)(3) of the Act defines the term "person with an ownership or control interest," in part, as a person who has a direct or indirect ownership interest in an entity of at least 5 percent. We also believe that clarifying when an entity under common ownership has to report (as explained in this section) will help reduce the number of entities under common ownership reporting.

Comment: Many commenters also requested additional clarification on how the agency was interpreting "assistance and support" for entities under common ownership, since only entities under common ownership which provide "assistance and support" for the listed manufacturing activities need to report. These commenters varied in their suggestions, but most advocated a narrow interpretation, such as only those involved in sales and marketing or those entities integral or necessary to the manufacturing process. In addition, some commenters questioned whether separate operating divisions, which are not related to covered products, such as the animal health division or over-the-counter drugs division, need to report. The commenters advocated that reporting of these divisions would be confusing, since they are unrelated to covered products.

Response: We appreciate these comments and agree that we should provide greater clarification to help identify the entities under common ownership which are required to report. We define "assistance and support" as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. For example, an entity under common ownership which produces the active ingredient for a covered drug and provides it to the applicable manufacturer for inclusion in the final product would be considered necessary to the manufacturing of that product, since the applicable manufacturer could not produce the drug without the active ingredient. Conversely, 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.

In general, we believe that all payments or other transfers of value related to covered products should be reported, but that we should minimize the reporting of payments or other transfers of value unrelated to covered products. The final rule does not require entities under common ownership to report when they are not necessary or integral to manufacturing, and are not applicable manufacturers in and of themselves. However, an indirect payment or other transfer of value made to a covered recipient through an entity under common ownership that is not necessary or integral to the manufacturing process must still be reported as required for indirect payments or other transfers of value. In addition, we believe that 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.

Finally, 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," we believe 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). We believe 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, we are finalizing 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.

Comment: Many commenters advocated that CMS should allow entities more flexibility to submit consolidated reports, regardless of whether an entity meets the definition of applicable manufacturer under paragraph 1 or 2 of the proposed definition and at the company or operating division level. These commenters explained that manufacturers may have complicated corporate structures and reporting systems and suggested that the agency provide additional flexibility in reporting. Additionally, the commenters noted that consumers may not be familiar with the names of manufacturers' smaller divisions and, therefore, publication of the data under the names of the smaller divisions could limit the usefulness of the published data to consumers. Other commenters agreed with increased flexibility, but advocated that the reports should clearly state what entities are included in the report, including reporting which payments were made by which entity.

Response: We agree that entities should have more flexibility to report together or separately. Therefore, we clarified in § 403.908(d) that applicable manufacturers under paragraph 1 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. Additionally, as we stated in the proposed rule, 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 of the definition also may, but are not required to, file a consolidated report. We believe that this will make reporting less burdensome to entities and will provide more clarity to consumers. However, we are concerned that it will not be clear to CMS or consumers which companies are under common ownership and are either reporting together or separately. Therefore, if multiple applicable manufacturers (under paragraph 1 and/or 2 of the definition) submit a consolidated report, we are requiring that the report must provide information specified by CMS to identify each applicable manufacturer and entity (or entities) under common ownership that the report covers. Additionally, applicable manufacturers submitting consolidated reports must specify on an individual payment line which entity made which discrete payment or other transfer of value. We believe this method is more useful for consumers

since it clarifies the specific entity making the payment. We also believe that this method provides significantly more clarity for covered recipients when reviewing their payments or other transfers of value, allowing them to better review the information submitted on their behalf. Regardless of whether applicable manufacturers file separate or consolidated reports, § 403.908(d)(1)(iv) and (d)(2)(ii) clarify that in no case shall a single payment or other transfer of value be reported more than once by multiple applicable manufacturers (under common ownership or not). Each transaction between an applicable manufacturer and a covered recipient must be reported only one time. Also, to support our ability to improve identity and data matching, regardless of whether applicable manufacturers file separate or consolidated reports, all covered recipients included in the report must be individually, uniquely and consistently identified. 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. For example, the same name and National Provider Identifier (NPI) (as required to be reported in this final rule) should be used consistently for all payment lines and any subsequent updates for the same individual. Finally, we did not receive any comments on our proposed reporting method for joint ventures and co-promotions, so we have finalized these provisions as proposed, which required reporting by the applicable manufacturer that actually made the payment or other transfer of value (unless decided by the parties to report differently) and that the payment or other transfer of value was only reported once.

In sum, after consideration of the public comments received, we are revising the interpretation of what it means that an entity is "operating in" the United States. We are finalizing the position that applicable manufacturers must report all payments or other transfers of value, but clarifying that manufacturers with less than 10 percent of their gross revenue coming from covered products only have to report payments related to covered products. In addition, we are also finalizing the definition of common ownership to require a threshold of 5 percent or more common ownership interest and providing additional clarification on the requirements for reporting by entities under common ownership. Finally, we are allowing additional flexibility for

applicable manufacturers (under paragraph 1 and/or 2 of the definition) to report separately or together depending on their internal structure.

b. Covered Drug, Device, Biological, or Medical Supply

The data collection and reporting requirements are limited to applicable manufacturers of a "covered drug, device, biological, or medical supply." The phrase "covered drug, device, biological, or medical supply" is defined in section 1128G(e)(5) of the Act as any drug, biological product, device, or medical supply for which payment is "available" under Medicare, Medicaid, or CHIP. Because there are numerous payment mechanisms in Medicare, Medicaid and CHIP, we proposed that drugs, devices, biologicals, or medical supplies for which payment is available through a composite payment rate, as well as those reimbursed separately, are considered to be covered products under section 1128G of the Act. We were particularly concerned about inadvertently excluding items, such as implantable devices, for which payment may be available only as part of a bundled payment.

We proposed to define "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 composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system).

The proposed definition included two exceptions to limit the entities reporting. We proposed to limit drugs and biologicals in the definition of "covered drug, device, biological, and medical supply," to drugs and biologicals that, by law, require a prescription to be dispensed, thus excluding drugs and biologicals that are considered "over-the-counter" (OTC). Similarly, we proposed an additional limitation to the definition as it pertains to devices and medical supplies, which would limit them to those devices (including medical supplies that are devices) that, by law, require premarket approval by or notification to FDA. This would exclude 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.

Beyond coverage, the proposed rule also discussed what payments or other

transfers of value must be reported. In the proposed rule, we specifically stated that manufacturers who manufacture both non-covered products (such as OTC drugs) and at least one product that falls within the definition of a covered drug, device, biological or medical supply would be required to report *all* payments or transfers of value to covered recipients required by section 1128G of the Act (whether or not associated with a covered drug, device, biological or medical supply).

Comment: Many commenters inquired about the definition of covered drug, device, biological, or medical supply. Many commenters supported the proposed definition, particularly the proposed limitations, which did not receive any opposition. However, a few commenters sought clarification on how the two parts of the definition work together. These commenters sought clarification, for example, on whether a drug or biological that requires a prescription to be dispensed or a device that requires premarket approval or clearance, but for which payment is not available under Medicare, Medicaid or CHIP, would be a covered product.

Response: We are pleased with the support for the proposed definition, including the limitations, and have finalized them. In addition, we agree with the commenters regarding a need for clarification concerning the relationship between the parts of the definition. We had intended the interpretation of the definition to require that a product must meet both parts of the definition in order to be considered covered. In order to make this more clear, we have revised the definition to clearly state 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). For example, a device which is of a type that requires premarket notification, but for which payment is not available under Medicare, Medicaid, or CHIP, would not be a covered device under the program. Finally, we do not intend to capture *all* items that require FDA premarket approval or premarket notification and for which payment is available under Medicare, Medicaid, or CHIP; rather, we only intend to include items that meet these criteria and that are devices (or medical supplies that are devices). For example, 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.

Comment: Many commenters requested additional clarification and details concerning the meaning of payment being "available" under Medicare, Medicaid or CHIP. Some commenters inquired whether the availability of payment referred only to those items that have been approved or cleared by FDA. Other commenters suggested that the definition should only include payments for products which are reimbursed separately, and not through a bundled payment. Finally, a few commenters inquired whether the proposed definition referred to payment availability on a single basis (for example, as a result of an appeal) or if payment was regularly available.

Response: We agree with the comments that additional clarification of the meaning of "availability" of payment would be useful. The statute provides that in order to be a covered product, payment must be available under Medicare, Medicaid or CHIP. While the statute does not discuss FDA approval, clearance or notification, most products for which payment is available under Medicare, Medicaid or CHIP will have received FDA approval or clearance. However, we note that there may be exceptions. For example, payment may be available under Medicare for certain investigative devices that receive an investigational device exemption (IDE) from the FDA and are classified as a Category B device, in accordance with 42 CFR part 405 Subpart B. In addition, payment may be available under Medicaid for certain drug products described in section 1927(k)(2) of the Act, that have not been approved by the FDA, but were commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 (or which are identical, similar, or related within the meaning of 21 CFR 310.6(b)(1) to such drugs) and have not been the subject of a final determination by the Secretary that they are a "new drug." While we understand that a bright line test would be useful, limiting covered products to those that have received FDA approval or clearance (or for which notification has been provided to the FDA) would not be comprehensive. We believe that manufacturers are generally aware when payment is available for their drugs, devices, biologicals, or medical supplies under a Federal health care program.

In addition, we do not agree with the suggestions to interpret payment availability as being limited to those provided separately, rather than through a bundled payment. We recognize that

it is not always clear whether a product is paid through a bundle, making it difficult to establish whether payment is available. We also recognize that this expands the number of products meeting the definition of covered drug, device, biological or medical supply. However, bundled payments constitute a significant portion of Medicare reimbursement and excluding products that are reimbursed only as part of bundled payments would exclude manufacturers of products who have historically had significant relationships with physicians and teaching hospitals. For example, we believe it would be inappropriate to exclude implanted devices that are reimbursed through the hospital inpatient prospective payment system (IPPS) or the outpatient prospective payment system (OPPS), as well as chronic kidney disease drugs and products reimbursed through the end stage renal disease (ESRD) bundled payment system. As a result, the final rule adopts the proposal to include products which are reimbursed separately or as part of a bundled payment. We note that because there was some confusion about the phrase “composite payment rate” in the proposed rule, we have replaced it with the phrase “bundled payment” and continue to interpret that as meaning IPPS, OPSS, and other prospective payment systems.

Comment: Many commenters also requested clarification on what products constituted a device or medical supply. The proposed rule did not define these terms, so commenters provided recommendations for ways to clarify the terms, such as limiting them to product classes or providing definitions. Additionally, commenters questioned whether specific products would or would not be considered a “device” or “medical supply” for the purposes of the reporting requirements.

Response: We appreciate the comments and note that covered devices and medical supplies are limited to those devices and medical supplies for which payment is available under Medicare, Medicaid or CHIP, and are of the type that require premarket notification to or premarket approval by the FDA. We believe that this provides applicable manufacturers with a clear sense of the devices and medical supplies that constitute covered devices and medical supplies, as well as those that do not. For example, FDA defines the devices (including certain medical supplies) that are exempted from the premarket notification requirements. This information can be found in 21 CFR parts 862 through 892 and is

publicly available on the FDA’s Web site.¹

Comment: A few commenters suggested that reporting on all payments or other transfers of value, including those related to products under development, is too broad. These commenters recommended that only payments or other transfers of value related to covered products should be reported. Similarly, other commenters requested that payments or other transfers of value for certain products, such as veterinary drugs, be excluded since the relationships related to such products are not intended to be included by the statute.

Response: As noted previously, we are finalizing the proposal that, in most circumstances, applicable manufacturers must report payments or other transfers of value to covered recipients regardless of whether they are related to a covered product. We believe that not all payments or other transfers of value will be related to specific drugs, devices, biologicals, or medical supplies, but they nevertheless represent a financial relationship between an applicable manufacturer and a covered recipient that has the potential to affect medical judgment and must be reported under the requirements in section 1128G of the Act. Additionally, we are concerned that limiting the reporting requirements to payments or other transfers of value related to covered products would create loopholes that would allow entities to avoid reporting of certain payments or other transfers of value. However, we do understand that payments related to products that will never become covered by Medicare, Medicaid or CHIP (such as animal health products) may unnecessarily increase the scope of reporting. Therefore, we have limited the reporting requirements to address this situation, as well as other situations described previously in the discussion of the limitations to the definition of “applicable manufacturer,” where requiring an applicable manufacturer to report payments related to non-covered products would be unnecessarily burdensome and not particularly useful to the public. We are finalizing that separate divisions that manufacture only non-covered products do not need to report payments or other transfers of value unless the payments or other transfers of value are in fact related to covered products (see the applicable manufacturer and payments or other

transfers of value sections of this final rule). Similarly, we do not intend to capture payments made to a veterinary school that may be associated with a teaching hospital.

c. Covered Recipients

Under section 1128G(a)(1) of the Act, applicable manufacturers are required to disclose certain payments or other transfers of value made to covered recipients, or to entities or individuals at the request of, or designated on behalf of, a covered recipient. Section 1128G(e)(6) of the Act defines “covered recipient” as: (1) a physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital. As required by section 1128G(e)(11) of the Act, we proposed to define “physician” 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.

The statute excludes from the definition of covered recipient a physician who is an employee of the applicable manufacturer, as defined in section 1877(h)(2) of the Act. Section 1877(h)(2) defines “employee” as an individual who would be considered to be an employee of an entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986). We note that these common law rules are discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d) through 1(c).

Finally, we proposed to define the term “teaching hospital” by linking it to Medicare graduate medical education (GME). The proposed rule defined teaching hospital as any institution that received payments under section 1886(d)(5)(B) of the Act (indirect medical education (IME)); section 1886(h) of the Act (direct GME); or section 1886(s) of the Act (psychiatric hospital IME) during the most recent year for which such information is available.

Comment: Many commenters recommended changes to the proposed definition of physician. Some commenters requested that CMS expand the definition of physician to include other entities with prescribing privileges. Other commenters inquired about whether residents would be considered physicians. Some commenters requested that the definition exclude physicians who are not actively engaged in (or who do not

¹ List of exempt products: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>.

“perform”) the practice of medicine, which would include physicians not acting solely within their role as a physician, as well as medical researchers. They refer to the phrase in the statutory definition that a physician is an individual licensed in the State “in which he performs such function or action.” Other commenters recommended that the reporting requirements should be limited to physicians enrolled in Medicare, Medicaid or CHIP, on the basis of recent reimbursement or expected reimbursement. Finally, a few commenters recommended that CMS establish an “opt-out” function for physicians to declare that they have opted out, and no payments would appear on the public Web site attributed to them.

Response: We appreciate the comments, but we will not expand the definition to include other provider types nor will we limit the definition to exclude those clearly intended in the statutory definition. The statute defines the term “physician” as having the same meaning as in section 1861(r) of the Act. We recognize that, as a result, we will 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.

Additionally, we believe 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. By holding a current license to practice, the physician is legally authorized to practice regardless of the extent to which they do so.

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. We recognize that some States require or allow residents to obtain licenses to practice, whereas other States do not require or allow residents to obtain them. We do not want to treat residents differently depending on their State of residency by requiring reporting on payments to residents in only those States that require or allow residents to have a license. Moreover, we believe it

will be difficult for us to accurately identify residents and ensure that payments or other transfers of value are attributed across applicable manufacturers appropriately because many of them do not have a NPI and/or State professional license number (used for physician identification, discussed later in this section). Due to the operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither an NPI nor a State professional license number, applicable manufacturers will not be required to report such payments or other transfers of value.

With regard to the comment that the term “physician” should be limited to those enrolled in Medicare, we believe such an interpretation would be contrary to the language of the statute. In contrast to the statutory requirement that products are limited to those for which payment is available under Medicare, Medicaid or CHIP, the statute did not indicate that physician covered recipients be limited to those enrolled in Medicare, Medicaid or CHIP.

Finally, while we appreciate the interest in allowing physicians the opportunity to “opt-out” of the reporting requirements, we do not believe it would be possible to implement a system of this kind. We believe it 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. Additionally, we would need to create a system to reconcile any payments reported as having been made to physicians stating that they have opted out. We believe 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 Web site (unless they hold ownership or investment interests in an applicable manufacturer or applicable GPO).

Comment: Many commenters addressed the exclusion for employees of applicable manufacturers from the definition of physician covered recipient. A few commenters recommended revising the definition to ensure that only “bona fide” employee relationships are excluded from reporting, similar to the language in the employee exception in the Anti-Kickback Statute in section 1128(b)(3)(B) of the Act and the corresponding HHS OIG regulation at 42 CFR 1001.952(i). Other commenters questioned whether employees of agents of the applicable manufacturer would be

included in the exception. The commenters also noted that the language in the proposed rule indicated that the exception included physicians employed by an applicable manufacturer, so it was not limited to employees of the applicable manufacturer making and reporting the payment or other transfer of value. In addition to these more general definitional comments, we also received numerous comments recommending other situations (such as physicians who serve as medical directors or retirees) that should be included in the employee exception.

Response: We appreciate the comments and have clarified the definition of covered recipient to ensure that only bona fide employment relationships are included in the employee exclusion. We are concerned that in the absence of this clarification, applicable manufacturers could circumvent the reporting requirements by styling a physician as an “employee” and not reporting payments made to such a physician. Additionally, we did not intend to allow the exception for employees to include physician employees at any applicable manufacturer, rather than only the reporting applicable manufacturer itself. The proposed rule incorrectly quoted the statute, which in section 1128G(e)(6)(B) of the Act states that the term covered recipient “does not include a physician who is an employee of the applicable manufacturer.” For the final rule, we have reverted to the statutory language. Additionally, regarding employees of agents of the applicable manufacturer, we do 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), we do 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.

We appreciate the comments regarding other situations that commenters would like to see included in the employee exclusion, such as an applicable manufacturer’s board members and medical directors. However, we believe 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. Therefore, we are not able to adopt a bright-line policy that all board members or medical directors are (or are not) bona fide employees for purposes of the reporting exclusion.

Similarly, with regard to the comments suggesting that prospective employees and retirees should be treated as employees for purposes of being excluded from the reporting requirements, we believe that whether such individuals fall within the statutory definition of employee in section 1877(h)(2) of the Act will require a case-specific analysis. Therefore, we are unable to state that payments to such physicians, such as recruiting costs paid to prospective employees, do not need to be reported.

Comment: We received significant support for our proposed definition of teaching hospital. However, some commenters recommended that CMS clarify that payments or other transfers of value to non-healthcare departments at universities affiliated with teaching hospitals should not be included in the reporting requirements.

Response: We have decided to finalize the proposed definition. As explained in the proposed rule, we recognize that this definition may not capture hospitals with accredited medical residency programs that do not receive IME or direct GME payments; however, we are unable to include these hospitals since we cannot readily identify them based on Medicare payment data. Finally, we do agree; 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.

d. Identification of Covered Recipients

In order to accurately identify and distinguish covered recipients, section 1128G(a)(1) of the Act requires that applicable manufacturers report the covered recipient's name and business address, and for physician covered recipients, the physician's NPI, and specialty. The collection of this information is necessary for applicable manufacturers, in order to distinguish individual covered recipients when reporting to CMS, and for CMS, in order to be able to aggregate the data. This section outlines the comments received regarding identification of both physician and teaching hospital covered recipients.

(1) Identification of Physicians

Section 1128G of the Act requires that applicable manufacturers report a physician covered recipient's name, business address, NPI and specialty. This information will be used to distinguish physicians and allow us to match physicians across applicable manufacturers. We proposed that applicable manufacturers use the National Plan & Provider Enumeration System (NPPES), which we currently maintain and update on the public Web site, to assist with identifying physician covered recipients. The NPPES Web site includes a database of physician NPIs and has an NPI Registry function that allows applicable manufacturers to look up individual physician's NPIs.² The full database can be downloaded from the CMS Web site.³ We proposed that if the physician NPI was not available in NPPES, the applicable manufacturer would be responsible for obtaining the physician's individual NPI directly from the physician, if the physician has an NPI. Other than NPI, in the proposed rule, we considered whether we should require, under the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, that applicable manufacturers report another unique identifier, such as State professional license number, for physicians who are identified, but do not have an NPI.

Comment: A number of commenters provided input on the processes and requirements for applicable manufacturers to report the NPI for a physician. Some commenters noted that reporting a physician covered recipient's NPI is complicated, since not all physicians have an NPI and manufacturers typically do not collect such information. Additionally, a few commenters did not support the requirement that applicable manufacturers must obtain an NPI from a physician, if it was not readily available in the NPPES database. They explained it would be difficult to obtain and questioned how an applicable manufacturer would really know if a physician did not have an NPI. Some other commenters requested clarification that if an applicable manufacturer cannot identify an NPI for a physician then the NPI field can be left blank. Beyond determining a physician's NPI, a few commenters recommended that CMS clarify that physicians are not required to provide their NPI when requested and that applicable manufacturers should state

that it will not be made public. Finally, some commenters recommended that CMS should require physicians to obtain NPIs to ensure that all physicians have one.

Response: We appreciate the comments, but want to reiterate that reporting a physician covered recipient's NPI is a statutory requirement, so the agency does not have flexibility to waive the requirement. Similarly, we do not believe that section 1128G of the Act provides the agency with authority to require all physicians to obtain an NPI. We agree that it may be difficult for an applicable manufacturer to definitively know whether a physician does not have an NPI; however we believe 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. We believe that a good faith effort includes, but is not limited to, specifically requesting an NPI from the physician, checking the NPPES database, and calling the NPPES help desk. This statute does not impose requirements on covered recipients, so we do not believe we can require physicians to disclose their NPI to applicable manufacturers when requested; however, we strongly encourage physicians to provide this information because it is essential for matching payments or other transfers of value to physicians accurately. We believe it is in the best interest of all parties (applicable manufacturers, physician covered recipients, consumers and others) that payments be attributed to the correct physician, and we hope that physicians will be willing to provide their NPI to applicable manufacturers to make this possible, especially since their NPI will not be made public on the public Web site. If, after a good faith effort, the applicable manufacturer cannot determine an NPI for a physician covered recipient, or a physician does not have an NPI, we agree with the commenters and have finalized 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 we determine that a physician covered recipient does have an NPI, we 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

² NPI Registry can be found at: <https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do>.

³ Database can be downloaded at http://nppes.viva-it.com/NPI_Files.html.

recipients that do have an NPI will be considered inaccurate reporting, which may be subject to penalties. Finally, we want to reiterate 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 Web site.

Comment: Some commenters discussed the proposal to allow reporting of an alternative identifier for physicians without an NPI. Many of these commenters supported reporting a State professional license number as an alternative to an NPI. Conversely, a few advocated that CMS not require an additional alternative unique identifier, whether it is a State professional license number or another identifier. Some commenters that supported State professional license number recommended that CMS should allow State professional license number instead of NPI at the discretion of the applicable manufacturer, since they believe it is could be burdensome for the applicable manufacturer to find the NPI.

Response: We agree that obtaining a unique identifier is particularly important for physicians who do not have an NPI or for whom an NPI cannot be reasonably identified. Without this information, it will be difficult for us to ensure that payments are attributed to the appropriate physician and to aggregate payments accurately. We believe that the more unique identifiers supplied for a physician covered recipient, the more accurate the data will be, since they are essential for us to appropriately match data about the same physician within and across reports, and publish data appropriately on the public Web site. Therefore, pursuant to the discretion granted in section 1128G(a)(1)(A)(viii) of the Act, we will finalize 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. While this is slightly broader than what was proposed in the proposed rule, we believe (based on the comments) that reporting applicable State professional license numbers for all physician covered recipients, rather than only the subset that do not have NPIs, will significantly improve data accuracy and will not represent a significant

additional burden on applicable manufacturers. Many commenters indicated that applicable manufacturers maintain this information already. Moreover, we believe that any additional burden associated with collecting and reporting physicians' State professional license numbers will be outweighed by the increased accuracy of the data attributing payments or other transfers of value to physician covered recipients.

Comment: Many commenters discussed the proposal that applicable manufacturers use NPPES to identify physician covered recipients. Many commenters did not support requiring applicable manufacturers to use the information listed in NPPES, rather than what was in their internal files, particularly for specialty and business address. The commenters explained that the data in NPPES is not as accurate in some cases, as their internal databases and information. Similarly, some commenters did not believe it made sense to report information from NPPES back to CMS. Many commenters also discussed how applicable manufacturers should use NPPES. These commenters inquired whether there would be point in time (such as 90 days before the reporting year) when the NPIs in the database would be finalized and no longer changed, and whether manufacturers could rely on it. A few commenters recommended that applicable manufacturers should be notified of changes in NPPES. For example, a commenter advocated that CMS should keep past "versions" of NPPES in case of an audit. In addition, some commenters stated that NPPES is not user friendly and CMS should be responsible for improving it. Finally, a few commenters requested that CMS create a list of physician covered recipients rather than using NPPES.

Response: We appreciate the comments on NPPES and note that we did not intend to require applicable manufacturers to specifically or solely use NPPES in order to obtain the NPI of a covered recipient. Applicable manufacturers may obtain physician NPI information (or any other information) in any manner they see fit, as long as they report NPIs accurately as required. This may include matching NPIs obtained elsewhere with the NPIs provided in NPPES. The NPPES database is continually updated, so it is difficult to set a point in time to freeze the database for a reporting year or notify applicable manufacturers of all changes. Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year.

However, just because an NPI is not listed in NPPES does not mean that the applicable manufacturer does not need to make a good faith effort to obtain the NPI or that the payment should not be reported. While it is not possible to keep past "versions" of NPPES due to the continual updates, we would like to point out that each provider entry is date stamped to include the date the entry was created, as well as the date of each update, which will help establish the information available at a particular time. Beyond the specific concerns regarding using NPPES, we understand that NPPES is not perfect, but the agency is working to improve it. In addition, we do not believe it is appropriate for us to create a new system specifically for this program, as it would be duplicative and unnecessary.

Finally, while we are sensitive to the request for a physician covered recipient list, we do not believe it is a viable option. Any list of physicians would be created based on NPPES, since it is the most comprehensive database available. However, as stated in this section, NPPES is not complete since not all physicians meeting the definition of covered recipient have an NPI. We also do not want the reporting requirements to be based on a list, which will be difficult to maintain and invariably include mistakes and inaccuracies. Instead, the statute that requires reporting of payments to physicians who meet the statutory definition. We believe applicable manufacturers are in the best position to identify the individuals with whom they have financial relationships who meet this definition.

(2) Identification of Teaching Hospitals

Regarding the identification of teaching hospitals, we proposed to publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct GME or IME payments during the last calendar year for which such information is available) on the CMS Web site once per year. We proposed to do so since it may not be immediately apparent to applicable manufacturers whether a particular hospital meets our definition of a teaching hospital, and there is no currently published database that includes this information. We proposed that the list of teaching hospital covered recipients should include the name and address of each teaching hospital.

Comment: Many commenters supported CMS's proposal to publish a list of teaching hospitals, but recommended that the agency provide additional details regarding the list. The

commenters suggested that CMS publish the list prior to the beginning of the reporting year and ensure that applicable manufacturers will be able to download the list. The majority of these commenters recommended that the list be published 90 days before the end of the year, but the comments varied. Additionally, some commenters requested that CMS clarify that applicable manufacturers could rely on the teaching hospital list for the entire year and that entities not included on the list would not be covered recipients for the whole data collection year. They also advocated that the list should remove hospitals classified in error. Finally, a few commenters also requested that the list contain additional information to help clarify corporate identities (such as inclusion of a tax identification number (TIN) or an OSCAR number), as well as an institutional contact or officer for all hospitals.

Response: We agree that the teaching hospital list will be useful for applicable manufacturers and appreciate the comments making suggestions for how to improve the list. We 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. Finally, we will not include an institutional contact, since we do not have this information readily available and do not believe it is integral to the success of the program.

e. Payments or Other Transfers of Value

Section 1128G(a)(1)(A) of the Act requires that applicable manufacturers report a “payment or other transfer of value” made to a covered recipient or “to an entity or individual at the request of or designated on behalf of a covered recipient.” Under Section 1128G(a)(1)(B), if an applicable manufacturer makes a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer must disclose the payment or other transfer of value under the name of the covered recipient. Section 1128G(e)(10)(A) of the statute defines

“payment or other transfer of value” broadly as “a transfer of anything of value.”

We would like to clarify that we interpret payments or other transfers of value to an entity or individual at the request of or designated on behalf of a covered recipient to refer to a situation in which an entity or individual receives and keeps the payment that was made on behalf of (or at the request of) the covered recipient and the covered recipient does not receive the payment or other transfer of value. Rather, the covered recipient directs the payment or other transfer of value and does not receive the payment personally. Such payments or other transfers of value to third party recipients are somewhat different than indirect payments to a covered recipient made through a third party (discussed in section II.B.1.k. of this final rule). Indirect payments or other transfers of value are made to an entity or individual (that is, a third party) to be passed through to a covered recipient. In the case of indirect payments or other transfers of value, we believe that the applicable manufacturer will generally direct the payment path.

We proposed that payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient included payments or other transfers of value provided to a physician (or physicians) through a physician group or practice. We proposed that payments or other transfers of value provided through a group or practice should be reported individually under the name(s) of the physician covered recipient(s).

When reporting payments or other transfers of value made at the request of, or designated on behalf of a covered recipient, we proposed that applicable manufacturers should report the payment or other transfers of value in the name of the covered recipient, but include the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. We believed that reporting the entity or individual paid would maximize transparency about the details of the payment or other transfer of value, by allowing end users to discern whether a covered recipient actually received the payment, and if not, where the payment went. Additionally, we proposed that we did not believe it was feasible to provide a review period for these entities before the data is made public. Instead, we explained that review by the covered recipient was sufficient.

Comment: Many commenters requested additional information on

how to determine the amount and value of a payment or other transfer of value since neither the statute nor the proposed rule provided much guidance. While some commenters recommended specific options, such as interpreting value as discernible economic value on the open market, the majority advocated that the applicable manufacturers be allowed flexibility to determine whether a payment or other transfer of value has a cognizable economic value, and if so, to allow flexibility to determine such value. Several commenters also recommended that if a payment or other transfer of value does not have a measurable economic value to a covered recipient, then it does not need to be reported. In addition, a few commenters requested clarification on how to handle tax and other additional payments, such as shipping. Finally, a few commenters recommended that CMS clarify that goods purchased for market value should not be reportable.

Response: We appreciate the comments and agree that more information will be useful for applicable manufacturers. In general, for purposes of this rule only, we interpret value similarly to many comments as the discernible economic value on the open market in the United States. However, we agree and support that applicable manufacturers should be allowed flexibility to determine value, so we do not plan to create numerous rules for calculating value. We have outlined a few guidelines to help manufacturers. First, 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. For example, an applicable manufacturer may provide a physician with a textbook that the physician already owns. Since it is a duplicate, it may not have a value to the physician; however, the textbook does have an economic value, so it must be reported. Second, even if a covered recipient does not formally request the payment or other transfer of value, it still must be reported. Similarly, when calculating value we believe that all aspects of a payment or transfer of value, such as tax or shipping, should be included in the reported value. Finally, 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 (discussed in section II.B.1.h.

of this final rule). Finally, we added the statutory definition of “payment or other transfer of value” to the regulatory text to ensure consistency with the statute.

Comment: A few commenters stated that applicable manufacturers should not report payments or other transfers of value provided to a group practice as if the payment or other transfer of value had been provided to all members of the group.

Response: We agree that payments or other transfers of value being provided to a specific physician through a group practice should not necessarily be attributed to all physicians in that group. However, we also do not want payments or other transfers of value to go unreported because they were provided to a group or practice rather than to a specific physician. This was the intent of our proposal for reporting payments to group practices. We have 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. This means that the payment or other transfer of value does not necessarily need to be reported in the name of all members of a practice. For example, if an applicable manufacturer donates a set of dermatology textbooks to a group practice, we believe that applicable manufacturers should attribute the transfer of value to only the dermatologists at the practice by dividing the cost equally across all dermatologists. We intend for applicable manufacturers to divide payments or other transfers of value in a manner that most fairly represents the situation. For example, many payments or other transfers of value may need to be divided evenly, whereas others may need to be divided in a different manner to represent who requested the payment, on whose behalf the payment was made, or who was intended to benefit from the payment or other transfer of value. We agree with the commenters that this approach attributes payments more fairly, since some physicians in a group practice may not make use of a payment or other transfer of value and may have concerns about such payments or other transfers of value being attributed to them.

Comment: A few commenters requested clarification of the reporting requirements for payments or other transfers of value provided through a covered recipient to another covered

recipient. We did not address this specific situation in the proposed rule. These commenters generally refer to a situation when a payment is provided to a physician covered recipient, but made through a teaching hospital covered recipient.

Response: We appreciate the comments and agree that this is an area of potential confusion, so we believe that clarification is necessary. While the comments are generally limited to payments or other transfers of value to a physician through a teaching hospital, we provide clarification more generally. However, we recognize that the majority of payments to one covered recipient through another will likely involve a physician and teaching hospital.

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. For example, if an applicable manufacturer provides a payment to a teaching hospital intended for a physician employee of the teaching hospital, then the payment should be reported in the name of the physician covered recipient, since that is who ultimately received 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. We note that the rules regarding research-related payments made to teaching hospital covered recipients differ somewhat and are discussed further in the section on research herein.

Comment: A few commenters recommended that CMS set a limit for the total amount a physician can receive annually.

Response: This statute does not afford us the authority to limit the payments or other transfers of value made to covered recipients. The statute requires applicable manufacturers to report the relationships, but does not limit or ban them in any way. This is a transparency initiative, and inclusion on the public Web site does not indicate that the relationships are necessarily improper or illegal.

Comment: There were a number of comments, some which supported reporting the name of the entity or individual that received the payment and others opposing this approach. However the most common suggestion was to only report the name of entities that receive the payment, rather than individuals, due to privacy concerns. Additionally, a few commenters stated that the applicable manufacturer may not know the amount if it was at the request or designated on behalf of a covered recipient.

Response: We appreciate the comments and continue to believe that reporting the name of the entity which received the payment at the request of or designated on behalf of a covered recipient is beneficial. However, we agree that reporting the name of an individual that received the payment could be problematic. We will finalize that 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.

Finally, we do not agree with the comment that the applicable manufacturer may not know the amount of the payment. We believe that because the applicable manufacturer is making the payment, it should know the amount being provided. We believe regardless of what entity received the payment or other transfer of value, the details are available to the applicable manufacturer.

Comment: Many commenters recommended that CMS should provide 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) should have the opportunity to review and correct the information. However,

other commenters supported the CMS proposal.

Response: While we appreciate the interest in allowing these entities the opportunity for review, dispute and proposing corrections, we do not believe there is a viable method for administering it. The agency will not have any information on the entities beyond their name, so we 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 Web site and stating that he or she is from a specific entity. Additionally, we believe 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. As explained in this section, we have 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. We believe this should alleviate some of the concerns regarding review and correction because personal payments to an individual will not be made public on the Web site. Given these considerations, we will finalize 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.

Comment: Numerous commenters noted various situations when a payment or other transfer of value may be at the request of or designated on behalf of a covered recipient. In some cases, a covered recipient may direct the payment elsewhere; conversely, in others, the covered recipient may simply waive the payment and the applicable manufacturer provides it to a third-party recipient of their choosing. In addition, there are also models when a covered recipient does not have any claim to the payment and it is automatically provided elsewhere (such as a charity) on his/her behalf. The commenters recommended various methods to report these situations, including categorizing some as non-reportable.

Response: We appreciate these comments and recognize that there are various circumstances where a payment will be made at the request of or on behalf of a covered recipient, which will all be slightly different. In general, we do not believe it will be possible to

create rules for each situation. Instead, we are providing the following general guidelines and information on how we intend to interpret the phrases “at the request of” and “designated on behalf of.”

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). For example, in the event that a covered recipient directs an applicable manufacturer to donate a payment or other transfer of value—to which he would have otherwise been entitled—to a particular charity, the applicable manufacturer must report the payment in the name of the covered recipient and provide the name of the charity that received the payment at the covered recipient’s request. However, 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 this situation, there is nothing to report because no reportable payment or other transfer of value was made to a covered recipient or to an individual or entity at the request of or designated on behalf of a covered recipient.

In addition, we interpret “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. For example, a covered recipient may waive his payment, and the applicable manufacturer nevertheless donates the payment to a charity “on behalf of” the covered recipient. We recognize that this could result in a covered recipient who waived a payment nevertheless having a payment reported in his or her name; therefore, we encourage covered recipients to make very clear to applicable manufacturers whether they would like their waived fee to be paid to another individual or entity—

After consideration of the public comments received, we are finalizing that reporting of payments or other transfers of value at the request of or designated on behalf of a covered recipient should be reported, but should

include the name of the entity paid or that another individual received the payment. The covered recipient will have the opportunity to review and correct the payment on behalf of the entity or individual that received the payment.

f. Payment and Other Transfer of Value Report Content

The specific categories of information required to be reported for each payment or other transfer of value provided to a covered recipient are set forth in section 1128G(a)(1)(A) of the Act. In the proposed rule, we provided explanations and details on how we proposed that applicable manufacturers report some of this information to CMS. This section outlines the comments we received on the data elements.

(1) Name

We proposed that applicable manufacturers should report the first name, last name, and middle initial for physician covered recipients.

Comment: A few commenters stated that not all physicians have middle names and not all existing systems include middle name or initial, so they recommended middle initial not be reported.

Response: We appreciate the comments, but believe that given the number of physicians with the same first and last name, reporting a middle initial will be important when identifying and distinguishing physician covered recipients and aggregating payments across applicable manufacturers. While we recognize that not all physicians have middle names, we believe that this information should be reported whenever possible. As required in § 403.904(c)(1), 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. Additionally, as stated previously, we hope that applicable manufacturers provide as much identifying detail as possible on physician covered recipients to ensure we can attribute payments appropriately. 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, we will require applicable manufacturers to report a physician covered recipient’s name as listed in NPPES.

(2) Business Address

We proposed that applicable manufacturers should report the full street address. For teaching hospital covered recipients, we proposed using only the address included in the CMS-published list of teaching hospitals. For physician covered recipients, we proposed that applicable manufacturers report the physician's primary practice location address, since this is more easily recognizable to end users of the data.

Comment: A few commenters recommended that CMS allow applicable manufacturers to use the address kept on file for a physician covered recipient, rather than the address in NPES, since the address on file may be more accurate than the NPES address. Regarding NPES, a few commenters also suggested that CMS should require physicians to keep their address updated. Some commenters recommended reporting the address used for correspondence, rather than business location. Finally, a few commenters discussed that providing the full street address for the business address field for each payment or other transfer of value will increase the data elements significantly.

Response: We appreciate the comments. We agree that (unlike with a physician covered recipient's name) applicable manufacturers do *not* need to use NPES when reporting addresses. In the proposed rule, we simply wanted to be clear that it was available and explain what field to use, if an applicable manufacturer chose to use NPES. Regarding the requirement to keep addresses updated, we encourage physicians to keep their NPES profiles updated, but we do not believe that we have the authority to force all physicians to do so.

We also have finalized our proposal to require the primary practice location address to be reported as the business address. We realize that a physician can be associated with multiple addresses, but we believe that primary practice location is the most recognizable to consumers. However, we understand that it may be difficult for an applicable manufacturer to know which address represents the primary practice location, so we plan to not penalize applicable manufacturers for providing the incorrect address, as long as applicable manufacturer reports a legitimate business address for the covered recipient.

Finally, we appreciate the comment that the reporting of a full street address (as opposed to a portion of the address, such as City and State) will require a

significant amount of data to be submitted. We agree that we want to minimize the data submitted; however, we believe that full street address is important since in large urban areas there may be multiple physicians with the same name in the same city, so we will continue to require reporting of full street business address.

(3) Specialty and NPI

In the proposed rule, we stated that, as required by the statute, applicable manufacturers are required to report the specialty and NPI for physician covered recipients. We suggested that applicable manufacturers use the "provider taxonomy" field when reporting physician specialty. We proposed that applicable manufacturers only report a single specialty and use only the specialties available for the "provider taxonomy" field in NPES. More details on these terms are available online.⁴ For NPI, we proposed that applicable manufacturers report the physician's individual NPI, rather than any group NPI, with which the physician may be associated.

Comment: Many commenters addressed the requirements for reporting physician specialty and NPI. Some commenters recommended that applicable manufacturers be able to use their own internal files for reporting specialty, rather than NPES. They were concerned that specialty in NPES may not be accurate and could lead to concerns about off-label marketing. Regarding the NPES list, a few commenters recommended that CMS include the nine recognized American Dental Association (ADA) specialties. Some commenters also requested clarification on whether applicable manufacturers should report both the specialty name and the associated NPES code. In addition, a few commenters recommended that CMS allow methods for an applicable manufacturer to provide more context regarding physician specialty, such as reporting multiple specialties with one listed as primary or allowing a statement justifying specialty choice.

Response: We appreciate the comments and agree that applicable manufacturers may use their internal information when reporting specialty. However, the NPES "provider taxonomy" list (as referenced previously) 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. We note that the NPES list does include the nine recognized ADA specialties. When reporting specialty, applicable manufacturers should list both the specialty name and code to ensure consistency.

Additionally, we do not believe applicable manufacturers need to provide more information when reporting physician covered recipient specialty. We believe that a single specialty should be sufficient and that allowing applicable manufacturers to provide a justification of physician specialty would be too much information to be beneficial.

(4) Date of Payment

In the proposed rule, we required applicable manufacturers to provide the date on which a payment or transfer of value was provided to the covered recipient. We recognized that some payments or other transfers of value might be provided over multiple dates, such as a consulting agreement with monthly payments. We proposed that applicable manufacturers use their discretion as to whether to report the total payment on the date of the first payment as a single line item, or to report each individual payment as a separate line item.

Comment: Many commenters supported the proposed requirements for reporting the date(s) of payment. These comments appreciated the flexibility since applicable manufacturers may use different tracking systems. However, some commenters requested additional flexibility on how to report the payment date. For example, some commenters suggested that applicable manufacturers should have flexibility, depending on their individual systems, to report the date a flight actually occurred or the date the trip was booked, as long as this information is reported consistently within a category. Additionally, the commenters recommended that CMS clarify how to report payments which may happen across a reporting year.

Response: We appreciate the comments and have finalized the proposal 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. In addition, we will allow flexibility for what specific date to report for a nature of payment category. We believe 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

⁴ Health care provider taxonomy codes are available through a link on the NPES Web site: <https://npes.cms.hhs.gov/NPES/StaticForward.do?forward=static.instructions>.

date or ticket purchase date). In addition, 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.

(5) Context

Comment: Some commenters recommended that CMS allow applicable manufacturers to voluntarily report contextual information about each payment or other transfer of value and make the information publicly available. CMS did not propose including this in the proposed rule.

Response: We agree that information on the context of a payment or other transfer of value could be useful. We believe it could help the public better understand the relationships between the industry and covered recipients. In addition to consumers, we believe contextual information will be useful for covered recipients when reviewing the payments or other transfers of value. Hopefully, the context will provide information to help the covered recipient assess the accuracy of the payment. However, we do not want this information to overwhelm users or significantly increase the data reported, so will limit the amount of data that can be reported in that field. Section 403.904(c)(12) allows applicable manufacturers to provide brief contextual information for each payment or other transfer of value, but does not require them to do so.

(6) Related Covered Drug, Device, Biological or Medical Supply

Section 1128G(a)(1)(A)(vii) of the Act requires applicable manufacturers to report the name of the covered drug, device, biological or medical supply associated with that payment, if the payment is related to “marketing, education, or research” of a particular covered drug, device, biological, or medical supply. We proposed that in cases when a payment or other transfer of value is reasonably associated with a specific drug, device, biological or

medical supply, the name of the specific product must be reported. We realize that not every financial relationship between an applicable manufacturer and a covered recipient is explicitly linked to a particular covered drug, device, biological or medical supply, but many are, and we proposed that those must be reported.

When reporting a related product, we proposed that applicable manufacturers could report only one covered drug, device, biological or medical supply as related to a payment or other transfer of value, even though there arguably may be multiple covered products related to the payment. However, we considered, as an alternative, allowing applicable manufacturers to report multiple covered drugs, devices, biologicals or medical supplies as related to a single payment or other transfer of value. We believed that reporting of multiple covered drugs, devices, biologicals, and medical supplies may be easier for applicable manufacturers since many financial relationships are not specific to one product only, but could make aggregating payments by product difficult.

With regard to reporting a product name, we proposed that the applicable manufacturer should report the name under which the product is marketed, since this name is probably most recognizable to the consumer. In the event that a covered drug, device, biological or medical supply does not yet have a market name, we proposed the applicable manufacturer should report the scientific name.

Comment: Many commenters questioned how and when to report an associated product. A number of these commenters discussed whether a product name should be reported for payments associated with non-covered products (such as pre-commercial or OTC drugs) and recommended only requiring reporting of a product when the payment is related to “marketing, education, or research.” Many commenters also recommended that CMS allow the reporting of “n/a” or “none” in instances when a product is not associated or when associated with a non-covered product. Similarly, a few commenters recommended that applicable manufacturers should not have to report an associated product for research on a new indication of a covered product.

A few commenters provided more specific requirements, such as only reporting a covered product for a payment or other transfer of value, when there is a written agreement or an understanding with the covered recipient that the product will be

named. Similarly, some commenters suggested that CMS should allow flexibility to report business purpose, in addition to product family or a single product.

Response: We appreciate the comments and agree that it is important to provide additional information on when and how a related product should be reported. Section 1128G(a)(1)(A)(vii) of the Act requires that “if a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply,” applicable manufacturers must report the name of the covered product. We believe that many financial relationships between applicable manufacturers and covered recipients are related to marketing, education or research associated with a particular product, often a covered product. Therefore, we will finalize 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. However, we do not believe applicable manufacturers should be 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, we do believe it is 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. This distinction will not be possible if applicable manufacturers leave the associated products fields blank in cases when it is not applicable. Given this interest, the final rule directs applicable manufacturers to fill in associated product fields as appropriate. Instead, if the payment or other transfer of value is not related to at least one covered product, then applicable manufacturers should report “none.” Conversely, 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.” Finally, 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.

Comment: Many comments addressed the number of associated products that may be reported for each payment or other transfer of value. Several commenters supported allowing

reporting of only a single product, whereas several others supported allowing applicable manufacturers to report multiple products as being associated with the a payment or other transfer of value. The commenters who advocated reporting multiple products explained that often a financial relationship is associated with multiple products, and it would be misleading to attribute it to a single product. Conversely, some commenters were sympathetic to the need to aggregate the payments or other transfers of value by product. As a compromise, some of these commenters suggested reporting a single product would be sufficient, as long as we allowed applicable manufacturers to report "multiple," as well. Other commenters recommended that CMS allow reporting of up to five products. However, these comments cautioned that aggregation by product should not give the impression that there were multiple interactions. A commenter recommended requiring applicable manufacturers to report a percentage of the interaction to be attributed to each product listed. The comments also addressed what product name should be used. Many commenters advocated that applicable manufacturers should be allowed to report the product category or therapeutic area rather than the product-specific name. Many commenters recommending this method referenced implantable devices, since consumers may not know the specific name of the device that had been implanted during a medical procedure. Many devices are given a complex name and number combination, which consumers may not know. For example, a patient may be aware that she received a hip implant manufactured by company A, but may not know the specific model number of the implant. Similarly, some commenters recommended slight changes to the name required to be reported, such as using the clinicaltrials.gov name for drugs without a name or allowing reporting of the generic name. Finally, a few commenters suggested that we require reporting of National Drug Code (NDC), as well as brand and generic name.

Response: We appreciate the comments and agree that reporting multiple products will likely improve the accuracy of the database in a way that is more beneficial than the difficulty in aggregating by product. Therefore, we will finalize 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. Additionally, when aggregating payments or other transfers of value by product, we will not represent a single interaction related to multiple products as multiple interactions. However, we do not agree that the applicable manufacturer should report the percentage of the interaction dedicated to each product. We believe this will be burdensome to the applicable manufacturers and would not be beneficial to consumers, since it will greatly increase the volume of the data.

We also agree that we should allow greater flexibility in reporting the product name, particularly for devices where the product name is less recognizable to consumers. For drugs and biologicals, we are finalizing 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. We believe that reporting the NDC will greatly help CMS aggregating the data by product. However, 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. We believe that reporting devices and medical supplies in this manner is appropriate, since device names are less known to consumers and a single product may actually be comprised of multiple devices. Conversely, we believe that the names of drugs and biologicals are more readily available to consumers, since they are often listed on a prescription.

(7) Form of Payment and Nature of Payment

The statute requires reporting on both the form of payment and the nature of payment for each payment or transfer of value made by an applicable manufacturer to a covered recipient. The statute provides a list of categories for both the form of payment and nature of payment and gives the Secretary discretion to add additional categories.

Section 1128G(a)(1)(A)(v) of the Act 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.

Section 1128G(a)(1)(A)(vi) of the Act 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.

In this section, we discuss the general policies for reporting the form of payment and the nature of payment, rather than the specific categories, which will be discussed in sections II.B.1.g and h. of this final rule.

In the proposed rule, we proposed 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, we proposed that the travel expenses should remain distinct from the consulting fee expenses and both categories would need to be reported to accurately describe the relationship. In these cases, we proposed that for each payment or other transfer of value reported, applicable manufacturers may only report a single nature of payment and a single form of payment. For example, if a physician received meals and travel in association with a consulting fee, we proposed that each segregable payment be reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items, one for consulting fees, one for meals and one for travel. The amount of the payment would be based on the amount of the consulting fee, and the payments for the meals and travel. For lump sum payments or other transfers of value, we proposed 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. We also solicited comment on an alternative approach of allowing a payment or other transfer of value for an activity that is

associated with multiple segregable categories to be reported as a single lump sum, rather than separately by each segregable category.

Finally, in the proposed rule we also discussed the interpretations of various forms of payment and natures of payment categories. We did not define the categories individually and instead proposed that they would have their dictionary definitions.

Comment: Many commenters addressed our proposed method for reporting form of payment and nature of payment. A number of these commenters supported our proposed method of reporting a single form of payment and a single nature of payment for each reported payment, whereas others supported the alternative of reporting multiple forms of payment and natures of payment for a single payment. The commenters supporting multiple forms of payment and natures of payment recommended that the applicable manufacturer should be allowed flexibility to report, but should explain their decisions and methodology for reporting form and nature of payment in the assumptions document. Additionally, a few commenters suggested that the applicable manufacturer should be allowed to report lump payments, but should be required to produce segregated payments in an audit. Finally, a few commenters recommended that CMS allow applicable manufacturers to report additional details beyond form of payment and nature of payment to allow end users to understand that not all reported relationships are payments.

Response: We appreciate the comments and believe they provided important background on the processes of reporting. However, we have finalized these provisions as proposed. We believe that flexibility in the reporting requirements is important to aid applicable manufacturers with different systems. However, we believe that there should also be consistency in the way payments or other transfers of value are reported across applicable manufacturers, particularly when describing and classifying payments or other transfers of value. We believe that a single form of payment and a single nature of payment for each line item characterizes a payment or other transfer of value much differently than reporting multiple forms of payment and natures of payment for a lump sum payment. We are concerned that allowing this flexibility will be confusing to covered recipients and end users, since they will not be able to readily tell a specific applicable

manufacturer's method for reporting the payment or other transfer of value, since the assumptions document will not be made public. We also believe that a flexible method would create additional disputes because a covered recipient would not know what was included in a single line item, since some line items would be separated, whereas others would be aggregated. Additionally, a State with a similar reporting requirement for manufacturers that allows the reporting of secondary natures of payment stated in its public comment that reporting entities seldom use the secondary field, indicating that a single field should be sufficient.

With regard to choosing the appropriate nature of payment, we agree 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. However, this should not be used to bundle payments of separate categories into a single payment. For example, a meal should be reported as a meal, even if associated with travel or a consulting contract. Additionally, serving as a faculty for a medical education program should be reported separately from a consulting contract, even if the medical education program speech was similar in content to the consulting services provided by the covered recipient.

Comment: A number of commenters generally questioned the form of payment and nature of payment categories. Many commenters requested that CMS develop precise definitions, and a few commenters provided recommended definitions. However, in the event that the agency does retain the dictionary definitions, some commenters suggested that CMS should ensure that the dictionary definitions are sufficient to provide clarity. Additionally, a few commenters recommended that CMS publish and allow for Q&As to further clarify the categories. A few commenters provided additional categories for CMS to add, whereas others recommended methods for categorizing payments or other transfers of value to explain the details of the payment. For example, a commenter recommended that we create separate reporting categories for payments or other transfers of value made directly and indirectly. Finally, a few commenters recommended that we should consider form of payment as "payment type" or the modality used to transfer value, whereas we should consider nature of payment as "payment nature" or the reason the payment was made.

Response: We appreciate the comments and have carefully considered the best way to provide additional context to the categories. Given the very specific statutory requirements, we are unable to fully reconfigure the categories; while the Secretary is granted discretion to add forms of payment and natures of payment, she is not given discretion to remove or collapse them. However, we appreciate the clarification on form of payment being considered the modality used to transfer value and nature of payment being the reason the payment was made. We believe these classifications should help applicable manufacturers when assigning categories, and will help us provide more accurate guidance on the categories.

In order to provide additional information we have provided general discussions and additional contextual information, particularly for the nature of payment categories, since we believe most comments were concerned with the nature of payment categories. We provide additional details in the following two sections of this final rule dedicated to form of payment and nature of payment.

g. Form of Payment

Section 1128G(a)(1)(A)(v) of the Act lists forms of payment that applicable manufacturers must use to describe payments or other transfers of value. Applicable manufacturers must assign each individual payment or other transfer of value, or separate parts of a payment, to one and only one of these categories. In the proposed rule, we did not add any forms of payment beyond those outlined in the statute because we believed what is provided in the statute was sufficient to describe payments and other transfers of value. Additionally, as explained, we proposed that each form of payment be defined by the term's dictionary definition, since we believed that these terms are understandable as written.

Comment: We received a few comments supporting the categories, as well as a few recommending small changes to the categories. A few commenters advocated adding a category for "grant" to make clear that it was not personal income. Another few commenters recommended separating stock, stock option, or any other investment interest from dividend, profit or other return on investment, since they are materially different. These commenters explained that stocks, stock options, and investment interests are different from dividends, profits, and return on investments

because the former are actively granted to a covered recipient while the latter are earned on existing investments. Finally, regarding the definitions, a few commenters suggested that CMS use standard legal definitions.

Response: We appreciate the comments and agree that the forms of payment categories are sufficient. However, we do agree that the “stock, stock option, or any other ownership investment interest, dividend, profit or other return on investment” category should be divided into two categories. We agree that the categories are different and separating them would create additional specificity in the categories, without changing them significantly. Conversely, we do not agree that grant should be a form of payment. Instead, we believe “grant” should remain as a nature of payment (as included in the statute), since it best describes a reason a covered recipient might receive a payment. After consideration of the public comments received, we are finalizing the 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. We agree that stock, stock options, and other ownership investment interests are different than dividends, profits and other returns of investment, so separating these categories may provide additional clarity to consumers. We do not believe that this changes the way forms of payments will be reported, since the categories existed previously, we are simply providing more clarity and specificity to the categories. We believe the dictionary definitions are sufficient, particularly since these terms are generally understandable to consumers.

h. Nature of Payment

Section 1128G(a)(1)(A)(vi) of the Act lists the categories for the nature of payment or other transfer of value that applicable manufacturers must use to describe each payment. In the proposed rule, we encouraged applicable manufacturers to consider the purpose and the manner of the payment or other transfer of value; if a payment could conceivably fall into more than one category, we proposed that applicable manufacturers should make reasonable determinations about the nature of payment reported for the payment or transfer of value. Additionally, as explained, we believed that the nature of payment categories have meanings to the general public that are familiar to the industry and proposed defining each

nature of payment category by its dictionary definition.

Comment: Many commenters discussed the nature of payment categories, including our proposed method for defining the categories. A few commenters recommended that CMS provide more guidance on how these categories should be applied. For example, one commenter recommended that CMS rank the categories and if multiple categories could apply to a single payment or other transfer of value, the applicable manufacturer should report it in the “higher” ranked category. Another commenter requested that CMS break the categories into two groups: those made in exchange for value (such as services or intellectual property rights) and those made without any expectation of benefit. Beyond categorizing payments or other transfers of value, many commenters requested additional guidance on the definitions for the nature of payment categories. We also received a few recommendations for additional nature of payment categories. For example, a few commenters recommended including a category for agreements to appear as an “author” of an industry ghost-written publication. Another commenter recommended that we include a category for space or facility fee for events at a teaching hospital.

Response: We appreciate the comments. However, we believe that providing precise definitions for applicable manufacturers to use in categorizing nature of payments will be too restrictive. Applicable manufacturers are required to report all payments or other transfers of value, unless they specifically fall within an exception. The nature of payment categories are simply used to describe these payments or other transfers of value. We believe precise definitions could make these descriptors less useful and could make reporting more challenging for applicable manufacturers. For example, if a payment or other transfer of value that the applicable manufacturer generally would classify as a consulting fee does not meet our precise definition, the applicable manufacturer would be forced to report it in another category, which would likely be less accurate than the consulting fee category. The relationships between applicable manufacturers and covered recipients are extremely diverse; we are concerned that providing specific, narrow definitions would not encompass every situation, forcing applicable manufacturers to describe payments or other transfers of value by less specific categories that do not accurately

describe the relationship. Additionally, since all payments or transfers of value must be reported, we do not believe we should rank the categories and indicate some as more desirable or beneficial than others. Instead, we believe that the nature of payment categories are descriptors and that applicable manufacturers should select the most appropriate description. However, we do understand the interest in consistency to enhance of the usefulness of the data, so we will provide some additional explanations for the categories.

Finally, we appreciate the recommended additional categories. We have tried to limit the number of additional categories as much as possible, so we have only added categories for those recommendations that we believe cannot be described by existing nature of payment categories. For example, we believe that agreement to appear as an author of a ghostwritten article is an important relationship that should be reported, but believe there are sufficient existing nature of payment categories, such as compensation for services other than consulting, which can be used to describe the relationship. Conversely, regarding space rentals, we do agree that this represents a specific relationship between a covered recipient (likely a teaching hospital) and an applicable manufacturer that cannot be accurately described by the existing nature of payment categories. We understand that space rental or facility fees are commonly part of hosting an event at a hospital and believe that including them in another category would inflate the amount in that category. Similarly, the statutory nature of payment categories are mostly directed towards physician covered recipients, so it is important to consider the common relationships between teaching hospital covered recipients and applicable manufacturers. Given these considerations, we will add space rental and facilities fees as a nature of payment category under our authority in section 1128G(a)(1)(A)(vi)(XV) of the Act, but will not add appearing as an author for a ghostwritten article.

We are providing some additional explanation of the nature of payment categories to provide additional context. These explanations are not exhaustive (unless specified as such), but rather are intended to provide additional guidance to applicable manufacturers when they are categorizing payments. Additionally, we will discuss research in a separate section in light of the additional complexities in reporting research-related payments or other transfers of

value, which warrants additional consideration.

(1) Charitable Contributions

In the proposed rule, we stated that charitable contributions to, at the request of, or on behalf of covered recipients by applicable manufacturers must be reported. For purposes of the reporting requirement, a charitable contribution is any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, but only if it is not more specifically described by one of the other nature or payment categories. We did not receive any comments on the definition of charitable contribution and intend to finalize it as proposed.

Comment: Many commenters questioned how to report payments or other transfers of value for when a covered recipient (usually a physician) does not receive a payment personally and instead the payment is provided to a charity. In these situations, the covered recipient may or may not choose the charity and may be waiving his or her customary fee.

Response: We appreciate the comments and understand these payments or other transfers of value can be complicated. We discussed general guidelines for reporting payments through another covered recipient in the payments or other transfer of value section of the final rule, but will provide additional detail in this section for situations when a payment or other transfer of value is directed to charity. We believe 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. For example, in circumstances where a physician provides consulting services to an applicable manufacturer, but requests that his payment for the services be made to a charity, this would not be a charitable contribution for purposes of this rule because the payment was not provided by the applicable manufacturer as a charitable contribution, but rather as a directed consulting fee. This payment would be reported as a consulting fee with the physician as the covered recipient, but the entity paid would be the charity.

Additionally, we note that in the cases of teaching hospital covered recipients that have tax-exempt status under the Internal Revenue Code of 1986, payments or other transfers of value made to these organizations (other

than payments or other transfers of value made for expected services or benefits, such as consulting services or rental of space in a hospital for an event) would be considered and reported as charitable contributions for purposes of this rule.

(2) Food and Beverage

When reporting food and beverage, we proposed that in group settings, such as the office of a group practice, where it is more difficult to keep track of which covered recipients actually partook in the food and beverage provided by an applicable manufacturer, the applicable manufacturer should report the cost per covered recipient receiving the meal even if the covered recipient does not actually partake of the meal.

Comment: Numerous commenters questioned our proposed allocation method for food and beverage. The majority of commenters recommended that we revise our proposed allocation methodology, but we did receive some support for it. Many commenters recommended various options for dividing the cost of group meals; however, there were some common themes in the recommendations. The majority of these commenters recommended that applicable manufacturers should report the amount based on the cost per participant (including, for example, support staff members who are not covered recipients), rather than the cost per covered recipient. Many commenters also strongly recommended that we should not attribute meals to *all* covered recipients in a practice because it may be difficult for applicable manufacturers to identify all the physicians within a practice, and this methodology could implicate concerns of off-label marketing in large multispecialty practices. These commenters suggested that the cost of a meal should only be attributed to physicians who actually partook of the food. They suggested that it would not be unduly burdensome to keep track of which physicians actually participated in the meal. Some commenters also recommended that CMS allow applicable manufacturers flexibility in allocating the value of meals depending on their internal systems or that the value should be based on the amount actually received. Finally, a few commenters recommended that CMS provide covered recipients with the opportunity to “opt-out” of interactions with applicable manufacturers, including meals, and attest that they never partake in such meals.

Beyond the allocation method, we received significant support for our proposal that applicable manufacturers do not need to report any offerings of buffet meals, snacks or coffee at booths at conferences or other similar events where it would be difficult for applicable manufacturers to definitively establish the identities of the individuals who accept the offerings. However, a few commenters also recommended that meals that are dropped off at a physician’s office should also be excluded, as well as meals when the attendees are outside the control of an applicable manufacturer.

Response: We appreciate the comments and understand that reporting payments or other transfers of value that fall under the “food” nature of payment category is quite complicated, both in terms of calculating the value of the payments and determining who should be reported as having received payments. We believe that while reporting the transactions accurately is important, tracking exactly what a person ate or drank may not be practical for purposes of the reporting requirements. We have considered how to improve accuracy in reporting, while ensuring that the reporting requirements for this nature of payment are not overly burdensome. For meals in a group setting (other than buffet meals provided at conferences or other similar large-scale settings), we 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). In other words, applicable manufacturers should divide the total value of the food provided by the number of people who actually partook in the food and beverage including both covered recipients and non-covered recipients (such as support staff). 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. For example, a sales representative brings a catered lunch costing \$165 to a 10-physician group practice. Six of the ten physicians and five support staff participate in the meal. Because the meal cost \$15 per participant (\$165/11 participants = \$15), the meal needs to be reported for the 6 physicians who participated in it. However, the meal does not need to be reported for the 4

other physicians in the group who did not participate in the meal (that is, did not eat or drink any of the offerings). Additionally, if the total cost of the meal was \$100, making the cost per participant less than \$10, then the meal would not have to be reported since it was below the minimum threshold. We decided to make this modification to the proposed rule because we agree with commenters that for the purposes of this rule this method will more accurately reflect the actual transaction, and will not unfairly attribute a payment to a physician who did not partake in it. Additionally, we believe this approach will reduce disputes between applicable manufacturers and physicians, since food-related payments or other transfers of value will not be attributed to physicians that did not actually receive them. Finally, this method does not require the reporting of meals eaten by support staff, for the purposes of this reporting requirement. However, we recognize that in other contexts, transfers of value to a physician's office support staff (which may include meals) may constitute transfers of value to the physician.

While we appreciate the importance of flexibility, we believe that we need to set out the attribution methodology in order to ensure as much consistency as possible. If we did not provide a methodology, it could result in very different amounts being reported across applicable manufacturers and could lead to increased disputes since covered recipients would not know how a particular applicable manufacturer attributed the value of a meal. We believe that there must be some consistency across applicable manufacturers in this complicated area, so we have finalized the position that applicable manufacturers must report the cost per participant for covered recipients in attendance.

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, we believe 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.

We also appreciate the comments regarding allowing covered recipients

the opportunity to opt-out from receiving meals; however, we believe that this would be operationally difficult for CMS. We would need to track the covered recipients and would have to develop a method of arbitration if an applicable manufacturer reports a meal for a physician who has opted-out. We believe that covered recipients who do not want to receive meals simply should make clear to applicable manufacturers that they do not accept them. The finalized methodology will no longer attribute meals to physicians who do not attend the meal, so a physician who does not want to receive meals should not attend or accept them.

Finally, we appreciate the support regarding offerings of buffet meals, snacks, or coffee at conferences or other large-scale events where it would be difficult for applicable manufacturers to definitively establish the identities of the physicians who partake in the food or beverage. Accordingly, we have 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. This applies to situations when an applicable manufacturer provides a large buffet meal, snacks or coffee which are made available to all conference attendees and where it would be difficult to establish the identities of the physicians who partook in the meal or snack. We do 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.

(3) Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program

In the proposed rule, we interpreted this category broadly to encompass all instances in which applicable manufacturers pay physicians to serve as speakers, and not just those situations involving "medical education programs." We acknowledged that this interpretation does not allow for differentiation between continuing education accredited speaking engagements, and all other speaking engagements.

Comment: Many comments addressed our proposed interpretation of this category, particularly regarding its relationship to accredited and/or certified continuing medical and dental education.

A few commenters supported our interpretation to include all speaking engagements in one category; however, numerous others were concerned about payments for accredited and/or certified

continuing education-related speaking engagements and recommended that they be treated differently than unaccredited and/or certified continuing education speaking engagements. Many of these commenters provided significant background information on accredited and certified continuing education. Accredited Continuing Medical Education (CME) refers to CME activities that have been deemed to meet the requirements and standards of a CME accrediting body, as authorized by the Accreditation Council for Continuing Medical Education (ACCME). Certified CME refers to CME activities that carry credit offered by the grantors of CME credit (the American Osteopathic Association (AOA), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA)). Continuing dental education is similarly accredited through the American Dental Association's Continuing Education Recognition Program (ADA CERP).

These commenters explained that accredited and certified continuing education speaker payments will generally not be made directly by an applicable manufacturer to a covered recipient, as this category suggests, due to the accreditation requirements. Some commenters suggested that these be reported in another "indirect" speaking engagement category. Conversely, other commenters recommended that this category be limited to accredited and certified continuing education payments, and that compensation for other speaking engagements should be described by other natures or payments.

Response: We appreciate the comments and agree that it is important that CMS clarify this category. We understand the importance of continuing medical education and discuss the requirements for reporting it generally in section II.B.1.k. of the final rule, dedicated to indirect payments or other transfers of value. We agree that given the title of this nature of payment category, which was set out in the statute itself, it should not include compensation for accredited or certified continuing education payments. However, we do not believe that all payments to physicians for serving as speakers at an accredited or certified continuing education program should be granted a blanket exclusion (as discussed in the indirect payment section), so we have added an additional nature of payment category for serving as a faculty or speaker at an accredited or certified continuing education event, at § 403.904(e)(2)(xv). This category, named "compensation for

servicing 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 § 403.904(g)(1)(i) through (iii), and further discussed in section II.B.1.k. of this final rule. Additionally, we also renamed the category for direct compensation to include speaking engagements at unaccredited and non-certified continuing education events at § 403.904(e)(xiv). We recognize that not all payments or other transfers of value related to unaccredited and non-certified continuing education will be provided directly. Therefore, we retitled the category as "compensation for serving as a faculty or as a speaker for an unaccredited and non-certified continuing education program." This renamed category 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. Finally, the nature of payment category for "compensation for services other than consulting" at § 403.904(e)(2)(ii) now explicitly includes payments or other transfers of value for speaking engagements that are not for continuing education.

We believe this reporting strategy appropriately separates accredited and certified continuing education from unaccredited and non-certified continuing education, so that consumers can better understand the nature of the payment received by a covered recipient. Accredited and certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to reduce industry influence, so we believe that, when reportable (that is, when the payments or transfers of value do not meet the conditions delineated at § 403.904(g)(1)(i) through (iii)), payments or transfers of value made to support accredited and certified continuing medical education should remain in a distinct category from unaccredited or non-certified continuing education. We also believe that educational speaking engagements should be separated from all other speaking engagements, promotional or otherwise, to have separated them appropriately. Finally, we believe the renaming of the statutory nature of payment category for "direct compensation for serving as a faculty or

as a speaker for a medical education program" to include indirect compensation as well, provides applicable manufacturers flexibility to describe payments or other transfers of value more accurately.

(4) Other

In the proposed rule, we added a nature of payment category, titled "other," to serve as a catch all for payments or other transfers of value that do not fit into one of the listed natures of payment.

Comment: Many commenters recommended that CMS remove the proposed additional nature of payment category "other."

Response: We appreciate the comments and agree that an "other" category could dilute the usefulness of the nature of payment categories. Therefore, the final rule omits "other" category from the nature of payment categories at § 403.904(e). However, all payments or transfers of value from applicable manufacturers to covered recipients (other than those excluded under section 1128G(e)(10) of the Act) must be reported. Any payments or transfers of value that are not specifically excluded, must be reported and described based on the nature of payment categories included in the final rule. Applicable manufacturers are required to report each payment under the nature of payment category that most closely describes the payment; the absence of a nature of payment category that closely describes the payment does not constitute a basis for not reporting an otherwise reportable payment or other transfer of value. Failure to report such a payment may result in the imposition of a civil monetary penalty on the applicable manufacturer.

(5) Other Nature of Payment Categories

Although we did not address these categories in the proposed rule, we received comments requesting additional information on these categories and what CMS intends them to include. In the following sections, we have provided additional guidance on how we interpret the categories. Once again, this is not intended to define the categories, but rather to provide additional information for applicable manufacturers when considering the categories.

(A) Consulting Fees

This category is intended to include fees paid by an applicable manufacturer to a covered recipient for services traditionally viewed as consulting services. While we believe there is likely variation, we believe that

consulting services are typically provided under a written agreement and in response to a legitimate need by the applicable manufacturer. Similarly, we believe there is often a connection between the competence of the covered recipient paid and the purpose of the arrangement, as well as a reasonable number of individuals hired to achieve the intended purpose.

(B) Compensation for Services Other than Consulting

This category is 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. As discussed in the section on direct compensation for serving as a faculty or as a speaker for a medical education program, this category should include payments or other transfers of value for speaking engagements that are not related to continuing education, such as promotional or marketing activities.

(C) Honoraria

We believe this category is similar to "compensation for services other than consulting." However, honoraria are distinguishable in that they are generally provided for services for which custom prohibits a price from being set.

(D) Gift

This category is a general category, which will often include anything provided to a covered recipient that does not fit into another category. For example, the provision of small trinkets (above the minimum threshold) would need to be reported as a "gift" since they are not included in any other category. However, provision of tickets to a professional sporting event should not be reported as a "gift" since this transaction is better described by the nature of payment category "entertainment" even if the provision of the tickets was a gift.

(E) Entertainment

This category is intended to include, but is not limited to, attendance at recreational, cultural, sporting or other events that would generally have a cost.

(F) Travel and Lodging

This category includes travel, including any means of transportation, as well as lodging. As required in section 1128G(a)(1)(A)(vi)(VII) of the Act, the destination, including City, State and country must be reported.

(G) Education

We believe this category generally 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. As stated in the section on indirect payments or other transfers of value, we do 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, we believe 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.

(H) Royalty or License

This category includes, but is not limited to, the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes. We believe this may be pursuant to a written agreement and could entail various payment schedules (such as scheduled or milestones methods). Applicable manufacturers may report total aggregated payment amounts for payments made under a single agreement, in order to consolidate reporting.

(I) Current or Prospective Ownership or Investment Interests

We believe this category 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. Details on current ownership or investment interests is discussed in the section of the final rule dedicated to reporting ownership or investment interests of physicians.

(J) Grant

This category generally refers to payments to covered recipients in support of a specific cause or activity.

(6) Nature of Payment Categories

Based on the comments, and the discussion and justifications included in this section, we will allow applicable manufacturers to report the following categories in the nature of payment field to describe payments or other transfers of value. However, as stated previously, all payments or other transfers of value must be reported, unless excluded, even if they do not explicitly fit into one of the outlined nature of payment categories. Applicable manufacturers

must select the nature of payment category that best describes the payment or other transfer of value. The nature of payment categories in the final rule 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.

(7) Assumptions Document

In order to monitor how applicable manufacturers were classifying payments or other transfer of value, we proposed that applicable manufacturers could submit along with their data a document describing the assumptions used when categorizing the natures of payments. We proposed that submission of the assumptions document would be voluntary and would not be made public. We explained that the documents could aid the agency in offering further guidance to applicable manufacturers regarding how natures of payment should be classified.

Comment: A few commenters questioned the CMS proposal to allow applicable manufacturers to submit an assumptions document in order to ensure consistency in the reporting and selection of categories. Many of these commenters supported the submission of the assumptions document; however, the commenters varied as to whether the assumptions documents should be mandatory. Some commenters recommended that it be mandatory, while others supported that it be voluntary. Additionally, the commenters also both supported and opposed the proposal not to make the assumptions document public. A few commenters expressed that the assumptions documents should not be published on the public Web site and should also not be subject to a Freedom

of Information Act (FOIA) request. Conversely, other commenters recommended that even if the assumptions documents were not made public, they should be available to covered recipients upon request to help mitigate disputes.

Beyond the publication of the assumptions document, some commenters discussed the expected content for the assumptions document, as well as how CMS intends to use the documents. Regarding the content of the assumptions document, a few commenters recommended that applicable manufacturers may include other reporting assumptions and methodologies, beyond natures of payment, such as determining whether an interaction constitutes a payment or other transfer of value. Other commenters recommended that CMS create its own assumptions document for applicable manufacturers to use when characterizing payments or other transfers of value. Finally, a few commenters recommended that CMS clarify that it intends to review the submitted assumptions documents and does not plan to use them for purposes of prosecution for failure to report.

Response: We appreciate the comments, and given the support for the assumptions document, we are finalizing the voluntary submission of an assumptions document in this final rule. As discussed in the section of the preamble to this final rule on payments or other transfers of value (section II.B.1.F. of this final rule), applicable manufacturers may include in the assumptions document assumptions and methodologies other than only those employed when classifying nature of payment categories. Furthermore, 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.

After review of the comments, we continue to believe that submission of the assumptions document should be voluntary and that the contents of the assumptions documents submitted should not be made public. We believe that they will likely contain significant detailed information, which will not necessarily be consumer friendly, so it could be overwhelming on the public Web site. We encourage applicable

manufacturers to be as clear and specific as possible with regard to the information submitted within the assumptions document. If a statement within the assumptions document pertains to a particular section of the report, applicable manufacturers should explicitly refer to that section in the assumptions document. Additionally, we do not believe that we should provide the assumptions documents to covered recipients. This would be difficult for the agency to track and would greatly reduce the confidentiality of the documents. Applicable manufacturers may provide their assumptions document to covered recipients upon the request of covered recipients independently from CMS. To the extent an assumptions document is requested under the FOIA, we would follow our predisclosure notification procedures at 45 CFR 5.65(d) and seek the submitter's input on the applicability of FOIA Exemption 4, which protects trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

The agency intends to carefully review the assumptions documents to determine whether we need 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, we intend to provide assistance to applicable manufacturers to help classify payments or other transfers of value and hope that such guidance will be useful. Finally, we do not intend to use the assumptions document for prosecution, but acknowledge 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.

i. Research

We received numerous comments on our proposed methods for reporting and presenting research-related payments. We recognize that reporting payments or other transfers of value for research activities is extremely complicated, since many research activities include large payment amounts which are spread across numerous activities and parties, and acknowledge that our proposed method did not fully address this complexity. We understand the need for a simple and clear reporting process, which allows the agency to

accurately present research payments to consumers. We appreciate the comments and have revised the system to try to improve the process and ensure that the research is reported in a manner that most accurately describes the research relationship. A summary of the comments and our finalized process are outlined in this section.

(1) Scope of Research

In the proposed rule, we proposed to limit the research category to bona fide research activities, including clinical investigations that are subject to a written agreement or contract between the applicable manufacturer and the organization conducting the research *and* a research protocol. We based this criteria on the method used to identify payments eligible for delayed publication.

Comment: We received a number of suggestions from commenters about which types of research payments should be reportable. Many commenters recommended including a definition of research and suggested many different definitions. Additionally, some commenters recommended that CMS provide information on what constitutes a research protocol or written agreement. These commenters stated that not all research has a "research protocol" and recommended that the agency interpret the term broadly or not require that one exist in order for a payment to be described as research. For example, clinical research for devices is often different from clinical drug research and does not require a research protocol. Finally, many commenters recommended that CMS exclude certain research-related payments from the reporting requirements altogether, such as payments related to pre-clinical research, indirect research, or research by Principal Investigators (PI) not practicing medicine, due to the importance of research-related relationships in developing new treatments and products.

Additionally, a few comments addressed how to handle payments that could conceivably be related to research, but do not meet the definition of research. In the proposed rule, we solicited comments on the preferred method for these payments and the comments were mixed. Some recommended that CMS create another nature of payment category for these payments (such as one titled "other research"); others recommended that CMS require applicable manufacturers to report the payment in another category.

Response: We appreciate the comments and agree that we should

provide additional information and clarification about what constitutes research and what research-related payments must be reported. Based on suggestions in the comments received, we have 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." We believe this definition includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations. We have finalized that payments reported as research should be made in connection with an activity that meets the definition. In addition, we agree that requiring both a written agreement or contract *and* a research protocol is limiting for some types research, so we are finalizing 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 we understand 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. For example, agreements between an applicable manufacturer and a CRO, between a CRO and an SMO, and then between an SMO and a teaching hospital would be considered a continuous chain of agreements from the applicable manufacturer to a covered recipient and would be considered a research agreement.

Regarding reporting of research-related payments which do not meet the definition of research, applicable manufacturers should report using the other categories available. We believe that the categories are sufficiently broad to provide applicable manufacturers options; for example, we believe the grant category could be used to sufficiently describe some of the transactions.

We also seek to respond to comments about which research-related payments should be reportable. In general, we believe that any payments related to the definition of research discussed previously should be reportable. We

recognize that research is important and have allowed research to be reported in a manner that acknowledges its special role. Given this consideration, we do not believe we should further limit the scope of research payments to be reported. Many of the comments sought to limit the reporting of research related payment in significant ways, such as only reporting direct research. However, we believe Congress clearly intended research-related payments or other transfers of value to be included in the reporting requirements, based on the inclusion of "research" as a nature of payment, the statutory definition of "clinical investigation," and the procedures for delayed reporting for certain research-related payments or other transfers of value. We believe that excluding payments or other transfers of value related to clinical research or indirect research from the reporting requirements would be inconsistent with the intent of Congress. We do agree that pre-clinical research is slightly different, so we have outlined reporting requirements tailored to its unique structure which are discussed more in this section.

Additionally, as explained in the section on covered recipients, we do not believe the statute limits the reporting requirements to licensed physicians who regularly treat patients, so we plan to require reporting of research payments to PIs who meet the definition of "physician," even if they do not regularly treat patients. Finally, 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. We believe for the purposes of this regulation that due to the early stage of the research process, the transferred material does not have independent value.

(2) Reporting Research Payments

We also understand that research payments are unique and should be reported differently than other payments or other transfers of value. We proposed special rules to report research payments, including a rule to separate the classification of research payments to clarify whether the payment or other transfer of value went indirectly or directly to the covered recipient. When reporting payments or other transfers of value designated as research, we proposed that applicable manufacturers must report the payment or other transfer of value as either "indirect research" or "direct research." Additionally, we proposed that the

payment or other transfer of value (whether direct or indirect research) should be reported individually under the names and NPIs of physician covered recipients serving as principal investigators. For indirect payments, this included the physician covered recipient(s) serving as principal investigator(s) who would ultimately receive payments from the clinic, hospital, or other research institution, assuming the applicable manufacturer is aware of the identity of the principal investigator(s). Finally, we proposed that for both direct and indirect research, applicable manufacturers must report the entire payment amount for each research payment (whether to the covered recipient or research institution), rather than the specific amount that was provided to the covered recipient.

Comment: A significant number of comments addressed the method proposed for reporting research payments. While there was some support for our proposed methods, the majority of the commenters did not support it and recommended a new method. Many commenters stated that allocating 100 percent of the research payment to the physician PI would be misleading, even if the payment amount was not aggregated into the physician's total payments. Similarly, many commenters did not support reporting a single payment multiple times, which some commenters feared could lead to double counting of research payments. These commenters provided numerous recommendations for how to report and present research related payments. The most common recommendation was to report research in a separate reporting template, which would include a single line item for each payment. The payment would include both the entity paid (such as the research institution) and list the name of the principal investigator. There were some variations in the recommendations, including reporting only the amount the PI received and that the applicable manufacturer must control the selection of the PI; however, the majority of comments followed this basic process. A few commenters also requested that applicable manufacturers should be allowed to report context of research or additional information on the research payment. Finally, a few commenters recommended that research payments be presented separately on the public Web site to clearly delineate them as a research-related payment or other transfer of value.

Response: We appreciate the comments and agree that reporting of research-related payments should be

more representative of the actual payment stream for research. Applicable manufacturers must report research-related payments that ultimately are paid, in whole or in part, to a covered recipient (physician or teaching hospital). We have finalized that applicable manufacturers must report research payments separately in a different template, since we will be requiring the reporting of modified information. Applicable manufacturers will not be responsible for indicating whether a payment was direct or indirect. We have 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, we intend 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. We believe that the recipient of the payment could include individual principal investigators, teaching hospitals, nonteaching hospitals or clinics. We intend for the principal investigator(s) to include the individual(s) conducting the research or providing the services on behalf of the research institution.

As discussed regarding the reporting elements for all payments or other transfers of value, in order to better identify and match covered recipients, the same identifying information will be required to be reported for each PI meeting the definition of covered recipient.

The applicable manufacturer 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).

We believe 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. We believe the study name will provide information on the research topics, but we have also included an optional field allowing applicable manufacturers to provide additional contextual information on or the objectives of the research. We intend this to be used similarly to the additional context allowed for reporting all payments or other transfers of value. Additionally, we also 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, we recognize that not all research studies will be posted on ClinicalTrials.gov, so this category will be optional. Finally, 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 Web site.

For pre-clinical research, we finalize slightly modified reporting requirements since such early stage research is often not connected to a specific product. We intend 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.

We are also finalizing 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. We envision that this would include the 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. For example, 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. In addition to research payments, we also believe that 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.

We realize that reporting requirements for research will be somewhat different than the procedure outlined for other natures of payment, but we believe that this is appropriate for research-related payments or other transfers of value. As several comments pointed out, due to the flow of research payments from sponsor to research institution, an applicable manufacturer might not know the specific details or amounts of how the larger research payment was spent. We do 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, we do not require the reporting of payments to non-covered recipients that are not passed on to covered recipients. For example, if an applicable manufacturer paid separately for a non-covered recipient to travel to a meeting, then it would not need to be reported. However, if an applicable manufacturer paid separately for a covered recipient (regardless of whether the individual was a PI or not) to travel to a meeting, then the travel would have to be reported in the name of the covered recipient traveling.

When reporting research payments, we also acknowledge 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, we will list research studies separately from all other payments provided to the covered recipient. For teaching hospitals, we 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.

We believe that presenting research payments in this method reflects the fact that research payments are unique and do not necessarily represent a personal payment to physicians; however, it still allows for research payments to be reported as intended by Congress, but in a less burdensome way for applicable manufacturers. In light of the public comments received, we believe that the modifications represent a better, more accurate method of reporting research payments.

j. Exclusions

Section 1128G(e)(10) of the Act excludes specific types of payments or other transfers of value from the reporting requirements.

Comment: We received numerous comments on the exclusions section of the proposed rule. Many of the comments focused on the statutory exclusions and the explanations CMS provided in the proposed rule. Beyond these comments, we also received numerous recommendations for additional exclusion categories to be included in the final rule. The recommended exclusions covered numerous specific relationships between applicable manufacturers and covered recipients, some related to healthcare, such as paying a physician at an on-site clinic, whereas others did not, such as campaign contributions to physicians running for political office.

Response: We appreciate these recommendations, but do not believe that we have the statutory authority to add exclusions beyond what was outlined in the statute. The statute expressly provides the Secretary discretion to require the reporting of additional information of payments or other transfers or value, and ownership or investment interests, but it does not provide a similar authority to add exclusion categories. We have finalized our policy that the exclusions will be defined by their dictionary definitions, but plan to provide additional clarification in response to the comments in this section. We believe that some of the recommended exclusions could be included in some of the statutory exclusions, so we have provided additional information to clarify our interpretation of these categories.

(1) Existing Personal Relationships

In the proposed rule we stated that we did not intend to require reporting of purely personal transfers of value (for example, if one spouse, who works for an applicable manufacturer, gives a present to the other spouse who is a covered recipient), and we solicited comments on this proposal.

Comment: Many commenters supported our intention to exclude payments or other transfers of value between individuals who happen to have existing personal relationships and recommended that it be included as a listed exclusion. A few commenters also recommended specific requirements, such as to include relationships between family members, to limit to bona fide relationships or to mirror the Federal employee exemption.

Response: We appreciate the comments and do not intend existing personal relationships to be reported, so we have finalized this provision in § 403.904(i)(14).

(2) Payments or Other Transfers of Value of Less Than \$10

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. As required by section 1128G of the Act, for subsequent calendar years, the dollar amounts specified will be increased by the same percentage as the percentage increase in the consumer price index (CPI) for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. In the

proposed rule, we proposed that applicable manufacturers should not report to CMS any payments or other transfers of value less than \$10 individually and all small payments or transfers of value in the same nature of payment category should be reported as one total amount for that category. We believed this would simplify reporting for applicable manufacturers and prevent the reporting of payments less than \$10 individually. Given the timing of this final rule, we have 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. We believe this simplifies reporting for the first year of data collection by employing simple numbers as thresholds. Also because these were the statutory thresholds, we believe applicable manufacturers should be prepared to collect data and report using these thresholds for CY 2013.

Comment: We received various comments on small payments or other transfers of value. Some commenters indicated that our proposed method for reporting small payments together might (for some applicable manufacturers) be more difficult than reporting small payments individually; these commenters recommended that CMS allow applicable manufacturers discretion in their reporting mechanism. Some commenters also recommended that CMS not change the thresholds within a single reporting year. Beyond comments on reporting of small payments, many commenters also addressed the small payment or transfer of value exclusion more generally. Many commenters questioned the thresholds and indicated that they were too low and recommended various higher thresholds. Similarly, some commenters recommended that CMS consider methods within the statutory requirements to reduce the number of small payments being reported. Finally, many commenters supported CMS's proposal to not report food and beverages at conferences and indicated that CMS should extend this to other items provided at conferences (both above and below the \$10 threshold).

Response: We appreciate the comments and agree that applicable manufacturers should have discretion when reporting small payments. We had proposed requiring applicable manufacturers to bundle payments in order to reduce burden, but we do not want to require that method if some applicable manufacturers actually believe it to be more burdensome. Therefore, we will finalize 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. Additionally, we agree that the de minimis thresholds should not change within a reporting year and will be constant for the entire year. For example, for the entirety of data collection in 2014, the thresholds will be those adjusted based on CPI published in June 2013. We will report the new de minimis value with the reporting template for the next reporting year.

We appreciate the comments on the threshold for small payments and understand that they may be low for some stakeholders. Nevertheless, the thresholds were mandated by the statute, and we do not have discretion to change them. However, we recognize that we do not want the database to be overwhelmed by small payments. We have considered options for reducing the number of small payments, but we believe that we do not have authority to change the reporting requirements for small payments or other transfers of value.

Regarding reporting of payment or other transfers of value at conferences or similar events, we appreciate the comments and have provided additional guidelines expanding on the proposed rule. In general, we will finalize that these guidelines will apply to conference and similar events, as well as events open to the public. We believe that at events open to the public, it will be extremely difficult for applicable manufacturer to identify physician covered recipients. Therefore, we 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. While these small payments are excluded by statute, the \$100 aggregate payment requirement generally requires the tracking of small payments in order to determine whether covered recipients received more than \$100 annually. For these covered recipients, we believe it would be difficult for applicable manufacturers to track who receives these small items at conferences or similar events, due to the nature and disparate attendance at large-scale conferences or similar events. Additionally, this method is consistent with our decision to not require

reporting of food and beverage at large-scale conferences. We note that payments or other transfers of value of \$10 or more (for calendar year (CY) 2013) need to be tracked and reported even when provided at large-scale conferences or similar events. We believe 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.

Finally, we will not be providing a standard template for reporting by entities that organize and oversee events and conferences. These event and conference vendors are not applicable manufacturers, so we do not believe we should have any contact with them or impose requirements on them. We recognize that applicable manufacturers and their vendors will need to devise business practices to meet the requirements; however, we believe that many of the interactions at large-scale conferences and similar events will not be reportable, so we do not believe this will be excessively burdensome.

(3) Educational Materials That Directly Benefit Patients or are Intended For Patient Use

In the proposed rule, we explained that this exclusion was limited to materials (including, but not limited to, written or electronic materials) and did not include services or other items. Additionally, we considered whether certain materials provided by applicable manufacturers to covered recipients for their own education, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that “directly benefit patients.”

Comment: Many commenters addressed this exclusion, particularly questioning the meaning of “materials.” A few commenters stated that “materials” should be interpreted more broadly to include “programs, services, and items” since many applicable manufacturers provide services and items to patients in order to support disease management or increase medication adherence. These items are generally provided to patients through covered recipients. Finally, a few commenters also asked for clarification on what form these materials needed to be in and whether overhead costs for educational materials, such as time and printing, were included in the exclusion.

Response: We appreciate the comments and agree that “materials” should be interpreted somewhat more broadly for purposes of this exclusion. We understand that patient education is

important and recognize that it may take a form other than written material, especially in the device context. For example, a device manufacturer may give a physician an anatomical model to help explain to patients how a procedure would work. We agree that such an item, which is given to physicians for the purpose of educating patients, falls within the exclusion. Similarly, if a manufacturer provides educational materials to a physician on a flash drive to be distributed to patients, the flash drive would also be included in the exclusion. However, if the drive was provided as a gift alongside the materials, then it would have to be reported, since it was secondary to the materials. Similarly, we believe that 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.

Comment: Numerous commenters questioned CMS’s interpretation of “directly benefit patients or are intended for patient use.” These commenters had mixed reactions to CMS’s proposed interpretation. Some recommended that all materials provided to educate physicians (such as textbooks or journals) should be included in the exclusion, since educating the physician benefits patients. Others suggested that these should not be included, since they do not benefit patients directly. Some commenters also recommended that materials that are used “for or with” patients, but not taken home (such as anatomical models or wall charts) should be included in the exclusion because they are intended for patient use. Finally, a few commenters recommended that all materials intended for patients should be included in the exclusion.

Response: We appreciate the comments and agree that additional clarification is required. We agree that items that are educational to covered recipients (such as medical textbooks and journal reprints), but are not intended for patient use are important for physicians; however, we do not believe that these materials fall within the statutory exclusion. Although these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients, nor are they intended for patient use, as required by section 1128G(e)(10)(B)(iii) of the Act. Therefore, we will finalize 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. Conversely, we have finalized that this exclusion does encompass materials, such as wall models and anatomical models which are ultimately intended to be used with a patient. In addition, we believe that pursuant to the statutory text, the exclusion is limited to educational materials only, and not marketing or promotional materials.

(4) Discounts and Rebates

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.

We did not receive any comments on this exclusion, so we have finalized it as proposed.

(5) In-Kind Items for the Provision of Charity Care

In the proposed rule, we defined “in-kind items for the provision of charity care” as items provided to a covered recipient for one or more patients who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient’s inability to pay. Any items provided by the applicable manufacturer to a covered recipient that meet the definition of in-kind items for the provision of charity care, are excluded from reporting. This does not include the provision of in-kind items to a covered recipient, even if the covered recipient is a charitable organization, for the care of *all* of the covered recipient’s patients (both those who can and cannot pay). If a payment or other transfer of value is not an in-kind item and/or not for the provision of charity care, as defined, then the payment must be reported as required under section 1128G of the Act.

Comment: Many commenters provided recommendations on the charity care exclusion. These comments fell in two categories: first, on the interpretation of a patient’s ability to pay, and second, on the interpretation of in-kind items. Regarding a patient’s ability to pay, the commenters generally supported the proposed interpretation, but recommended that CMS provide additional clarification that a patient’s ability to pay includes whether the patient can afford the copayment or coinsurance, but not the entire visit. Additionally, a few commenters recommended that ability to pay should be based on whether payment will be a significant burden to a patient. Regarding in-kind items, the

commenters discussed whether payments to a covered recipient and/or a third party should be excluded if used to support charities or other charitable activities, such as patient assistance programs. Finally, a few commenters advocated that this exclusion should be based on the mission of the organization receiving the items, rather than what actually happened to them, since it will be impossible for applicable manufacturers to track the uses of these items.

Response: We appreciate the comments and agree that an analysis of a patient's ability to pay should include whether the patient can afford his or her copayment or coinsurance and whether the patient has insurance to cover the care. We intend 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.

Finally, we do 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. We believe 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.

Secondly, we believe that the statutory text for this exclusion (section 1128G(e)(10)(B)(viii) of the Act) clearly states that the exclusion should only apply to "in-kind items" and not all payments, so we have finalized that only in-kind items will be included in the exclusion, which does not include financial support for charitable covered recipients. However, we recognize that some payments made to charitable third parties may at some point indirectly benefit a covered recipient. We believe that these payments or other transfers of value should be reported based on the reporting requirements for indirect payments or other transfers of value. However, we believe that charitable contributions made directly to or intended for a covered recipient should be reported as a charitable contribution.

(6) Product Samples

Even though this exclusion was not specifically discussed in the proposed rule, we received comments on the exclusion for product samples from section 1128G(e)(10)(B)(ii) of the Act which states that "product samples that are not intended to be sold and are intended for patient use" are excluded from the reporting requirements.

Comment: Many commenters recommend that CMS clarify the

boundaries of the exclusion and interpret it widely to include samples beyond traditional drug samples, such as single use or disposable devices, demonstration devices, and evaluation equipment. A few commenters also recommended that the exclusion should include products used for research studies, as well as coupons and vouchers. Finally, a commenter stated that an applicable manufacturer may not know what actually happens to samples and should not be required to track them.

Response: We appreciate the comments and agree that further clarification is necessary. We believe that the statutory text is clear that this exclusion applies to products intended for patient use; therefore, 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. Given this interpretation, 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. Otherwise, we believe these items may be excluded from the reporting requirements under the exclusions for short term loans, as explained in that section. In addition, we believe that products used for research studies should be included as a part of the larger research payment. Regarding coupons and vouchers, we believe they fall within the exclusion, so we have 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. For the purposes of this rule, we believe such coupons and vouchers are materially similar to samples. Finally, we do not believe the applicable manufacturer should be responsible for tracking what actually happens to samples. Instead, we believe 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.

(7) Short Term Loans

This exclusion was also not addressed in detail in the proposed rule; however we did receive some comments recommending clarifications. Section 1128G(e)(10)(b)(iv) of the Act excludes "the loan of a covered device for a short-term trial period, not to exceed 90 days,

to permit evaluation of the covered device by the covered recipient."

Comment: A few commenters recommended that we include loans of a broad range of devices (including medical supplies) such as both covered and non-covered devices, as well as a short-term supply of disposable devices. Additionally, some commenters requested clarification on the timing of the 90-day loan period and what to report if the loan goes beyond 90 days. We also received a comment to shorten the loan period to 60 days.

Response: We appreciate the comments and agree that this exclusion can include a broad range of devices. We have finalized that this exclusion may include loans for covered devices, as well as those under development. We also have finalized that this will include a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days. We believe that these products should be treated similarly to non-disposable devices and, therefore, should be included in the exclusion. However, we do not believe that applicable manufacturers should be allowed to provide an unlimited supply of these products and still fall within the exclusion, so we are 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. We believe that this aligns with the intention of the statute to limit the loan period to 90 days and not allow a new loan to start at the end of the previous loan period, thus avoiding the reporting requirements. 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. We do not believe that reporting the prior 90 days as a payment or other transfer of value would greatly increase the payment value which would be misleading to consumers. Additionally, 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. The loan period is statutorily defined, so we do not have the authority to lower it, but appreciate the input that 90 days should be more than sufficient for the loan period.

(8) Contractual Warranty

While this exclusion was not addressed in the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(v) excludes “items and services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.”

Comment: Some commenters recommended that CMS allow the exclusion to extend to items and services provided under a contractual warranty, regardless of whether or not the warranty period had expired. These comments stated that often applicable manufacturers grant the terms of a warranty even after the period has expired. Additionally, a few commenters recommended that the exclusion should include other product contracts, such as product sale agreements, maintenance service agreements, and technical support agreements. Finally, a few commenters also recommended that replacement products as a part of a product recall should be included in this category.

Response: We appreciate the comments and agree that it is not materially different for an applicable manufacturer to grant the terms of a contractual warranty before the period expires or afterwards. We have 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. We believe the exclusion should extend beyond the express time period of the warranty, since the warranty terms, and thus the relationship, are the same before or after the expiration period and it will be misleading to consumers to only include a portion of the relationships.

In addition, we agree that there are numerous other contractual agreements that are similar to a warranty agreement, but are not specifically excluded. We believe that service or maintenance agreements are so similar to warranty agreements that it may be difficult to consumers and applicable manufacturers to meaningfully separate. We also believe the replacement products in the case of a product recall are materially similar and should be included. Given the similarities, we have finalized that items and services provided under a contractual service or maintenance agreement will also be subject to the exclusion.

(9) Covered Recipient Acting as a Patient

While this exclusion was not addressed specifically in the proposed rule, we received a few comments on it. Section 1128G(e)(10)(B)(vi) of the Act excludes “a transfer or anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.”

Comment: A few commenters recommended that CMS include in this exclusion situations when a covered recipient is a subject in a research study.

Response: We appreciate the comments and agree that a covered recipient 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.

(10) Provision of Healthcare

Although the exclusion was not discussed in detail in the proposed rule, we did receive a few comments. Section 1128G(e)(10)(B)(x) excludes “in the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.”

Comment: A few commenters recommended that CMS clarify that this exclusion includes the provision of health care to both covered recipients and their families covered under the self-insured plan. Similarly, received few commenters discussed other situations, outside a self-insured plan when an applicable manufacturer may reimburse a physician for provision of health care services to employees.

Response: We appreciate the comments and agree that payments to covered recipients for services rendered to family members receiving care under a self-insured plan should also be excluded from the reporting requirements. Similarly, we believe that the provision of healthcare to employees should extend beyond that offered under a self-insured plan. We understand that applicable manufacturers, both self-insured and otherwise, may provide healthcare services to employees beyond traditional insurance. We believe that for the purposes of this exclusion there is little material difference between the provision of healthcare under a self-insured plan and provision of healthcare outside a self-insured plan. We have 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.

(11) Nonmedical Professional

This exclusion was not specifically addressed in the proposed rule and we did not receive specific comments on it, and we have finalized it as proposed. 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.”

(12) Civil or Criminal Action or Administrative Proceeding

Although this exclusion was not specifically addressed in the proposed rule, we did receive a few comments on it. Section 1128G(e)(10)(B)(xii) of the Act excludes “in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of a covered recipient with respect to a civil or criminal action or an administrative proceeding.”

Comment: A few commenters recommended that CMS clarify the exclusion to include specific legal proceedings or arrangements, such as legal defense, prosecution, settlement or judgment of a civil or criminal action and arbitration or other legal action.

Response: We appreciate the comments and agree that the agency can help clarify this exclusion. We will finalize that other specific legal relationships will be included in the exclusion. We believe that there are numerous legal proceedings that require physician involvement and we plan to exclude all of them, in order to allow for clear, consistent reporting requirements for applicable manufacturers, covered recipients, and consumers.

k. Indirect Payments or Other Transfers of Value Through a Third Party

Section 1128G(e)(10)(A) of the Act also excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party where the applicable manufacturer is unaware of the identity of the covered recipient. However, any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an applicable manufacturer or operating in the U.S., must be reported if the

applicable manufacturer is aware of the covered recipient's identity.

In the proposed rule, we proposed that indirect payments are excludable when an applicable manufacturer is unaware of the identity of the covered recipient and explained that an applicable manufacturer is unaware of the identity if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient. The definition of "know" in § 403.902 provides that a person, with respect to information, has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information. This standard is consistent with the knowledge standard set forth in many laws, including the False Claims Act, and we believed it is one with which many applicable manufacturers are already familiar.

Comment: Numerous commenters discussed when an applicable manufacturer should be required to report indirect payments to covered recipients made through a third party. Many commenters recommended additional interpretations to further clarify when an indirect payment is reportable. A few commenters recommended that all indirect payments should be excluded from the reporting requirements; however, some other commenters supported the reporting of indirect payments. Similarly, some commenters requested that payments or other transfers of value made through certain third parties, such as medical professional societies, be carved out of the third party reporting requirements such that payments to covered recipients made through these entities would not be reportable.

Many commenters did not advocate excluding all indirect payments, but instead recommended ways to limit which indirect payments would be reported. One common recommendation was to limit the reporting of indirect payments to those under control of the applicable manufacturer. Commenters described this concept in various ways, but generally suggested that reporting should be limited to when an applicable manufacturer has control of the selection of the recipient of the payment, and not merely when they are aware of the covered recipient's identity.

Another common comment was that indirect payments or other transfers of value should only be reported if they are at the request of or designated on behalf of a covered recipient. These commenters stated that this was the statutory intent for reporting indirect

payments given the language requiring reporting of payments made at the request of or designated on behalf of a covered recipient to a third party recipient. A subset of these commenters recommended that in order for a payment to be reportable, the applicable manufacturer must notify both the covered recipient and the third party that the payment will be reported and receive concurrence that it is accurate. Finally, a few commenters recommended that the applicable manufacturer must require, instruct or direct the third party to provide a payment or other transfer of value (or a portion of one) to a covered recipient(s).

Response: We appreciate the comments and agree that CMS should consider ways to further clarify when an indirect payment or other transfer of value should be reported. In addition, we intend that this exclusion refers to both payments and other transfers of value, despite references in the proposed rule to only transfers of value.

We do not agree that all indirect payments or other transfers of value should be excluded from the reporting requirements. Section 1128G(e)(10)(A) of the Act states that the exclusion of indirect payments or other transfers made through a third party is limited to situations "where the applicable manufacturer is unaware if the identity of the covered recipient." This indicates that indirect payments or other transfers of value where the applicable manufacturer *is aware* of the identity of the covered recipient must be reported, and only those where the applicable manufacturer is unaware of the identity are excluded. Moreover, we believe that 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. Additionally, we do not believe that we have statutory authority to carve out otherwise reportable indirect payments made through particular third parties, such as medical professional societies.

With regard to the recommendation that indirect payments should only be reported when under the control of the applicable manufacturer, we believe that controlling the selection of a recipient is different than being aware of the identity of the recipient. Congress based the exclusion on an applicable manufacturer being unaware of a covered recipient's identity, not on the applicable manufacturer lacking control over the selection of the covered

recipient. Accordingly, we do not believe that Congress intended lack of control to be the basis for the indirect payment exclusion. Additionally, we believe that receiving a payment or other transfers of value from an applicable manufacturer could lead to conflicts of interest, even in the event that the applicable manufacturer does not directly control the selection of the covered recipient.

Similarly, we also do not believe that the statutory language suggests that indirect payments or other transfers of value are only reportable if they are made at the request of or designated on behalf of a covered recipient. The parenthetical reference in section 1128G(a)(1)(A) of the Act refers to payments or other transfers of value made to an entity or individual other than a covered recipient on behalf of or at the request of a covered recipient. We believe this situation is different from one in which a payment is provided to a third party and passed through to a covered recipient, as referenced in the exclusion in section 1128G(e)(10)(A) of the Act. In situations where a covered recipient requests that a payment or other transfer of value be provided to a third party, and the third party in turn provides the payment or other transfer of value to the covered recipient, the payment must be reported under the name of the covered recipient.

We agree with the comments that we should provide some guidance on when indirect payments must be reported. We understand that there are circumstances where an applicable manufacturer makes a payment to a third party, which will be passed indirectly to a covered recipient, unbeknownst to the applicable manufacturer. For example, an applicable manufacturer could make a payment to a consulting firm for professional services and the consulting firm incidentally employs a physician on the project. The applicable manufacturer's payment was ultimately transmitted, at least in part, to a physician covered recipient, but not because the applicable manufacturer directed that the payment be made to a specific physician, or to any physician at all. We believe that in these situations, it would be misleading to require reporting of the relationship, since the applicable manufacturer did not intend or expect that a covered recipient would receive any portion of the payment or other transfer of value.

In order to address this concern and clarify when an indirect payment must be reported, we have 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. In another example, an applicable manufacturer may provide a general payment to a clinic for one of its employed physicians to review materials. In this case, the applicable manufacturer directed that the payment be provided to a physician covered recipient, so it would constitute an indirect payment and would be a reportable indirect payment or other transfer of value.

Comment: A number of commenters recommended alternative definitions of "aware." For example, many commenters recommended that we use a standard of "actual knowledge" or "constructive knowledge," rather than the False Claims Act standard. Additionally, many commenters also discussed an applicable manufacturer's affirmative duty to investigate the identities of covered recipients. The commenters suggested that applicable manufacturers should not have an affirmative duty to determine the identity of a covered recipient, but that the proposed definition of awareness meant that applicable manufacturers would have an affirmative duty. These commenters stated that an applicable manufacturer would be in reckless or

other transfer of value went to a covered recipient, but did not specifically know the identity of the covered recipient.

Similarly, some commenters also discussed the language in the proposed rule that attributes awareness of the identity of the covered recipient by an agent of the applicable manufacturer to the applicable manufacturer. Commenters both supported and opposed the proposal. Some of these commenters recommended that CMS provide additional information on how the agency interpreted "agent."

Finally, many commenters also recommended that CMS apply some sort of time restriction on the awareness requirement. The proposed rule did not specify whether there was a specific time period for awareness of the identity of the covered recipient, so the commenter requested clarification. Many of the commenters recommended that an applicable manufacturer must be aware of the identity of a covered recipient at the time of payment. Whereas, other comments provided slight variations, such as awareness at the time the payment is committed or agreed upon, but in general the majority of commenters focused on the time of payment.

Response: We appreciate the comments on alternative interpretations of the statutory term "unaware"; however, we have decided to finalize our 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. We appreciate the concerns about the knowledge standard, but we are concerned that the actual knowledge standard suggested by several commenters is too limiting. An actual knowledge standard could potentially allow applicable manufacturers to direct payments to a limited category or subset of individuals and avoid the reporting requirements by not knowing the names of the specific covered recipients and claiming a lack of actual knowledge. We believe that by clarifying that applicable manufacturers must only report indirect payments or other transfers of value that they direct or instruct third parties to pay to covered recipients, we will address some of the commenters' concerns about the broader knowledge standard. Therefore, 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. However, we want to clarify that, for purposes of this rule only, we 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. For example, an applicable manufacturer may hire a market research firm to conduct a double-blinded market research study, which includes paying physicians \$50 for responding to a set of questions. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value.

We recognize that by finalizing the proposed definition, applicable manufacturers may still feel they have an affirmative duty to determine the identity of covered recipients. However, our 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. For example, we believe that a manufacturer that directs a third party to make payments to the top billing cardiologists in a certain city or the chiefs of staff of a certain class of hospitals should be required to report these payments, even though they do not have actual knowledge of the identities of such individuals. However, we do 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.

We appreciate the comments regarding awareness of an agent of an applicable manufacturer of the identity of a covered recipient; however, we have finalized the requirements as proposed. We understand that awareness by an agent is somewhat different than awareness of the applicable manufacturer, but believe the reporting of indirect payments in this situation is warranted. Otherwise, applicable manufacturers could structure their business model, so that

payments are funneled through an agent that selects the recipients. However, we do not intend the concept of an agent of the applicable manufacturer to be merely any third party with a connection to the applicable manufacturer. Instead, we intend the term to refer to legal agents acting on behalf of the applicable manufacturer.

Finally, we agree that applicable manufacturers should not be responsible for tracking and reporting indirect payments or other transfers of value indefinitely. However, we do not agree that the time period for awareness of the identity of the covered recipient should be limited to the time the applicable manufacturer made the payment to the third party. We are concerned that this would allow applicable manufacturers to funnel payments or other transfers of value to third parties, and thereafter direct them to specific covered recipients, thus potentially avoiding the reporting requirements. Additionally, we believe there are multiple dates which could be reported, such as the date the applicable manufacturer decides to make the payment, or the date the payment is sent to or received by the third party, making it difficult to standardize a policy. After reviewing the comments, we will finalize 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. For example, an applicable manufacturer makes a payment to a medical professional society in March 2013 with instructions to use the money to provide grants to physicians. This payment meets the definition of an indirect payment, since the applicable manufacturer earmarked the payment for the physician grants. The professional society selects and makes payments to the grantees in April 2013 and alerts the sponsoring applicable manufacturer to the grant recipients in June 2013. Since the applicable manufacturer became aware of the identity of the covered recipients receiving the grants during the reporting year in which the payment was made, the payment or other transfer of value must be reported. Similarly, if the

payment was made in November 2013, and the professional society provided the names of the grantees to the applicable manufacturer in April 2014, the payment would be reportable as part of the applicable manufacturer's report for CY 2014.

In determining this standard, we sought a definite time period, since the applicable manufacturer may not know the selection and payment process of the third party making the actual payment to the covered recipient. We also sought a uniform cut off point for all payments or other transfers of value in a reporting year, rather than a rolling time period, which would be based on the date of payment (such as 6 or 12 months after the date of payment). We believe a rolling date would be difficult due to the reasons outlined previously regarding inconsistency in the date of payment, as well as due to operational difficulties for both CMS and applicable manufacturers to track the awareness standard for each payment or other transfer of value. In order to set a date which applied to an entire year, we needed to set a date beyond the end of the reporting calendar year (December 31), which allows some time for indirect payments or other transfers of value made late in the year to be finalized. However, we did not want to set a time period which was too long and would require applicable manufacturers to report indirect payments that were made several years prior. We believe that two quarters beyond the end of the payment reporting year is sufficient for payments or other transfers of value made late in the year.

Comment: Several commenters questioned the process for reporting indirect payments, which was not addressed in detail in the proposed rule. A few commenters suggested that applicable manufacturers should be required to label all payments as direct or indirect and report the entity paid. Similarly, some commenters recommended that CMS clarify the amount of information that a third party should be required to provide to applicable manufacturers regarding indirect payments or other transfer of value. These commenters expressed that it would be burdensome for third parties to provide detailed information to applicable manufacturers regarding the recipients of payments made using the manufacturer's funding. Finally, a few commenters also inquired about the process for reporting payments when multiple applicable manufacturers contribute to a specific payment or other transfer of value. For example, multiple applicable manufacturers may fund a single speaker.

Response: We appreciate the comments and agree that providing more detail is necessary. However, we do not believe it is necessary to significantly change the reporting requirements for indirect payments. Given the unfavorable comments submitted regarding the proposal to classify research payments as direct or indirect, we believe that it would be similarly confusing to classify *all* payments or other transfers of value as either direct or indirect. Additionally, we do not believe it is necessary or appropriate for CMS to provide any requirements on the information third parties should or should not report. 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. We recognize that this will, in some cases, require the third parties to put in place new tracking systems, but we believe that in many cases, such tracking systems already exist. For example, we believe that physician professional societies generally keep track of the physicians to whom they provide industry-funded grants and may not need to put new accounting systems in place in order for applicable manufacturers to be able to comply with the reporting requirements of this rule. Finally, we seek to clarify the situation when multiple applicable manufacturers provide a payment or other transfer of value to a covered recipient through a third party. We intend to allow for flexibility because we want 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. We believe payments or other transfers of value made through a third party to a covered recipient using funds from multiple applicable manufacturers will be limited, since the companies will be required to report only those payments or other transfers of value directed to covered recipients and not unrestricted, non-earmarked payments.

Comment: Numerous commenters questioned the reporting on indirect payments or other transfers of value for education, particularly accredited or certified continuing education (both CME and continuing dental education). A large number of these commenters recommended that accredited or certified continuing education payments

to speakers (and payments for supporting materials) should not be reported because there are safeguards already in place, and they are not direct payments or other transfers of value to a covered recipient. Many of these commenters also stated that requiring that the reporting of payments or other transfers of value related to continuing education would be detrimental to continuing education and would reduce the funding for and attendance at continuing education programs. Additionally, some of these commenters also strongly indicated that they believe that Congress did not intend to require applicable manufacturers to report payments related to accredited or certified continuing education programs. However, we did receive some comments supporting the reporting of accredited or certified continuing education-related payments or other transfers of value, particularly when the sponsor provides suggestions to the CME vendor for potential faculty or speakers at a CME program. No commenters recommended that payments made to subsidize the costs of attendees of continuing education programs (as opposed to payments for faculty or speakers) should be reported.

Beyond accredited or certified continuing education, these comments were mixed on whether unaccredited and non-certified speaking engagements should be reported. A few commenters also addressed other types of education, such as Risk Evaluation and Mitigation Strategies (REMS), suggesting that since they were required by FDA, sponsorship of REMS education should be exempted from the reporting requirements.

Response: We appreciate the comments and agree 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, we believe 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, we believe that it may often be impossible to distinguish when a suggestion is influential and when it is not.

We have 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. We believe 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. Additionally, 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. We believe that this approach will greatly reduce the number of payments to speakers at accredited or certified continuing education programs that must be reported. 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, we believe that since this type of education program does not require the same safeguards as an accredited and certified program, 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 this final rule, dedicated to nature of payment categories.

Finally, we do not agree with comments that payments related to REMS with elements to assure safe use that require prescriber education should have a blanket exclusion from the reporting requirements. We recognize that REMS are required by FDA for some prescription drug products to ensure that the benefits of a drug outweigh the risks and that REMS often requires a sponsor to inform or educate health care providers about the risks associated with a product. However, we believe 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).

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

Section 1128G(a)(2) of the Act requires applicable manufacturers, as well as applicable GPOs, to report to the Secretary, in electronic form, certain information concerning ownership and investment interests held by physicians or their immediate family members in such applicable manufacturers and applicable GPOs, and payments or other transfers of value to such physician owners or investors. In the proposed rule, we proposed that applicable GPOs were only required to report under section 1128G(a)(2) of the Act.

Comment: A few commenters suggested that Congress intended applicable GPOs to report under section 1128G(a)(1) of the Act, as well as under section 1128G(a)(2) of the Act. These commenters supported their interpretation with the introductory language of section 1128G(a)(2) stating that "[i]n addition to the requirement under paragraph (1)(A)" regarding reporting of payments to covered recipients, applicable manufacturers and applicable GPOs must report information regarding physician ownership and investment interests.

Response: We appreciate the comment but do not agree that applicable GPOs are required to report under section 1128G(a)(1) of the Act. While the phrasing in section 1128(a)(2) could be phrased more clearly, we do not believe it suggests that applicable GPOs need to report under both sections. 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.

a. Reporting Entities

(1) Applicable Manufacturers

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.

(2) Applicable Group Purchasing Organizations

Section 1128G(a)(2) of the Act also includes applicable GPOs as entities required to submit reports on physician ownership or investment interests; these reports are also required to include payments or other transfers of value provided to the applicable GPO's physician owners or investors. Section 1128G(e)(1) of the Act defines "applicable group purchasing organization" as "a group purchasing organization (as defined by the Secretary) that purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply, which is operating in the United States, or in a territory, commonwealth or possession of the United States."

We proposed to define "applicable GPOs" as an entity that: (1) operates in the United States, or in a territory, possession or commonwealth of the United States; and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

We proposed that the definition will not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians). Rather, it is our intent to capture entities

(including physician-owned entities) that purchase, arrange for or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for resale or distribution to others. Additionally, we also interpreted the statute to encompass not only more traditional GPOs that negotiate contracts for their members, but also entities that purchase covered drugs, devices, biologicals, and medical supplies for resale or distribution to groups of individuals or entities. These interpretations would include, for example, physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies.

Comment: A number of commenter supported the definition of "applicable GPOs," particularly the inclusion of PODs. However, some commenters suggested revisions to the definition in order to capture additional PODs. For example, these comments included removing the reference to "group" in the definition, as well as limiting the exclusion for entities that purchase the products for their own use to only those entities that are the end users of the device based on billing under the same provider or supplier number as the entities that purchased the product. The commenters suggested that this would capture both fee-based and buy-and-sell POD models. Finally, a few commenters recommended that CMS issue a few clarifications, including allowing reselling in case of shortages and explicitly including commonly owned entities purchasing together as "own use."

Response: We appreciate the comments, but do not agree with the recommended changes to the definition to include additional PODs. While we appreciate the need to include as many PODs as possible, we are concerned that removing the word "group" from the definition would be contrary to the statutory phrase "group purchasing organization" which clearly implies that in order to be a GPO, the entity must be purchasing for a group. Therefore, we are not going to remove the word "group" from the definition. We are also concerned that hospitals and large group practices may not always purchase under the same provider or supplier number with which they bill, making it difficult to determine the end user by billing number. Therefore, we will not be changing the language in the definition to require use of the same provider or supplier number. Based on these considerations, we have decided to finalize the proposed definition. We recognize that this definition may not include every POD model; however, we intend for it to capture as many PODs

as possible, while still aligning with the statutory language. Finally, we do not intend our definition to apply to rare and circumstantial resale of a product in response to a documented drug shortage. Similarly, we believe that bulk purchasing of covered products for commonly owned entities, which will be used only by those entities, would be considered "own use."

b. Physician Owners or Investors

Section 1128G(a)(2) of the Act differs from section 1128G(a)(1) of the Act in that section 1128G(a)(2) of the Act does not use the term "covered recipient" as defined in 1128G(e)(6) of the Act, which explicitly excludes payments or other transfers of value to employees of an applicable manufacturer from the reporting requirements. Instead, section 1128G(a)(2) of the Act uses the term "physician" as defined in section 1861(r) of the Act. Based on this definition of "physician," we proposed 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. We did not receive any comments on this interpretation, and we will finalize it.

Additionally, as required by statute, ownership and investment interests of immediate family members of physicians must also be reported under this provision. In the proposed rule, we defined immediate family member as one of the following (as defined for purposes of section 1877(a) of the Act at 42 CFR 411.351):

- 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.

In the proposed rule, we also stated that in cases when the ownership or investment interest is held by an immediate family member of a physician, applicable manufacturers and applicable GPOs should report not only the required information for the physician, but also that the ownership or investment interest is held by an immediate family member of the physician. We considered whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, but did not propose to require it.

Comment: A few commenters recommended that ownership or investment interests held by immediate family members of physicians should not be reported at all. Similarly, a few other commenters advocated that CMS employ a narrower definition of “immediate family member.”

Response: We appreciate the comments; however, both the requirement to report ownership or investment interests of immediate family members of physicians, as well as the proposed definition of immediate family member, are required by statute. Section 1128G(a)(2) requires the reporting of ownership or investment interests held by an immediate family member of a physician and states that “immediate family member” is defined as it is for purposes of section 1877(a) of the Act, which is codified at 42 CFR 411.351. Given the statutory requirements, we have finalized the definition as proposed.

Comment: Many commenters supported *not* reporting the name and relationship of the immediate family member. However, a few commenters suggested that applicable manufacturers should not be required to report the name or relationship of immediate family members, but applicable GPOs should be required to report the information. Additionally, some commenters requested that CMS clarify expectations for how applicable manufacturers and applicable GPOs should obtain ownership or investment interest information. A few commenters also recommended that CMS should not require physicians to disclose this information and applicable manufacturers may rely on the representations by owners or investors regarding immediate family members. Finally, a few commenters recommended that in the event that multiple family members hold an ownership or investment interest in a specific entity, then the applicable manufacturer or applicable GPO should only report the ownership or investment interest in aggregate.

Response: We appreciate the comments and agree 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. However, we do not agree that this standard should be applied differently for applicable manufacturers and applicable GPOs since we believe the privacy for immediate family members is the same regardless of the entity at issue.

Regarding the requirements for obtaining information on ownership or investment interests, we have revised the definition to help clarify situations when the applicable manufacturer or applicable GPO does not know that a reportable ownership or investment interest exists. We do not have the authority to require physicians or owners or investors to report this information; however, we believe that an applicable manufacturer or applicable GPO may inquire about these relationships. These situations are discussed more fully in the section on the definition of “ownership or investment interests.”

Finally, we also agree that applicable manufacturers and applicable GPOs may report a specific ownership or investment interest in aggregate across multiple family members. Since we are finalizing that applicable manufacturers and applicable GPOs do not need to report the name or relationship for an immediate family member holding an ownership or investment interest in such entity, we do not believe the reported interests need to be on the individual level and instead can be aggregated across multiple immediate family members. However, we intend that 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.

c. Ownership or Investment Interests

We proposed to define an ownership or investment interest in an applicable manufacturer or applicable GPO in a similar manner as in the physician self-referral regulation (42 CFR 411.354(b)). Specifically, we proposed to define an ownership or investment interest as one that may be direct or indirect, and through debt, equity, or other means. We further proposed that ownership or investment interest includes, but is not limited to, stock, stock options (other than those received as compensation, until they are exercised), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity’s property or revenue or a portion of that property of revenue. As required by statute, we proposed that an ownership or investment interest shall not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act. Additionally, we proposed that

ownership or investment interest must not include the following:

- An interest in an applicable manufacturer or applicable GPO that arises from a retirement plan offered by that applicable manufacturer or applicable GPO to the physician (or a member of his or her immediate family) through the physician’s (or immediate family member’s) employment with that applicable manufacturer or applicable GPO;

- Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity;

- An unsecured loan subordinated to a credit facility.

Comment: Some commenters recommended that CMS only require that applicable manufacturers and applicable GPOs report direct ownership or investment interests, rather than both direct and indirect interests. However, the commenters also recommended a few limitations in the event the agency decided to require reporting of indirect ownership or investment interests. These recommendations included setting a minimum threshold amount for ownership interests, following the knowledge requirements in the physician self-referral regulation, and requiring that the physician has sole control of the interest. Beyond indirect ownership interests, a few commenters also recommended that CMS require reporting of stock options as ownership or investment interests when they are granted, rather than only when exercised. Similarly, a few commenters recommended that CMS not distinguish between ownership or investment interests arising from a retirement plan and stock options once exercised.

Response: We appreciate the comments. However, we do not agree that applicable manufacturers and applicable GPOs should only report direct ownership or investment interests. Section 1128G(a)(2) of the Act requires that applicable manufacturers and applicable GPOs report “any ownership or investment interest * * * held by a physician.” We believe that “any ownership or investment interest” encompasses both direct and indirect interests, since indirect ownership or investment interests are also true interests. However, we do agree that there should be some limitation on indirect ownership or investment interests. We appreciate the comments on ways to limit reporting of indirect ownership or investment interests. We believe that limiting ownership or investment interests to those when the

physician has sole control and right to receive the proceeds is too narrow. We believe this will eliminate a significant number of ownership or investment interests, greatly reducing those reported. Similarly, we believe that setting a threshold for indirect ownership or investment interest creates an incentive to structure relationships to remain below the threshold. However, we do understand that there should be some limitations. We have decided to finalize 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. We agree that this limitation is warranted, since it is impossible for an applicable manufacturer or applicable GPO to report an indirect ownership or investment interest that is unknown to it. Additionally, we believe that many stakeholders are already familiar with this standard from the physician self-referral regulation. Therefore, we have 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).

Finally, we understand the concerns regarding stock options received as compensation and requiring reporting of options when granted, rather than when exercised. However, we believe that stock options before they are exercised are traditionally considered compensation, rather than an ownership or investment interest, so we do not believe that we should require them to be reported as held ownership or investment interests. This is consistent with the definition in the physician self-referral regulation. However, we note 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. Reporting under sections 1128G(a)(1) and 1128G(a)(2)(C) may not include all stock options that are granted to physicians. For example, stock options that are granted to a physician who is an employee of the applicable manufacturer and is not already an existing owner or investor of that entity would not be reported; however, we believe reporting under sections 1128G(a)(1) and 1128G(a)(2)(C) will capture a significant portion of stock options when granted.

d. Physician Ownership or Investment Report Content

Under section 1128G(a)(2) of the Act, applicable manufacturers and applicable GPOs are required to report information about each ownership or investment interest held by physician owners or investors (or their immediate family member(s)).

As required in section 1128G(a)(2) of the Act, we proposed that the applicable manufacturer or applicable GPOs should report the name, address, NPI, and specialty of the physician owner or investor, as well as the dollar amount invested and the value and terms of the ownership or investment interest. Section 1128G(a)(2)(C) of the Act requires the reporting of “[a]ny payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership interest) * * *”. Applicable manufacturers and applicable GPOs must report all the information required in section 1128G(a)(1)(A) of the Act for those physicians who hold ownership or investment interests in such entity. With regard to reporting payments and transfers of value to physician owners or investors, we proposed that applicable manufacturers and applicable GPOs follow the procedures outlined in this preamble for reporting payments and other transfers of value.

We also noted that there was some overlap between the requirements for reporting payments or other transfers of value and reporting ownership or investment interests. In order to help manage the overlap, we proposed that applicable manufacturers submit one report for all their payments and other transfers of value and another for all their physician ownership or investment interests. To comply with section 1128G(a)(2)(C) of the Act, we proposed that applicable manufacturers report the payments or other transfers of value provided to physician owners or investors (regardless of whether the physician owner is a covered recipient) in the report for payments and other transfers of value, but should note that the covered recipient receiving the payment or other transfers of value is a physician owner or investor.

Since applicable GPOs are not subject to the reporting requirements in section 1128G(a)(1) of the Act, we believe there is less of a potential for duplicative reporting. However, we proposed that when an applicable GPO has payments or other transfers of value to report for physician owners or investors, the

applicable GPOs should use the data elements outlined in section II.B.1.f. of the final rule on payments and other transfers of value report contents.

Comment: A few commenters discussed the content of physician ownership or investment interest reports. The commenters specifically recommended that CMS not require the reporting of the “terms” of the ownership or investment interest.

Response: We appreciate the comments. However, we are unable to waive reporting of the terms of an ownership or investment interest, since it is a statutory requirement. Because we did not receive any comments on other aspects, we will finalize 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.

Comment: We also received a few comments concerning the potential for duplicative reporting due to the overlap between the two sections. The comments requested clarification of the proposed rule but did not have any specific recommendation or advocate any particular changes.

Response: We appreciate the comments and seek to clarify as much as possible; however, we have finalized these provisions as proposed. 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).

Additionally, 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. All payments or other transfer of value should only be reported once regardless of whether it is required to be reported under section 1128G(a)(1) and/or section 1128G(a)(2)(C) of the Act.

C. Report Submission and Review

The statute requires the Secretary to establish procedures for applicable manufacturers and applicable GPOs to submit the required information and for the Secretary to make such information submitted available to the public. We recognize that these regulations require applicable manufacturers and applicable GPOs to collect and submit large amounts of new data, so we have tried to finalize flexible processes for data collection and submission. However, we also recognize that in order to accept and aggregate the data effectively and efficiently, there needs to be system standardization.

1. Prior to Submission

In the proposed rule, we considered that prior to submission of data to CMS, applicable manufacturers and applicable GPOs would provide each covered recipient or physician owner or investor with information regarding the information that the applicable manufacturer plans to report to CMS on the covered recipient’s or physician owner or investor’s behalf. While we did not propose to require this type of pre-review, we recommended that applicable manufacturers and applicable GPOs provide it.

Comment: Several commenters supported the pre-submission review. However, the commenters were divided over whether to require it or leave it voluntary. Many commenters stated that there simply was not time between the end of the data collection year and the data of submission to facilitate the review; whereas some commenters

recommended it, stating it would greatly reduce disputes and inaccuracies in the data.

Response: We appreciate the comments and agree that pre-submission review would help ensure the accuracy of the data. However, we have finalized that CMS will not administer or manage a pre-submission review process and will not make it mandatory. We 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. We understand that the processes and systems of applicable manufacturers and applicable GPOs may not allow for a review of this capacity. Similarly, since there is a post-submission review period, we do not believe that it is worth the additional burden for applicable manufacturers and applicable GPOs to make significant system changes in order to provide a pre-submission review. However, we do believe a pre-submission review could be extremely useful and recommend that applicable manufacturers and applicable GPOs consider ways that they could administer a pre-submission review external to CMS. Because CMS is not requiring the review, we do not feel it is appropriate for CMS to prescribe the process and standardize it; nevertheless, we believe that ongoing notice throughout the year of any reportable interactions would be ideal.

2. Report Submission

Applicable manufacturers and applicable GPOs are statutorily required to submit their reports for the preceding calendar year electronically to CMS on March 31, 2013 and on the 90th day of each calendar year thereafter. We proposed to 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. We did not receive any comments on this interpretation and have finalized it as proposed; however, as discussed in the timing section, because of the publication date of this final rule, reports including 2013 data will not be due until March 31, 2014.

a. Registration

In the proposed rule, we proposed that only applicable manufacturers that have payments or other transfers of value and/or physician ownership or investment interests to disclose for the

previous calendar year must register and submit reports. Similarly, we proposed that only applicable GPOs with physician owners or investors would be required to register and submit information. For applicable manufacturers and applicable GPOs that did have information to disclose, we proposed that applicable manufacturers and applicable GPOs register with us prior to submission to facilitate communication. We proposed the registration process would require the applicable manufacturer or applicable GPO to designate a point of contact, which we would use for communications related to the submitted data. Alternatively, we considered requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they had information to report, in order help us better understand the extent of these relationships and ensure compliance with the reporting requirements.

Comment: Many commenters supported the registration requirement, but disagreed on which entities should be required to register. Some commenters supported the proposal to require registration only by those entities with payments or other transfers of value or ownership or investment interests to report; other commenters recommended that CMS employ the alternative and require all entities that meet the definition of applicable manufacturer or applicable GPOs to register.

Response: Given the comments received, we believe that we do not need to require all entities that meet the definition of applicable manufacturer or applicable GPO to register and have finalized the position as proposed. Because the statute only requires the reporting of payments or other transfers of value, we 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. We believe this will better allow CMS to ensure that applicable manufacturers required to report are reporting under the reporting requirements. However, 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. Additionally, 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.

Comment: A few commenters discussed reporting of the point of contact, specifically recommending that two points of contact be provided for a single applicable manufacturer or applicable GPO.

Response: We agree that establishing and maintaining appropriate points of contact are important because it is essential that we be able to contact applicable manufacturers and applicable GPOs in the event that questions arise regarding their submission. We believe that requiring a second point of contact to serve as a backup will be beneficial and ensure that CMS can contact applicable manufacturers and applicable GPOs. We are finalizing 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).

We did not receive any comments on our proposed timing for registration, so we have finalized those provisions as proposed. We proposed 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. We intend 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. We proposed to 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, we may open registration earlier to allow additional time.

b. File Format

We also received several comments of the format of the data and process for submission to CMS. We proposed that applicable manufacturers and applicable GPOs submit their data electronically in a comma-separated value (CSV) format and solicited comments on and suggestions for alternatives to that format. Additionally, we proposed that each line item in the dataset should represent a unique payment or other transfer of value, or a unique ownership or investment interest. In the event that a single file does not have sufficient volume for all the data required, then we proposed the applicable manufacturer or applicable GPO could submit as many files as necessary to provide the entirety of its data.

Comment: Many commenters recommended that CMS create a standardized format and template and allow stakeholders an opportunity to review. Additionally, a few commenters supported the use of CSV files, whereas a few other commenters recommended using Pipe Line Delineated files rather than CSV files. These commenters explained that since some numbers are presented with comma separators (for example, \$100,000), CSV files may be problematic. Similarly, a few commenters recommended that CMS establish a uniform naming system for applicable manufacturers.

Besides the format of the report, we also received comments on the organization and submission of the data. A few commenters recommended that CMS accept submission of data multiple times throughout the year, such as quarterly or ongoing, and allow extensions. Conversely, other commenters recommended allowing applicable manufacturers to submit multiple reports, organized by topic or individual. Finally to receive the data, a few commenters recommended that CMS develop a data exchange and data portal to accept files.

Response: We appreciate the comments and agree that CMS should provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting. However, we do not believe it is necessary or beneficial to provide this information in regulation, in order to allow the agency more flexibility to make changes in response to feedback from stakeholders. If we intend to make changes to the reporting template or other details for reporting (which we envision could happen particularly as the program evolves in early years), we will provide them at least 90 days prior

to first day of data collection for the next reporting year. In providing revised templates, we will also 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 we will publish the list of teaching hospitals.

We appreciate the comments on the organization of the submitted files, but per the statute, we will only allow submission of a single report consisting of the entire reporting period (for example CY 2014). We will only be collecting and staging data for public posting in accordance with annual submissions, so we will not be accepting ongoing or quarterly submissions. We believe 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, we 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. Similarly, as required in the regulations, 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. Finally, we appreciate the comments regarding a data exchange portal and agree that CMS should create an electronic system for accepting the data. We plan to publish additional information along with greater detail on the submission process.

c. Attestation Process

In the proposed rule, we proposed that annually, following the submission of data, an authorized representative from each applicable manufacturer and applicable GPO will be required to submit a signed attestation certifying the timeliness, accuracy, and completeness of the data submitted to the best of the

signer's knowledge and belief. We specified that such attestations must be signed by the chief executive officer, chief financial officer or chief compliance officer.

Comment: The majority of commenters supported the attestation requirement. However, a few commenters recommended revising the attestation to certify that the entity made a reasonable effort to ensure that data meets regulatory requirements. These commenters explained that the reporting requirements are, in their view, complicated, so it would be impossible to know whether the data submitted was accurate. Similarly, a few commenters suggested that CMS allow other officers (at the discretion of the reporting entity) to attest.

Response: We appreciate the comments, but we continue to believe that applicable manufacturers and applicable GPOs can and should be confident that the data is accurate. We recognize that the reporting requirements require significant data to be collected, but the majority of comments supported the language without revision, suggesting that reporting entities can be confident in their data. Additionally, the penalties are significantly less for unknowing errors, so the statute provides safeguards for unexpected errors. Finally, we do understand that applicable manufacturers and applicable GPOs may have different business structures. We do not want to confine applicable manufacturers and applicable GPOs with regard to which officers must attest, so we have finalized that other officers will be allowed to attest, as designated by the company.

We also seek to clarify the timing of the attestation requirement. 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. This is discussed in more detail in the section on dispute resolution. However, we believe 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.

Finally, as discussed in the section on applicable manufacturers, 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. We also note that 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 we encourage 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.

3. Report Content

We have outlined the fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests. Some changes have been made below based on comments submitted; however, these decisions and changes are discussed throughout the final rule. The asterisks indicate the additional information that we 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). *

4. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, Covered Recipients, and Physician Owners or Investors

Section 1128G(c)(1)(C)(ix) of the Act requires that the Secretary allow applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors the opportunity to review the data submitted for a period of at least 45-days prior to the data being made available to the public. This section outlines the comments received on the processes for and length of this review and correction period.

a. Notification of Review and Correction Period

In the proposed rule, we stated that we would notify covered recipients and physician owners or investors about the review and correction period in a few ways. We proposed to allow, but not require, covered recipients, and physician owners or investors to register with CMS to ensure they receive communication about the processes for review. Additionally, we proposed to notify physicians and hospitals through CMS's list-serves and by posting the information publicly (for example: on

the CMS Web site or in the **Federal Register**). We also considered an alternative method, in which we would require applicable manufacturers and applicable GPOs to collect and report whether the covered recipient, or physician owner or investor would like to be notified by USPS or email of the processes for their review, as well as the individual's email address, if indicated. We received numerous comments on this which are described later in this section.

Finally, we proposed that the notification to physicians and teaching hospitals would be provided annually to announce the review and correction period, and would include the specific instructions for performing this review. We did not receive any comments on this provision, so we have decided to finalize it as proposed.

Comment: Many commenters addressed how to notify physicians and teaching hospitals of the opportunity to review payments or other transfers of value or ownership or investment interests that were attributed to them in reports submitted by applicable manufacturers or applicable GPOs. Some of these commenters supported the methods outlined in the proposed rule and provided other suggestions. Many commenters requested that physicians and teaching hospitals be notified personally of the processes for review and correction. Some of these commenters recommended the alternative method of collecting contact information (applicable manufacturers and applicable GPOs providing preferred method of communication), while others recommended another method or simply stated that CMS should notify physicians and teaching hospitals, but supported flexibility in the notification method. Conversely, many other commenters indicated that the proposed alternative would be overly burdensome, and recommended that CMS notify physicians and teaching hospitals in another manner. Finally, some commenters recommended more ongoing approaches to notification and allowing review to happen multiple times throughout the year.

Response: We appreciate the comments and have tried to balance the necessity to notify physicians and teaching hospitals with the desire to avoid adding any additional burden on applicable manufacturers and applicable GPOs. We have also considered what is operationally possible and concluded that we will notify physicians and teaching hospitals, as proposed, using email list serves, online postings (including both on the CMS Web site and the **Federal**

Register) and directly (likely by email) to any physicians or teaching hospitals that have registered with CMS ahead of time. We strongly recommend 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 we can appropriately match them to their data. In addition to the methods proposed, we plan to 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. We understand that these methods do not constitute direct, personal notification, but believe that these methods are sufficient and significantly more cost effective for both CMS, and applicable manufacturers and applicable GPOs.

Finally, we note that since applicable manufacturers and applicable GPOs only submit data for the previous calendar year to CMS once annually, the agency 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). Similarly, we will only provide for one formal review and correction period prior to the publication of that year's data. We discuss our plans to allow for updates to submitted data or submission of data previously omitted, as well as additional time to review and dispute, later in this section, but the formal review and correction period will only happen once annually prior to the next publication on the public Web site.

b. Length of Review and Correction Period

Section 1128G(c)(1)(D) of the Act requires that CMS provide a review and correction period of "not less than 45 days." We proposed a 45-day review period to maximize the time for the agency to aggregate and publish the data. Additionally to facilitate the review, we proposed that applicable manufacturers, applicable GPOs, covered recipients, and physician owners and investors would sign into a secure Web site to view the data submitted. We proposed that only the current and previous years would be available for review and correction. For example, during the 45-day review period in 2015, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors would be able to

review and amend the data submitted for 2013 and 2014. During the 2016 review, 2014 and 2015 would be available for changes.

Comment: Many commenters requested a longer review period, particularly to allow for additional time to resolve disputes. Many of these commenters recommended a 60- or 90-day review period and asked that the review period include a distinct phase to resolve disputes. These commenters stated that this was particularly important for disputes which may be initiated towards the end of the review and correction period.

Response: We appreciate the comments and are sympathetic to the need to provide time for review and correction and tried to maximize the time as much as possible. However, time constraints restrict flexibility in this area given the statutory date for publication of the submitted data on the public Web site. In finalizing the proposal, we tried to balance providing appropriate time for review which allows us sufficient time to process the data for review and publication. Following the first year of reporting, in which we must publish the data within approximately 6 months of receiving the data, we must thereafter publish the data within 90 days of the last day for data submission (March 31), so a 90-day review period is not feasible. Similarly, we also believe that a 60-day review period would not leave us enough time to aggregate the data and prepare it for publication within 90 days of data submission. Nevertheless, we do agree that there should be a distinct phase for correcting data to resolve disputes since we recognize that it is not practical to resolve disputes initiated at the end of the review and correction period, within the time allotted. We believe that there should be a distinct period after the review and correction period specifically for correcting data to resolve potential disputes.

Given these constraints, we have 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 Web site 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. Regarding the 15-day period for resolving and correcting disputes following the 45-day review period, we recognize that 15 days is not much time for applicable manufacturers and applicable GPOs to resolve disputes submitted late in the review and correction period. Because we do not believe that we have the authority to shorten the period when covered recipients and physician owners and investors can review and submit corrections to the data, the 15-day period to correct data and resolve disputes must be after the 45-day review and correction period. Extending the 15-day dispute resolution period would not allow us sufficient time to prepare for public posting and we cannot delay public posting for the review and correction period. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period for dispute resolution will be captured in the initial publication of the current reporting year of data on the public Web site. Disputes submitted earlier in the review and correction period will have more time to be resolved. In order to try to maximize the successful resolution of disputes and have more accurate data for publication, we plan to encourage 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.

We also note that covered recipients and physicians owners and investors will have the opportunity to review and submit corrections for data updated by applicable manufacturers and applicable GPOs (either in response to a dispute, omission, or other error). There is no limit to the number of times a particular transaction can be reviewed and disputed.

Comment: Many commenters also discussed the processes for the review and correction period, including what data would be available during the 45-day period. The majority of these commenters supported the secure Web site to view the data and recommended that CMS determine a process to validate the identities of the applicable manufacturers. Regarding the data available, many commenters

recommended that CMS allow review and correction of more data, beyond the 2 previous years. Additionally, a few commenters recommended that for data granted delayed publication, CMS should allow review and correction of the data in the year the data is submitted, rather than the year it will be published. These commenters explained that it will be easier for covered recipients and physician owners and investors to review and correct the data immediately after the payment was made, rather than up to four years later.

Response: We appreciate the comments on the review and correction process and what data should be available for review during the review and correction period. Regarding the review and correction process, we have finalized our proposal of facilitating the process on a CMS-secure Web site. We are 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. We agree that we will need to validate the identities of individuals signing on to the Web site and plan to employ a system that will allow for secure user identification and authorization. We also plan 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 requires that the actual individual register and interact with the system to ensure the utmost security of the data. The registration process will also help us collect additional information from the covered recipients and physician owners or investors to ensure that only the appropriate data is available to them and able to be aggregated and presented to the appropriate individual.

Beyond the process for accessing the information, we do not agree that more than 2 years of data should be available for review and correction. While we believe that covered recipients and physician owners and investors should have appropriate opportunity to review the data, we believe that the data should

be finalized and no longer open to disputes and updates after a certain time period. As discussed later in this section, we have worked to improve the review and correction processes to allow covered recipients and physician owners and investors the opportunity to review and correct their data and resolve disputes with applicable manufacturers and applicable GPOs throughout the year. Given this increased flexibility, we believe 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.

Additionally, we agree 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. For example, a payment or transfer of value granted delayed publication, but made in 2014 and reported in 2015, would be made available to the covered recipient for review and correction in 2015, but would not be published until the appropriate time for release. We believe covered recipients and physician owners and investors, as well as applicable manufacturers and applicable GPOs will be better able to review and correct the data during the period of time immediately following the transaction, rather than years afterward when the data is about to be published. Finally, we intend 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.

c. Dispute Resolution

In the proposed rule, we provided information on the public presentation of disputed, but unresolved transactions. We proposed that if an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradictory information that cannot be resolved by the parties involved, then the data would be identified as contradictory and both the original submission from the applicable manufacturer or applicable GPO, and the modified information provided by the covered recipient or physician owner or investor, would appear in the final publicly available Web site. We also proposed that for aggregation purposes, we would use the contradictory data, as corrected by the

covered recipient or physician owner or investor, for any aggregated totals.

We also received numerous comments on the proposed process for dispute resolution. In the proposed rule, we stated that we should not be actively involved in arbitrating disputes between applicable manufacturers or applicable GPOs, and covered recipients, or physician owners or investors regarding the receipt, classification or amount of any payment or other transfer of value, or ownership or investment interest. We proposed that covered recipients, and physician owners or investors may request from us the contact information for a specific applicable manufacturer or applicable GPO, in the event of a potential dispute over the reported data. However, it would be the responsibility of the covered recipient, or physician owner or investor, to contact and resolve the dispute with the applicable manufacturer or applicable GPO. We proposed that at least one of any entity involved (applicable manufacturer, applicable GPO, covered recipient, or physician owner or investor) must report to CMS that a payment or other transfer of value, or ownership or investment interest is disputed and the results of that dispute.

Regarding the timing for submitting disputes, we proposed that the 45-day review period is the primary opportunity to correct errors or contest the data submitted by applicable manufacturers and applicable GPOs to CMS. Once the 45-day review period has passed and the parties have identified all changes or disputes and we have made or noted them all, we proposed that neither applicable manufacturers, applicable GPOs, covered recipients, nor physician owners or investors would be permitted to amend the data for that calendar year. We also proposed that applicable manufacturers, applicable GPOs, covered recipients, or physician owners or investors alert us as soon as possible regarding any errors or omissions, but these changes may not be made until the data is updated for the following reporting year. At that time, all parties would once again have an opportunity to review and amend the data. However, we proposed that we would have the option to make changes to the data at any time (for example, to correct mathematical mistakes).

Comment: Commenters had mixed reactions to the proposal that CMS not play a central role in mediating disputes. Many commenters stated that CMS should manage the process to ensure it is standardized and intervene in situations when disputes cannot be resolved. Conversely, many other

commenters supported that CMS should not be involved and that it should be at the discretion of the disputing parties. Many commenters also recommended options for resolution, such as engaging a third party to mediate the disputes or developing an appeals process.

Several commenters recommended that CMS allow applicable manufacturers and applicable GPOs discretion over which payments or other transfers of value or ownership or investment interests to resolve. A few of these commenters noted that the statute only requires that CMS grant a review and correction period, but not that all disputes must be resolved. Conversely, a few commenters recommended that CMS impose a materiality threshold, and applicable manufacturers and applicable GPOs would not be required to resolve disputes below the threshold. Additionally, a few commenters recommended that applicable manufacturers and applicable GPOs should be responsible for reporting the resolution of disputes to CMS since they are subject to penalties for incorrect reporting. Most of these commenters recommended that applicable manufacturers and applicable GPOs should be allowed to re-certify the data after the dispute resolution. Finally, a few commenters discussed how the post-submission review process would interact with a pre-submission review.

Response: We appreciate the comments and agree that effective and accurate resolution of disputes is essential to the program. After reviewing the comments, we believe that we do have a responsibility to facilitate the capability for correcting the data and resolving disputes among the parties. However, we maintain that we should not be actively engaged in mediating dispute resolutions. The relationship exists between the applicable manufacturer or applicable GPO, and the covered recipient or physician owner or investor, so these parties should be involved in the resolution of the dispute, not CMS. We believe that we are not the appropriate party to mediate the disputes. However, we do plan to provide the opportunity for covered recipients, or physician owners or investors to review and correct the data submitted on their behalf. We also plan 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.

When covered recipients and physician owners or investors register and sign on to the secure CMS Web site,

all payments or other transfers of value, and all ownership or investment interests, submitted on their behalf will be available for review. The covered recipient or physician owner or investor will be responsible for reviewing each payment or other transfer of value, or ownership or investment interest, and will be able to initiate a dispute on a particular transaction, if he/she chooses. If a covered recipient or physician owner or investor decides to initiate a dispute, he or she will be directed to fill out electronic fields detailing the dispute, including the proposed corrections. The system will automatically flag that the transaction was disputed and the system will notify the appropriate applicable manufacturer or applicable GPO of the dispute, detailing the information submitted by the disputing covered recipient or physician owner or investor. The applicable manufacturer or applicable GPO and physician or teaching hospital will then 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, we 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. We recognize that this requirement adds a second attestation for applicable manufacturers and applicable GPOs that submit updated data, but we believe it is important that all the data presented on the public Web site be subject to the same attestation requirements. We also believe applicable manufacturers and applicable GPOs will appreciate the opportunity to re-attest in response to any updates to the data changed during the review and correction period.

Additionally, we do not agree that the statute does not require applicable manufacturers and applicable GPOs to resolve disputes. We believe that by requiring a review and correction period, Congress intended any disputes identified to be resolved; however, we do recognize that there may be

situations when the cost of initiating and resolving a dispute may not be worth the potential benefits. We intend to monitor the volume and terms of disputes and resolutions, and plan to provide additional guidance regarding situations when the cost of resolving a dispute may outweigh the benefits. Finally, since we are neither requiring, nor managing the pre-submission review process, we do not believe there should be any connection between any pre-submission processes and the CMS processes for data submission and review and correction. For example, we will not restrict a physician who reviewed and approved a payment in the pre-submission review from disputing such payment or other transfer of value during the CMS process for review and correction, since we will not know whether the physician received an opportunity to pre-review the payments or the result of his/her pre-review.

Comment: Numerous commenters opposed CMS's proposed approach for presenting disputed data. Many commenters stated that it would be misleading to end users of the data to include both accounts. However, they differed in their preferred options for presenting unresolved transactions. Several commenters recommended that disputed transactions should be flagged as disputed, but only one account of the transaction be included. The majority of these commenters suggested that the information, as submitted by the applicable manufacturer or applicable GPO, should be the account of the transaction published, since they are the entities with the reporting requirements and subject to penalties. Other commenters recommended that the unresolved data should not be published until it has been resolved. Beyond the data reported, a few commenters recommended that CMS outline incentives for resolving disputes in order to ensure that applicable manufacturers, applicable GPOs, covered recipients and physician owners and investors participate in the dispute resolution process.

Response: We appreciate the comments and agree that publishing both accounts of a disputed transaction would be misleading. Although we believe publishing both accounts would provide the details of the dispute thereby providing the greatest transparency, we believe that this level of detail would not be useful for end users of the data. We also agree that any disputed transactions that have not yet been resolved should be labeled as such, but that only a single account of the

transaction should be listed on the public Web site.

We also do not agree that disputed transactions should not be published publicly until they are resolved. We believe that this method would potentially create an incentive for covered recipients and physician owners or investors to dispute each transaction of the public Web site to prevent them from being made public. We also believe that publication of disputed transactions will incentivize the parties to resolve disputes in a timely manner. We do not believe that any additional incentives are necessary. We believe that the interest to only publish accurate and undisputed information will push all parties to actively resolve disputes.

Therefore, we will finalize that on the public Web site, 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. We believe 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. The parties may continue to resolve disputes after the close of the resolution period and after the data has been published publicly, or may leave the data as disputed; however, we discouraged leaving data as disputed and advocate for timely dispute resolution.

Comment: Several commenters did not support the 45-day review period being the only opportunity to review and correct the data and recommended that review and correction be available more frequently. Many commenters also recommended that CMS allow for changes to be made more than once annually to ensure that mistakes are identified and corrected on the public Web site as soon as possible. Finally, a few commenters also recommended that applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors should not have to report mistakes immediately, but allow time to investigate the mistake internally.

Response: We appreciate the comments on updating the public Web site and agree that we have 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. We believe 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 Web site for a whole year, when they have in fact been resolved. Nevertheless, we also believe that we do not have the resources to make continual changes to the Web site and should not be required to continually update the data. We 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.

Similarly, we also believe that covered recipients, and physician owners or investors should be allowed to review and dispute the contents of the public Web site 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 Web site until the next update of the data. We believe this fairly allows covered recipients and physician owners or investors control over reviewing and correcting their data at all times, but does not require us to make continual changes to the published data. This system will also allow covered recipients and physician owners and investors the opportunity to easily and efficiently review (and dispute, if necessary) data updated and re-submitted by an applicable manufacturer or applicable GPO.

Finally, we also understand applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors may want to investigate errors internally before notifying CMS of errors or omissions. However, we believe that errors and changes need to be reported to us as soon as possible so that we have the most accurate information possible. We believe 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.

D. Public Availability

Under the statute, we are required to publish on a publicly available Web site the data reported by applicable manufacturers and applicable GPOs for CY 2012 by September 30, 2013. For each year thereafter, we must publish the data for the preceding calendar year by June 30th. Given the timing of the final rule, no data will be collected for CY 2012, so the first data publication will be in 2014 for data collected in 2013.

In the proposed rule, we noted that section 4 of Executive Order 13563 calls upon agencies to consider approaches that "maintain flexibility and freedom of choice for the public," including the "provision of information to the public in a form that is clear and intelligible." We requested comment on how to structure this Web site for ultimate usability and proposed, as required by statute, that the Web site will include information on any enforcement activities taken under section 1128G of the Act for the previous year; background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals; and publication of information on payments or other transfers of value that were granted delayed reporting.

Comment: Numerous commenters provided feedback on the public Web site, particularly the development of the Web site. Many commenters called upon CMS to solicit stakeholder assistance in the development of the public Web site and that stakeholders should be given the opportunity to comment on the Web site content prior to it being finalized. A few commenters also recommended various methods to better develop the Web site, such as reviewing existing Web sites with similar information as examples. Finally, a few other commenters requested that CMS provide more information on the public Web site in the final rule.

Response: We appreciate the comments and agree that stakeholder input is essential to the success of the public Web site. We plan to engage

stakeholders regarding the content of the Web site, since we recognize that stakeholders and the public must be a part of the development process. We agree that it is important that the final Web site is user-friendly and provide accurate and understandable information to the public. In order to regain flexibility over the details of the Web site and allow the opportunity to work with stakeholders on development, we have only provided general information on the public Web site in the final rule. We believe that it is important that we have flexibility to make changes to the Web site as they are identified, but do plan to engage the public on the future development. We intend to release additional information about the Web site through education and outreach to the stakeholder community.

Comment: In response to our request for comment on the structure of the public Web site, we received numerous comments recommending specific information to be included, as well as the Web site's capabilities. Some commenters recommended that specific information and research should be included on the Web site as background or contextual information, particularly including details of the reporting requirements and the benefits of relationships between manufacturers and physicians and teaching hospitals. Additionally, some other commenters recommended that CMS link to other Web sites, such as physician codes of conducts or a manufacturer's published data.

Regarding the capabilities of the Web site, some commenters recommended that the data should be easily searchable and downloadable. Other commenters recommended specific file structures and details for the data, for public use, as well as use by researchers, including allowing researchers to obtain information that is not publicly available.

Response: We appreciate the comments and agree that both the information included and capabilities of the Web site are extremely important. We support many of the recommendations and have provided general plans for the information to be presented, as well as the capabilities of the Web site. We plan to ensure that the public Web site accurately and completely describes the nature of relationships between physicians and teaching hospitals, and the industry, including an explanation of beneficial interactions. In addition, we plan to provide information to stakeholders regarding the data submission, review, dispute, dispute resolution and other

applicable operational processes. As proposed, the Web site will clearly state that disclosure of a payment or other transfer of value on the Web site does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. We appreciate the support of this language and plan to emphasize it on the Web site. We also plan to provide Frequently Asked Questions (FAQs) and other methods to help users find and understand this important contextual information.

While we appreciate that there is similar information available from industry and stakeholders that may be beneficial to include on the public Web site, we also want to try to reduce the promotional or company specific information on the Web site, so we will need to assess the best way to include this information, if at all. Finally, we are also cognizant that the Web site will include a significant amount of information and are considering the best way to provide sufficient context without overwhelming the consumer.

As required by statute, we plan to aggregate the data submitted and publish the data on a Web site that is searchable across multiple fields and available for downloads. In addition, we plan to establish mechanisms for researchers who may want information that is not publicly available. We believe that the data included in the database is primarily important for consumers, but understand that it also provides numerous opportunities for research on provider-industry relationships. We plan to provide opportunities to download the data that support researchers, as well as consumers, since we believe that research on this information is an important benefit of any transparency initiative.

1. Data Elements

In the proposed rule, we listed the data elements that would be available on the public Web site. We did not receive any comments on these, so we have finalized them as proposed. As required by statute, a physician's NPI will *not* be published on the public Web site. In these lists, we have included any necessary changes as required by other sections of the final rule. The asterisks indicate the additional information that we 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 Web site 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 Web site:
- 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 Web site 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).*

E. Delayed Publication for Payments Made Under Product Research or Development Agreements and Clinical Investigations

Section 1128G(c)(1)(E) of the Act provides for delayed publication of payments or other transfers of value from applicable manufacturers to covered recipients made pursuant to certain kinds of product research or development agreements and in connection with clinical investigations. This provision seeks to balance the need for confidentiality of proprietary information with the need for public transparency of payments to covered recipients that could affect prescribing habits or research outcomes.

In the proposed rule, we proposed that payments or other transfers of value would be granted delayed publication only if they were made in the context of a relationship for bona fide research or clinical investigation activities. We proposed that the "product research or development agreement" referenced in the statute included a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol.

Section 1128G(c)(1)(E) of the Act provides specific situations when delayed publication of payments or other transfers of value is appropriate, including the following:

- Research in connection with a potential new medical technology or a new application of an existing medical technology.
 - The development of a new drug, device, biological, or medical supply.
 - In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.
- In the proposed rule, we noted the difficulty in separating medical technology from the definition of covered drug, device, biological or medical supply and proposed to

consider “medical technology” broadly to include any drug, device, biological, or medical supply. Similarly, due to the overlap between the terms “research” and “development,” we proposed to treat them similarly in this provision. In the proposed rule, we noted that the definition of clinical investigations in section 1128G(e)(3) of the Act is distinct from both “research” and “development” for the purposes of section 1128G of the Act. We noted that this definition may also differ from those that applicable manufacturers may be familiar with in 21 CFR 312.3 and 812.3.

Given these interpretations, we proposed that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of, new drugs, devices, biologicals, or medical supplies, as well as new applications of existing drugs, devices, biologicals, or medical supplies. Conversely, we proposed limiting delayed publication for payments in connection with clinical investigations to new drugs, devices, biologicals, or medical supplies, but not new applications of existing drugs, devices, biologicals, or medical supplies.

Finally, the statute also requires that information about payments and other transfers of value that are delayed from publication must be made publicly available on the first publication date after the earlier of either: (1) the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or (2) 4 calendar years after the date of payment or other transfer of value.

Comment: Numerous commenters provided input on these interpretations and proposals. Some commenters recommended that CMS expand the situations when a payment or other transfer of value may be granted delayed publication. For example, a few commenters suggested that all research-related payments or other transfers of value should be granted a delay in publication, regardless of the product under consideration. Some commenters also explained that research on non-covered products should also be granted delayed publication, including pre-clinical research, which is often not expressly connected to a product. Conversely, other commenters recommended that CMS narrow the situations when a payment or other transfer of value is granted delayed publication. For example, a few commenters suggested interpreting medical technology as a subset of covered drugs, devices, biologicals or medical supplies, which would include

only devices or even only a subset of devices. A few commenters also recommended that CMS not allow any delayed publication for payments or other transfers of value related to new applications of existing products. Finally, a few other commenters requested that CMS allow for delayed publication of sensitive payments or other transfers of value that are not related to research, such as business development activities.

Response: We appreciate these comments. However, we believe that our proposal strikes a good balance for granting certain payments or other transfers of value a delay in publication. In order to provide additional context to stakeholders, we seek to clarify our interpretation of the proposed requirements for delayed publication.

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. However, payments or other transfers of value related to research for new applications of products already on the market will be treated differently due to the statutory distinction between new products and new applications of existing products. Pursuant to the statute, 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.” We recognize that clinical investigations are a subset of research; however, we believe that the statute clearly differentiates them for purposes of delayed publication from research and development, and indicates that payments or other transfers of value made in connection with clinical investigations (as defined in section 1128G(e)(3) of the Act) related to new applications of existing products should not be granted a delay. Given the broad scope of the statutory definition of “clinical investigation,” we believe this includes Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies). We 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.

We recognize that the interpretation of the meaning of a new product (as opposed to a new application of an existing product) for the purposes of section 1128G of the Act may differ from other definitions, such as the definition of new drug in 21 U.S.C. 355. 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.

Finally, while we recognize the potentially sensitive nature of business development activities, we do not believe that the statute grants us the ability to granted delays for payment types other than research.

Regarding the written agreement and research protocol, we discussed numerous comments on these requirements earlier in the research section, particularly regarding the requirement that a research study must be subject to both a written agreement and a research protocol. We have finalized the same requirements for payments or other transfers of value granted delayed publication. In general, 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 this final rule, will not be granted delayed publication.

Comment: Commenters specifically recommended that 4 years is not enough time for full development of a product, and that payments should only be published after FDA approval, licensure or clearance.

Response: We appreciate the comments, but the timelines are clearly delineated in section 1128G(c)(1)(E) of the Act. We do not have the authority to alter them. Additionally, we believe Congress clearly intended that all payments should be included on the public Web site, even if a product never received FDA approval, licensure or clearance.

1. Process for Reporting Payments or Other Transfers of Value Granted Delayed Publication

We received numerous comments on our proposed method for notification to CMS which payments or other transfers of value are eligible for delayed publication on the public Web site, as well as additional methods for reporting the information to CMS. We proposed that applicable manufacturers should indicate on their reports whether or not a payment or other transfer of value should be granted a delay from publication. In addition, we proposed that payments or other transfers of value

subject to delayed reporting need to be reported each year with a continued indication that publication should remain delayed and any updated information on the payment or other transfer of value, as necessary. Further, we proposed that following FDA approval, licensure or clearance, applicable manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published in the current reporting cycle. Finally, we proposed that if a report includes a date of payment 4 years prior to the current year, then the payment or other transfer of value would be automatically published, regardless of whether the applicable manufacturer indicates that the payment should be delayed.

Comment: A few commenters requested clarification on whether applicable manufacturers would be required to indicate that a payment or other transfer of value should be granted delayed publication. Other commenters provided alternative methods for reporting payments or other transfers of value eligible for delayed publication. For example, some commenters recommended that applicable manufacturers should only report the payment or other transfer of value to CMS in the year it was made and then again in the year it is to be published. Similarly, other commenters recommended that applicable manufacturers should only report payments or other transfers of value in the year they are to be published. In addition, a few commenters expressed concern about confidentiality and recommended that applicable manufacturers should not be required to report the identifying details of the payment or other transfer of value until the payment was scheduled to be published. Beyond identifying details, some commenters recommended that CMS allow applicable manufacturers to report "research and development" for the product name, rather than the product, in order to better protect proprietary interests. Similarly, commenters recommended that CMS never require the collection of research protocols in order to ensure a payment or other transfer of value should be granted delayed publication.

Response: We appreciate the comments and agree that applicable manufacturers are not *required* to indicate that payments or other transfers of value are eligible for delayed publication and may instead choose not to indicate eligibility for the delay. However, 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.

We also appreciate the comments regarding alternative methods for reporting payments or other transfers of value granted delayed publication; however, we believe that the proposed method is preferable. We believe that continual reporting is beneficial because it will allow us to ensure that payments or other transfers of value made more than four years earlier will be published appropriately. Otherwise, payments or other transfers of value from the same applicable manufacturer may be stored in various places. Additionally, we believe it will be difficult for us to enforce and audit payments or other transfers of value eligible for delayed publication if they are not reported until they are scheduled to be published. Nevertheless, we understand the confidentiality concerns, particularly for new products that have not yet been granted FDA approval, licensure, or clearance. However, after reviewing the comments, we believe 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. Additionally, section 1128G(c)(1)(E)(ii) of the Act requires CMS to keep the information submitted confidential prior to publication. We believe that creating separate requirements is too burdensome particularly when the statute and regulations already provide for confidentiality. We do not intend applicable manufacturers to provide research protocols or other such agreements to CMS for verification. Finally, pursuant to the statute, 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 Web site.

F. Penalties

Section 1128G(b) of the Act authorizes the imposition of CMPs for failures to report required information on a timely basis in accordance with the regulations. If an applicable manufacturer or applicable GPO fails to submit the required information, then the applicable manufacturer or applicable GPO will be subject to a CMP of at least \$1,000, but no more than \$10,000, for each payment or other

transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for failure to report is \$150,000. For knowing failure to submit required information in a timely manner, an applicable manufacturer or applicable GPO will be subject to a CMP of at least \$10,000, but no more than \$100,000, for each payment or other transfer of value, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for a knowing failure to report is \$1,000,000.

In the proposed rule, we outlined the penalty amounts as required by statute for failure to report and knowing failure to report. In addition, we proposed that all CMPs would be collected and imposed in the same manner as the CMPs collected and imposed under section 1128A of the Act. Additionally, we proposed that the procedures in 42 CFR part 402 subpart A would apply with regard to imposition and appeal of CMPs. Similarly, we defined the term "knowingly" based on the meaning in the False Claims Act, 31 U.S.C. 3729(b), as required by statute. Finally, we also proposed that a CMP may be imposed for failure to report information in a timely, accurate, or complete manner.

In the proposed rule, we outlined the factors that we would consider when determining the amount of a CMP, as well as when the maximum CMP would be imposed. We did not receive any comments on these factors, so we have decided to finalize these provisions as proposed. The factors to be considered include, but are not limited to, the following:

- The length of time the applicable manufacturer or applicable GPO failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.
- Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer or applicable GPO failed to report.
- Level of culpability.
- Nature and amount of information reported in error.
- Degree of diligence exercised in correcting information reported in error.

Finally, we proposed that in order to facilitate audits and enforcement, applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable

GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. We proposed that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

Comment: A few commenters discussed the proposed penalties for failure to report. These commenters generally supported higher CMP amounts for knowing failures to report. However, a few of these commenters suggested that the penalties were too low. The commenters also recommended that penalties should be imposed for inaccurate reporting, as well as omitted transactions.

Beyond the structure of the penalties, a few commenters also requested additional information on how CMS planned to enforce the program. They requested information on which agencies would be responsible for enforcement, as well as the enforcement mechanisms. Finally, a few commenters requested clarification on when the maximum penalty would be imposed and recommended that errors corrected during the review and correction period would not be subject to penalties.

Response: We appreciate the comments. However, we cannot change the amount or terms of the penalties, since they were authorized by statute. Section 1128G(b) of the Act outlines the CMP amounts and requires that they are imposed and collected in the same manner as those in section 1128A of the Act. Nevertheless, we do agree that the penalties should be imposed for inaccurate reporting. We have finalized our proposal that a 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. For example, this could entail reporting an erroneous payment amount or not reporting that an ownership or investment interest was held by an immediate family member of a physician. In order to clarify this, we have revised the regulation text in 42 CFR 402.105 to include the same text regarding reporting in a timely, accurate, or complete manner. In addition, we have 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. Finally, we also realized that in the proposed rule we did not refer to the procedures for collection of CMPs in 42 CFR part 402 subpart B, so we are clarifying in this final rule that the procedures in 42 CFR part 402 subpart A and subpart B will apply with regard to imposition, appeal, and collection of CMPs.

Regarding corrections made during the review and correction, and dispute resolution periods, we want applicable manufacturers and applicable GPOs to correct any errors they have submitted without fear of alerting CMS to errors that will be subject to penalties; however, we do not want to allow applicable manufacturers to submit grossly inaccurate or incomplete data by the original submission date without risk of sanction. Therefore, we are requiring 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. Applicable manufacturers and applicable GPOs should make a good faith effort to ensure that the original data submitted to CMS is correct. We do 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. As noted earlier, 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.

Finally, in light of the increased flexibility for consolidated reports, we have clarified how penalties will be enforced for applicable manufacturers submitting consolidated reports. As explained previously, 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. For example, an applicable manufacturer submitted a

consolidated report for itself (Company A) and two other applicable manufacturers (Subsidiary B and C). We discover six instances of a failure to report a payment or other transfer of value in Company A's submission (each penalized at \$10,000), seven instances of a knowing failure to report in Subsidiary B's submission (each penalized at \$100,000) and finally nine knowing instances of failure to report (each penalized at \$100,000) in Subsidiary C's submission. Company A, as the submitter and attester of the data, would be subject to a penalty of \$60,000 for Company A's failure to report, \$700,000 for Subsidiary B and \$900,000 for Subsidiary C. To be clear, Company A would be subject to the penalties for knowing failure to report from both Subsidiary B's and Subsidiary C's submissions even though the penalties together exceed \$1,000,000, because we interpret the maximum to apply individually to each applicable manufacturer's submission, even if the submission is contained within a consolidated report. We believe this appropriately handles the penalty requirements for applicable manufacturers submitting consolidated reports, since each applicable manufacturer should be subject to the same maximum penalties regardless of whether it submits individually, or as a part of a consolidated report. Two applicable manufacturers submitting a consolidated report should not be subject to lower penalties than two applicable manufacturers not submitting a consolidated report. Additionally, because the applicable manufacturer submitting the consolidated report is the entity attesting to the data, we believe it is fair that it be subject to the CMPs for each applicable manufacturer included in the consolidated report. Therefore, as noted previously we encourage applicable manufacturers considering consolidated reports to fully assess the requirements and potential penalties.

Comment: A few commenters discussed the retention period; in particular, many of them stated that the 5-year retention period was too long. A few other commenters recommended that the 5 years should begin on the date of first submission, rather than the date of publication. These commenters explained that retention based on date of publication would require applicable manufacturers and applicable GPOs to retain some records for longer than 5 years. Finally, a few commenters questioned whether the 5-year retention requirement was considered absolute in terms of liability.

Response: We appreciate the comments, but do not agree that 5 years is too long. We believe that 5 years is sufficient, since it is less than other retention requirements with which applicable manufacturers and applicable GPOs may be familiar. In addition, we believe that the retention period should begin at the date of publication. While we understand this policy may require the records to be retained for up to 9 years, we believe this information is essential for audits, and given the confidentiality requirements for data granted delayed publication, these activities may not be possible until after the data is published. If the date of retention began when the data was reported, in some cases there may be less than a year between when the data was published and the end of the retention period, which we do not believe is sufficient time to allow for audits, penalties, and appeals. Given these decisions, we have finalized the retention requirements as proposed. Finally, 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.

G. Annual Reports

We are 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. Similarly, we must report information submitted during the previous year to States annually by September 30, 2013 and June 30 for each year thereafter. In the preamble to the proposed rule, we explained that since we will not receive data for the prior year until the 90th day of each year, the data submitted that year will not be ready for the April 1st report. Instead, we proposed that we report to the Congress information submitted by applicable manufacturers and applicable GPOs during the preceding year.

Finally, we proposed that the State reports would be State-specific and include summary information on the data submitted regarding covered recipients and physician owners or investors in that State. Since these reports are due later in the year than the Report to Congress, we proposed that the reports would include data collected

during the previous calendar year which was submitted in the current year. We also proposed that neither the Congressional nor State reports will include any payments or other transfers of value that were not published under the delayed publication requirements in section 1128G(c)(1)(E) of the Act. We did not receive any comments on these provisions and have finalized them as proposed.

Comment: A few commenters did not support the proposed timing for the Congressional report and instead recommended that CMS publish the Congressional report along with the publication of the data. Additionally, a few commenters recommended that CMS provide more information on the content of the Congressional reports. Particularly, they recommended that the report provides aggregate spending across applicable manufacturers and applicable GPOs, including aggregate spending for payments or other transfers of value granted delayed publication. Finally, a few commenters also recommended that CMS establish a process for sharing information across government agencies, such as OIG and the Department of Justice (DOJ).

Response: We appreciate the comments. We agree that the annual Congressional report should include summary statistics on the annual aggregate totals across applicable manufacturers and applicable GPOs. We also agree that inclusion of the aggregate total of payments or other transfers of value would be useful for oversight of the program. We plan to include this information in our annual Congressional report; however, in general we believe that we should not include specific details in the final rule to allow us flexibility to include and present information as appropriate. We also plan to work closely with other Federal agencies, since we recognize that other agencies are involved in similar activities. However, the purpose of this program is not to prosecute reporting entities, but to promote transparency.

Regarding the timing of the Congressional report, we recognize the awkwardness of the timing, but note that the report could be submitted early since it is only required by April 1st. We do not believe we have the authority to change the statutory deadline in regulation, but will try to publish the report as soon as possible.

Based on the timing of the publication of the final rule we have 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.

H. Relation to State Laws

Section 1128G(d)(3) of the Act preempts any State or local laws requiring reporting, in any format, of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients. No State or local government may require the separate reporting of any information regarding a payment or other transfer of value that is required to be reported under section 1128G(a) of the Act, unless such information is being collected by a Federal, State or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight.

Comment: A few commenters discussed the relation of section 1128G of the Act to relevant State laws. These commenters strongly supported preemption, but requested information on how CMS interpreted the timing, given the missed statutory deadline. Many commenters also requested that CMS identify what elements of current State laws will be preempted. Additionally, these commenters recommended clarifying the statutory language to prevent preemption from being applied too narrowly to successfully consolidate reporting. A few commenters explained that a broad interpretation of the exceptions to preemption, particularly "other public health purposes or health oversight purposes" could require applicable manufacturers and applicable GPOs to report the same information to States, as well as the Federal program. These commenters recommended that CMS clarify these terms to prevent them from being interpreted so broadly to not allow for any preemption.

Response: We appreciate the comments and acknowledge that the statute seems to provide that preemption of State or local transparency and disclosure laws is effective for payments or other transfers of value made on or after January 1, 2012. We understand 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. We urge manufacturers to continue to report under State or local disclosure laws until the requirements under the Federal rule take effect.

We also seek to provide some additional guidelines to clarify the preemption requirements; however, we note that preemption determinations will need to be analyzed on a case-by-case basis.

We interpret “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. We believe this is consistent with the statutory exception from preemption in section 1128G(d)(3)(B)(i) of the Act pertaining to the reporting to States and localities of information not of the type required to be disclosed under Federal law. Thus, State and local entities may require reporting of nonrequired categories of information for payments or other transfers of value reported to CMS, which are not required under Federal law. This includes payment categories excluded by the Federal law (including those listed at section 1128G(e)(10)(B) of the Act), with the exception of those that do not meet the minimum dollar threshold set forth in section 1128G(e)(10)(B)(i) of the Act. In addition, States and localities may require reporting of payments or other transfers of value not required to be reported at all under the Federal law. For example, they may require the reporting of payments to non-covered recipients or by nonapplicable manufacturers. We believe this is consistent with the statutory exceptions from preemption in section 1128G(d)(3)(B)(iii) of the Act.

Finally, we understand the concern over other public health and oversight activities; however, this language is required by statute, so we cannot expressly change it. However, these exceptions cannot be used to avoid preemption. 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, we believe such a collection would be preempted, and the States or localities can obtain the information they want from the Federal program.

We have finalized the proposed discussion of public health agencies. We intend 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.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The information collections contained in this rulemaking are numerous and somewhat complex. We plan to obtain approval for the information collections in a step-wise fashion as we develop our system for receiving and displaying the required information and for allowing covered recipients and physician owners or investors to review the reported data prior to display on our Web site. Below, we provide an outline of the information collections and the current status of our requests for OMB approval.

A. Recordkeeping and Reporting of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906, § 403.908(a),(b),(d),(f) and (g), § 403.912(e))

Section 403.904 requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to CMS all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). This includes special reporting rules for research-related payments. Section 403.906 requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities. This information is to be aggregated and posted publicly by CMS on a searchable Web site. Annually, under § 403.908(g) applicable manufacturers and applicable GPOs will be able to review and correct the data provided in any reporting period during the 45 day period to review and correction period. Under § 403.912(e), applicable manufacturers and applicable GPOs must retain records to support their reports for 5 years from the date when the information is publicly posted on the CMS Web site. This is, in some cases, a recordkeeping requirement of at

most about 9 years for payments or other transfers of value eligible for delayed publication. In our proposed rule, we requested comment on the information required in the proposed regulation, but did not include all the data elements we expected applicable manufacturers and applicable GPO's to report, nor did we include detailed information about the mechanism for submission, amendment, or correction. For this reason, we are publishing a 60-day notice elsewhere in today's **Federal Register** seeking public comment on the information collection. As part of the process, we will be seeking public comment on templates that contain the data specifications for the system we will be building.

B. Registration for Applicable Manufacturers and Applicable GPOs (§ 403.908(c))

As required by § 403.908(c), any applicable manufacturer or applicable GPO that is required to report under this subpart must register with CMS within 90 days of the end of the calendar year for which a report is required. During registration, two points of contact must be provided, as well as other information. Registration is required once, but upon filing the annual reports the system will prompt applicable manufacturers and applicable GPOs to confirm that the registration information (for example, points of contact) is still accurate. If it is not accurate, the applicable manufacturers and applicable GPOs will be prompted to provide updated information. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

C. Attestation (§ 403.908(e))

As required by § 403.908(e), each report, including corrections, must include a certification that the information reported is timely, accurate, and complete. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

D. Assumptions Document (§ 403.908(f))

Under (§ 403.908(f)), applicable manufacturers and applicable GPOs may submit an assumptions document with their reports. This document can set out the assumptions and methodologies used to produce the reports. It will not be made available to the public, covered recipients or physician owners or investors, but it will provide CMS with information to help identify areas where additional guidance and clarity is needed. This is a voluntary collection and CMS does not plan to request that it be submitted in any particular way. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

E. Information Collections Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(g))

As required by section 1128G of the Act, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. To accomplish this review, we plan to ask covered recipients and physician owners and investors that would like to review the information to register with CMS using the CMS Enterprise Portal and associated identity and access management system. Once registered, they will be able to access a secure Web site that allows them to submit or review data securely. We have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

F. Notice of Resolved Disputes by Applicable Manufacturers and Applicable GPOs (§ 403.908(g)(4))

Under § 403.908(g)(4), applicable manufacturers and applicable GPOs must notify CMS of resolved disputes. We have not yet established the content or form of this notice, and therefore we

have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

G. Notice of Errors or Omissions (§ 403.908(h))

Under § 403.908(h), applicable manufacturers and applicable GPOs must notify CMS immediately upon discovering errors or omissions in their reports. We have not yet established the content or form of this notice, and therefore we have yet to seek OMB approval for the information collections associated with these provisions. We plan to seek public comment consistent with the requirement of the Paperwork Reduction Act and request OMB approval at a later date. Consistent with 5 CFR part 1320, these provisions will not be effective until OMB approves the collection of information.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to implement the requirements in section 1128G of the Act (as added by section 6002 of the Affordable Care Act), which requires applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report annually to the Secretary all payments and other transfers of value to physicians and teaching hospitals (collectively, covered recipients). Section 1128G of the Act also requires applicable manufacturers and applicable GPOs to report ownership and investment interests held by physicians or the immediate family members of physicians in such entities.

These provisions of the Act were modeled largely on the recommendations of the MedPAC, which voted in 2009 to recommend Congressional enactment of a new regulatory program. The problem addressed, as stated by MedPAC, is that “at least some” drug and device manufacturer interactions with physicians “are associated with rapid prescribing of new, more expensive drugs and with physician requests that such drugs be added to hospital formularies,” as well as “concern that manufacturers’ influence over physicians’ education may skew the information physicians receive.” MedPAC went on to say that “there is no doubt that those relationships should

be transparent,” while pointing out that “transparency does not imply that all—or even most—of these financial ties undermine physician-patient relationships.”⁵ While a few comments discussed the reliability of the data used for the MedPAC report, we believe that the overall conclusions of the report are valid and continue to see the report’s findings as a reason to promote transparency.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and promoting flexibility. Section 4 of Executive Order 13563 calls upon agencies to consider approaches that “maintain flexibility and freedom of choice for the public,” including the “provision of information to the public in a form that is clear and intelligible.” A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that presents estimated costs and benefits of the rulemaking. We solicited comments on all assumptions and estimates in this regulatory impact analysis, including some assumptions and estimates that were presented in the Collection of Information Requirements section of the proposed rule. As is standard practice in

⁵ All quotes from pages 315–316 of “Public reporting of physicians’ financial relationships” at http://www.medpac.gov/chapters/Mar09_Ch05.pdf.

meeting these various requirements for regulatory analysis, this section of the final rule addresses all of them together.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, “small entities” are those that fall below size thresholds set by the Small Business Administration, or are not-for-profit organizations or governmental jurisdictions with a population of less than 50,000. We did not receive any comments on these aspects of the RFA, so have finalized it as proposed. For purposes of the RFA, we estimate that the majority of teaching hospitals and physicians, and most applicable manufacturers and applicable GPOs are small entities under either the size or not-for-profit standard. According to the Small Business Administration size standards⁶ the threshold size standard for “small” pharmaceutical manufacturers is 750 employees, for biological products, and surgical equipment, surgical supplies, and electromedical/electrotherapeutic apparatus manufacturers is 500 employees and for drug and medical equipment wholesalers is 100 employees. We estimate that approximately 75 percent of applicable manufacturers and applicable GPOs are smaller than these size standards. In this final rule, we assume that applicable manufacturers that do not have payments or other transfers of value or physician ownership or investment interests to report do not need to submit a report. We believe that many small applicable manufacturers and applicable GPOs will have no relationships, thus will not have to report, so the burden on them will be negligible. For small entities with financial relationships to report, we believe that they will only have a small number to report, making the reporting process significantly less burdensome. We believe that the average burden of the reporting requirements will be about \$80,000 in the first year (the sum of 0.25 FTEs of compliance officer at \$48 hourly rate and 1 administrative support FTE at \$26 hourly rate times 40 hours and 52 weeks) for smaller manufacturers, and even less in subsequent years. This amount is far below the 3 percent of revenues that HHS uses as a threshold for “significant impact” under the RFA, so these regulations will not have a significant effect on these small entities. For example, if a firm with only 100

employees generates annual revenues of \$200,000 per employee, or \$20 million, a cost of \$80,000 would be less than 0.5 percent of the revenues. Firms this small would potentially face costs considerably less than \$80,000, and hence an even lower effect.

As previously noted, most teaching hospitals and physicians are small entities under the RFA, since most teaching hospitals are not-for-profit and some have revenues below \$34.5 million. We estimate that 95 percent of physician practices have revenues under \$10 million. We believe the regulatory effects of this provision on physicians and teaching hospitals are relatively minor. Physicians and teaching hospitals are provided with the opportunity to review and correct this information, but are not involved in the data collection or reporting processes. We estimated that this review would take 1 hour from the individual physicians and 5 hours for the supporting staff to perform the duty to maintain records and review the reports annually. For teaching hospitals, it is estimated that on average 40 hours of compliance officer and 80 hours of supporting staff would be needed. Given that their review will take such a small amount of their time annually, the costs faced by physicians and teaching hospitals are not substantial. As a result, we believe that the cost burden of this review and correction period will be far below the 3 percent threshold for “significant impact.” Therefore, we have determined that this proposed rule will not have a significant economic impact on a substantial number of small entities in any category of entities it affects.

In addition, as stated in the proposed rule, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. In the proposed rule, we stated that we did not believe that any of the affected teaching hospitals are small rural hospitals, so did not believe that the rule had a significant impact on the operations of small rural hospitals. We did not receive any comments on this, so we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)

also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any single year of \$100 million in 1995 dollars, updated annually for inflation. In early 2013, that threshold is approximately \$139 million. The estimates presented in this section of this rule exceed this threshold and as a result, we have provided a detailed assessment of the anticipated costs and benefits in section V.C.4. of this final rule. Reporting under section 1128G of the Act is required by law, so we are limited as to policy options. Section IV.D. of this final rule, as well as other parts of the preamble, provide detailed additional information on the alternatives we considered.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. While this final rule does preempt certain elements of State law, the regulatory standard simply follows the express preemption provision in the statute. Because of this and the fact that this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable. We offer a more detailed discussion of preemption in § 403.914 of this final rule.

C. Anticipated Effects

The regulatory impact of this provision includes applicable manufacturers and applicable GPOs collection and submitting this information to CMS, and physician and teaching hospital review and correction period. The costs of these requirements are outlined in section III. of this final rule. We estimate a total cost of about \$269 million for the first year of reporting, followed by about \$180 million in the second year and annually thereafter.

1. Effects on Applicable Manufacturers and Applicable GPOs

For applicable manufacturers, only those that made reportable payments or other transfers of value, or have physicians (or immediate family members of physicians) holding ownership and investment interests, will be required to submit reports. Similarly, only applicable GPOs that have ownership or investment interests held by physicians (or immediate family members of physicians) would be required to submit reports. We estimate that approximately 1,150 applicable

⁶ http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.

manufacturers, (150 drug and biologic manufacturers, and 1,000 device and medical supply manufacturers), and approximately 420 applicable GPOs would submit reports. We based these estimates on the number of manufacturers reporting in States with similar transparency provisions, as well as the number of manufacturers registered with FDA. The number of drug manufacturers is based on reporting in Massachusetts, Minnesota, and Vermont, whereas the number of device manufacturers is based on reporting in Massachusetts and Vermont, since Minnesota does not require device manufacturers to report. Because the State laws have higher payment thresholds and are specific to the physicians in the State, we estimated that the number of manufacturers reporting would be greater under section 1128G of the Act, so we increased the State reporting numbers by 50 percent. For device manufacturers, we also used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate, combining the two data sources we increased the State reporting numbers by 75 percent. We believe that device manufacturers are often smaller and more region specific, which is why we increased the State estimates by a greater percentage. We did not receive comments on the number of reporting entities, except for information on the number of device manufacturers reporting in Vermont, where the legislature amended the transparency scheme in 2009 to include reporting by device manufacturers, so have finalized these assumptions.

It is difficult to establish with precision the number of GPOs, as proposed, because the definition of GPO includes some physician owned distributorships (PODs). However, we did rely on a recent report by the Senate Finance Committee which identified 20 States with multiple PODs and more than 40 PODs in California.⁷ When we extrapolate these estimates to the national level, taking into account the disproportionately higher number in California, we estimate that there are approximately 260 PODs currently in the U.S. We further estimate that there are an additional 160 GPOs, which have some form of physician ownership or investment. This is based on a review of what little literature exists and discussions with knowledgeable persons. Our research found that there are approximately 800 GPOs and that approximately 20 percent of GPOs have at least one physician owner or investor. We did not receive comments on the

number of GPOs, so have finalized these assumptions.

In the public comments, we received comments on the estimated costs of the reporting requirements, but not the individual activities associated with them. Given these comments, we have revised the estimates, but have not revised the activities the FTEs will be required to perform, since we believe they accurately portray the requirements. Coordinating the data collection will require ensuring that all payments and other transfers of value are attributed to the correct covered recipient and reported in the manner required in this final rule. These estimates include our aggregate estimate of the overall time required to build and maintain the reporting systems (including the development of new information technology systems), train appropriate staff, obtain NPI and other information from the NPES system (and if necessary supplement that information), establish whether any owners or investors have physicians as immediate family members (if necessary), organize the data for submission to CMS (within the organization and with any third party vendors), register with CMS and submit the required data, review the aggregated data that CMS produces, respond to any physician or teaching hospital queries during the review process, and resubmit and re-attest to certain disputed information (if necessary). Finally, it also includes any time required to maintain records, as required. However, we believe that much of this information will be collected and stored already for financial reasons, so we do not anticipate a significant burden. It allows for time applicable manufacturers and applicable GPOs may sometimes use for “pre-submission” reviews but assumes that would be rarely used, and only for complex cases. It also includes the time that applicable manufacturers may elect to spend to submit with their data a document describing their assumptions and methodology for categorizing the nature of payments. The estimates also include a downward adjustment to reflect the potential time savings that would accrue to applicable manufacturers who register with the CMS system and thus have the ability to query CMS, receive informal guidance through a listserv or other methods of providing technical assistance, and ultimately obtain useful information on low cost methods of compliance.

Comment: Several commenters stated that the current cost estimation for applicable manufactures and applicable GPOs to comply with the reporting

requirements are too low, and CMS should increase the FTE estimates.

Response: We agree with the comment and have increased our estimates of the average FTE burden associated with the manufacturer and GPO reporting requirements. However, we believe that applicable manufacturers and applicable GPOs vary in their readiness to comply with the reporting requirements. Some companies have existing reporting systems in place, which can be used to comply with the government requirements. These systems track the wide range of financial interactions between the company, and physicians and teaching hospitals. Additionally, the efforts and workload varies with the size of the company as larger manufacturers will have more transactions, so may need more FTEs accordingly. As in the proposed rule, we estimated the impact based on all sizes of companies, recognizing that there are a few very large companies for which this would be a low estimate, but there are small companies which may need fewer FTEs. Additionally, we also took into account the finalized provisions that applicable manufacturers with less than 10 percent of gross revenues coming from covered products would only have to report payments or other transfers of value related to covered products, rather than all products. This will greatly reduce the reporting burden for these manufacturers, so we have considered them small companies for reporting purposes. Finally, we separated the FTE estimates to include a full time compliance officer, as well as multiple support staff for bookkeeping, accounting, and auditing; this change in approach yields a lower average cost per FTE than we estimated in the PRA.

We estimate that, for year 1, on average, smaller applicable manufacturers will have to dedicate 25 percent of an FTE employee (mainly in the range of zero to 50 percent), whereas larger applicable manufacturers may have to dedicate 1 to 10 FTE employees to comply with the reporting requirements (we assume 2 FTEs on average). Furthermore, we estimated that reporting activities will be conducted by the managerial staff and supporting staffs, the compliance or similar level of staffs will oversee the reporting activities, which will largely be supported by staff involved with bookkeeping, accounting and auditing. Since there are many more small companies, we estimate that on average, 0.5 FTEs of compliance officer and 2 FTEs of supporting staff would be needed for each applicable manufacturer in the first year (2 FTEs of

compliance officer and 8 FTEs of supporting staffs in 150 larger firms and 0.25 FTEs of compliance officer and 1 FTE of supporting staffs in 1,000 smaller firms). We appreciate that this is considerable simplification of a far more complex distribution of firms, but we believe that it captures the distribution in manufacturing sectors where a relative handful of firms have sales in the billions of dollars annually over a wide range of products, and a far larger number have annual sales in low millions of dollars annually for just a few products, with practices regarding financial relationships with physicians varying widely within each group and, in many cases by product or product class.

Therefore, for applicable manufacturers, the revised cost estimation assumes a compliance officer (0.5 full-time equivalents (FTEs)) and 2 FTEs of bookkeeping, accounting and auditing staff support in the first year. In the second year and thereafter, we reduced the estimates, since we believe the system will be more automated. In year 2 and thereafter we assumed 0.375 FTEs (780 hours) of a compliance officer and 1.5 FTEs (3,120 hours) of bookkeeping, accounting, and auditing support. Compared with the estimates we provided in the proposed rule, the total first-year FTE increased from 1.74 to 2.5 FTEs for applicable manufacturers. It should be noted that this is an average cost while the large manufacturers may need more and the small manufacturers may need less FTEs.

The greater staff time for year 1 represents time for applicable manufacturers to alter their systems to collect and report this data. We estimate that once procedures and systems are modified, costs would be 25 percent lower, which reduces this value to an average of 0.375 FTEs of compliance officer and 1.5 FTEs of support staff in year 2 and annually thereafter. We emphasize that these are very rough estimates. The actual burdens could easily average 25 percent lower or higher, and would depend on manufacturers' changes in practices after the regulations are made final. Some may welcome the new transparency; others may decide to

change or eliminate their current practices. Our assumption that smaller firms could in some cases incur no new costs assumes that some do not now have any such financial relationships and that this proportion would grow as some firms decide that the benefits of such relationships are less than the costs of reporting. Other smaller firms with only a few products and only a few financial relationships might well already have systems in place that essentially meet the proposed requirements or that could do so with minimal effort.

We anticipate it would be less burdensome for an applicable GPO to comply with these proposed reporting requirements, since we believe companies will have fewer relationships with physician owners or investors (or immediate family members). This will make it much easier for applicable GPOs to match ownership and investment interests to the appropriate physicians (or family members). Based on discussions with officials of some GPOs and industry observers, we estimate that it would take from 5 to 25 percent of a FTE staff member, depending on the size of the applicable GPO. We assume that applicable GPOs already know the ownership and investment interests of its major investors, so the burden of these requirements include any changes to internal procedures to record and report the information. Also again, we have not found any empirical studies to better inform this estimate. Accordingly, we estimate that on average, an applicable GPO would dedicate 10 percent of an FTE (208 hours) of compliance officer and 0.25 FTEs (520 hours) of support staff to reporting under this section for year 1, followed by 25-percent reductions in both the compliance officer's time and support staff's time for year 2 and annually thereafter. Compared with the estimates we provided in the proposed rule, the total first-year FTE estimates increased from 0.1 FTE (208 hours) to 0.35 (728 hours) for GPOs.

While many individuals within the applicable manufacturer or applicable GPO may contribute to the data collection and reporting, we believe that majority of the work will be performed by the support staff and overseen by a

compliance officer. According to the Bureau of Labor Statistics Occupational Employment Statistics, in May 2011, the average hourly rates for a compliance officer and bookkeeping, accounting and auditing staff in the pharmaceutical and medicine manufacturing field was \$35.75 and \$19.84, respectively. We applied a 33 percent increase to this amount to account for fringe benefits, making the total hourly compensation \$47.55 and \$26.39, respectively. The total number of hours for applicable manufacturers (including the hours for compliance officers and support staff) during year 1 would be 5,980,000 (1,150 applicable manufacturers × 100 hours (2.5 FTEs) × 52 weeks). For year 2 and subsequent years, we estimate a total of 4,485,000 hours (1,150 applicable manufacturers × 75 hours (1.875 FTEs) × 52 weeks). On average, this equals 4,983,333 hours annually for all applicable manufacturers for the first 3 years. The total number of hours for applicable GPOs (including the hours for compliance officers and support staff) for year 1 would be 305,760 (420 applicable GPOs × 14 hours (0.35 FTE) × 52 weeks) and for year 2 would be 229,320 hours (420 applicable GPOs × 10.5 hours (0.2625 FTEs) 52 weeks). For the first 3 years in total, applicable GPOs will spend on average 254,800 hours annually.

The following tables provide our total cost estimates for applicable manufacturers and applicable GPOs to comply with the data collection requirements in section 1128G of the Act such as collecting information, responding to inquiries, developing reports, and submitting reports to CMS. In total, we estimate that for applicable manufacturers and applicable GPOs required to report, it will cost \$193,037,104 for year 1 and will cost \$144,777,828 for year 2 and annually thereafter. For the first 3 years, this averages to a cost of \$160,864,253 annually. All estimates are in 2011 dollars.

We note that Tables 1A and 1B contain revised estimated labor costs. The original cost estimates were included in the December 19, 2011 proposed rule (76 FR 78742).

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	1,040	\$48	\$49,452	\$56,869,800
Supporting staffs in AM	1,150	4,160	26	109,782	126,249,760
Compliance officer in Applicable GPOs	420	208	48	9,890	4,153,968

TABLE 1A—YEAR 1 ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOs—Continued

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Supporting staffs in Applicable GPOs	420	520	26	13,723	5,763,576
Total					193,037,104

TABLE 1B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED LABOR COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOs
[Annual]

	Estimated reporting organizations	Estimated hours per reporting organization	Hourly rate	Average total cost per organization	Total cost
Compliance officer in AM	1,150	780	\$48	\$37,089	\$42,652,350
Supporting staffs in AM	1,150	3,120	26	82,337	94,687,320
Compliance officer in Applicable GPOs	420	156	48	7,418	3,115,476
Supporting staffs in Applicable GPOs	420	390	26	10,292	4,322,682
Total					144,777,828

In addition to FTE costs, we also assume that there would be some infrastructure costs associated with the reporting requirements under section 1128G of the Act. We acknowledge a substantial amount of uncertainty in these estimates. For example, we do not know how many companies will be using existing systems and technology to comply with the requirements and how many will be obtaining new equipment and technology; in both cases, there will be opportunity costs of using the systems for the reporting required by this rule, but with new systems, there might be higher-set-up costs. We also envision that companies of varying size will have different infrastructure needs, so have selected an average amount based on CMS infrastructure estimates of the requirements. We estimate that in year 1 the infrastructure costs for applicable manufacturers will be \$10,000. This represents an average of \$4,000 for small companies (estimated to be 1000 companies) and \$50,000 for large companies (estimated to be 150 companies). We assume that the majority of these costs will be infrastructure costs, such as purchasing equipment and initial training, but assume that some costs will be required to maintain the systems. Therefore, we estimate that in year 2 and annually thereafter, applicable manufacturers will spend about \$1,000 annually to maintain their systems. This represents 10 percent of the original infrastructure,

which we believe is reasonable given CMS’s experience with system maintenance. We note that this only covers the system and equipment maintenance and not the staff time to comply with the reporting requirements.

For applicable GPOs, we assume the infrastructure costs associated with the reporting requirements will be lower than that for applicable manufacturers. We assume that the applicable GPO costs will be roughly 20 percent of those for applicable manufacturers. This is based on the fact that estimated FTE costs for applicable GPOs are roughly 20 percent of that of applicable manufacturers. Therefore, we estimate that in year 1 the infrastructure costs for applicable GPOs will be \$2,000. Similarly, we estimate that maintenance costs will be 10 percent of the initial cost, so in year 2 and beyond the maintenance costs for applicable GPOs will be \$200. Table 2A and 2B contain the estimated infrastructure costs for applicable manufacturers and applicable GPOs in year 1 and year 2 and thereafter, respectively. We further assume that the combined infrastructure and maintenance costs per burden hour will be the same for physicians and teaching hospitals as for GPOs.

We note, and discuss in the benefits section later in this section, that the costs of applicable manufacturers may be partially offset because many companies are already required to report to States with similar disclosure requirements, but would no longer be

required to report the same information to States after the final rule is issued. In addition, a few large companies are already reporting similar information on a national level in order to comply with Corporate Integrity Agreements (CIAs) with HHS OIG. These companies may not have to invest as much as we estimated earlier in this section to comply with the requirements in section 1128G of the Act. However, given the differing requirements for each State and CIA, and broad scope of section 1128G of the Act, we do not believe it is possible to approximate any lessened burden for entities already reporting.

Because applicable manufacturers have some influence in getting their products on a Part D plan formulary, obtaining billing codes, or getting Medicaid coverage, they have some control over whether Medicare, Medicaid and CHIP payments are available for their products. If applicable manufacturers were to stop accepting such payments so as to avoid reporting requirements, it would reduce the rule-induced cost that they bear themselves, but might negatively affect the well-being of Medicare, Medicaid and CHIP patients who no longer have coverage for a full range of medical products. However, because these public programs represent a very large patient population, we do not anticipate that applicable manufacturers will refrain from participating in the programs just to avoid reporting requirements.

TABLE 2A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	\$50,000	\$7,500,000
Small Applicable Manufacturers	1000	4,000	4,000,000
Applicable GPOs	420	2,000	840,000
Total			12,340,000

TABLE 2B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

[Annual]

	Organizations	Annual cost	Total cost
Large Applicable Manufacturers	150	\$5,000	\$750,000
Small Applicable Manufacturers	1000	400	400,000
Applicable GPOs	420	200	84,000
Total			1,234,000

2. Effects on Physicians and Teaching Hospitals

We also have estimated costs for physicians and teaching hospitals, since they would have an opportunity to review and correct the data submitted by applicable manufacturers. The statute uses the definition of physician in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, dental surgeons, podiatrists, optometrists and licensed chiropractors. Using the Bureau of Labor Statistics Occupational Outlook Handbook, we estimate that information may be available for as many as 897,700 physicians. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs. In the proposed rule, we assumed that roughly 75 percent of physicians would have relationships. However, based on feedback we received from stakeholders, including a private firm with data of roughly 50 companies currently reporting, we now estimate that less

than 50 percent of the physicians have transactions with industry. We assume that 50 percent of physicians have no relationships with applicable manufacturers or applicable GPOs, which reduces our universe of affected physicians to approximately 448,850. Further, stakeholders have expressed that many physicians maintain relationships with applicable manufacturers that are relatively insignificant from a financial point of view, so we estimate that many physicians will not devote any time to reviewing and correct the aggregated reports from CMS. We estimate that only 50 percent of the remaining 448,850 physicians will review the report, which reduces our universe of affected physicians to 224,425 for year 1. For year 2, we anticipate that there would be a further reduction in the number of physicians choosing to review the data because they would be familiar with the type of information on the database, so we reduced the number of physicians reviewing by another 25 percent, to 168,319 physicians. We also

reduced the amount of time it would take the physicians choosing to review the information, since we believe they will be familiar with the review, correction and dispute process. For teaching hospitals, we know that about 1,100 hospitals receive Medicare GME or IME payments, all of which are defined as teaching hospitals for this provision. We believe that the vast majority of teaching hospitals would have at least one financial relationship with an applicable manufacturer, so we did not apply any adjustments to this estimate. We also anticipate that there would not be a reduction in the number of teaching hospitals that review the information after the first year because teaching hospitals probably have more complex financial relationships.

See the Table 3 for a breakdown of this calculation. In the proposed rule, we mistakenly omitted dental surgeons from the table, so have added estimates for them in the final rule. The definition of physician at section 1861(r) of the Act explicitly includes them.

TABLE 3—NUMBER OF PHYSICIANS BY TYPE

Physician type	Number
Doctor of Medicine/Doctor of Osteopathy	660,000
Doctor of Dental Medicine	155,700
Doctor of Podiatric Medicine	12,000
Doctor of Optometry	35,000
Licensed Chiropractors	* 35,000
Total	897,700
Adjustment for Physicians with no reports (only 50% had transaction with industry)	448,850
Adjustment for Physicians who do not review reports (Year 1—reduction by 50%)	224,425
Adjustment for Physicians who do not review reports (Year 2—reduction by 25%)	168,319

* Reduced from 50,000 in BLS to account for licensure.

We received numerous comments on the cost estimations for physicians and teaching hospitals, and have responded to them and revised our cost estimates accordingly.

Comment: Several commenters questioned the time and cost estimation for physicians. Specifically, the commenters stated that the time allotted for the physicians to review the data is too short, since physicians will need to maintain records in order to review the information submitted on their behalf accurately. Similarly, several commenters noted that the current hourly rate for the physician (\$75) is low.

Response: We agree with commenters that the physicians and teaching hospitals may need to maintain ongoing records of the activities for verification purposes, so have increased the time dedicated to the physician and teaching hospital review. However, we assume that most of these recordkeeping activities will fall on the duty of the office assistants, but the physician may need to review the records. The hours of bookkeeping are added in the revised cost estimation for physician and teaching hospital accordingly. Additionally, we agree that the physician hourly rate should be increased. The hourly rate for physicians in the final rule is updated to \$137 per hour, which is based on the most recent data from Bureau of Labor Statistics (BLS).

Comment: A few commenters questioned CMS's cost estimate of 10 hours of compliance officer in teaching hospitals, which state that teaching hospitals will need more time to review the transactions and maintain records to facilitate the review.

Response: We agree with commenters that teaching hospitals will likely need more time for their review. The hospital compliance officer's annual hours have been increased from 10 hours to 40 hours. In addition, we revised the cost estimation to include 80 hours of administrative supporting staff at teaching hospitals to maintain the records. The role of the compliance officer will be review and oversight, while the administrative supporting staff will conduct the recordkeeping.

In response to the comments, even though there is no requirement for physician and teaching hospitals to review the reports or maintain records of interaction, we estimated the covered recipients may maintain records to

facilitate reviews. In the final rule, we estimated the supporting staffs such as bookkeeping, accounting, and auditing would perform the tasks while the compliance officer would oversee the review process.

When reviewing the information reported, physicians and teaching hospitals are allowed to review the information attributed to them by applicable manufacturers and applicable GPOs that submitted data to CMS. A number of commenters suggested that physicians and teaching hospitals would spend some time during the year maintaining records to facilitate their review. In response to this feedback, we added estimates for recordkeeping for physicians and teaching hospitals and assumed that support staff would perform these functions. We estimate that on average, physicians would need 1 hour annually to review the information reported. For physicians that choose to review the information, this would range from a few minutes for physicians with few relationships with applicable manufacturers, to at most 10 or 20 hours for the small number of physicians who have lengthy disputes over a payment or other transfer of value, or ownership or investment interest. In addition, we also estimated 5 hours annually of supporting staff for each physician to help them to maintain records to facilitate the review. We believe that teaching hospitals will have to review more payments or other transfers of value and have more complex relationships, so we estimate that, on average, it would take a representative, such as a compliance officer, from a teaching hospital 40 hours annually to review the submitted data, ranging from 10 hours for small teaching hospitals that receive few payments or other transfer of value, to 200 hours for teaching hospitals that have lengthy disputes. In addition, we also estimated 80 hours annually of administrative support staff for each teaching hospital to help them maintain their records.

The Bureau of Labor Statistics Occupational Employment Statistics publishes data on hourly compensation for Healthcare Practitioners and Technical Occupations in physicians' offices. The average hourly rate for physicians and surgeons is \$103.32,⁸ which rises to \$137 with 33-percent fringe benefits. This average includes physicians, who account for about half of the employment in this category. In

the proposed rule, we used an estimate for the hourly wage that included other provider types, but having received numerous comments that the resulting wage was too low, we increased the estimate for this final RIA. The average hourly rate for the supporting staff is \$16.35 which rises to \$21.75 with 33 percent fringe benefits. The total number of hours for physicians (including supporting staffs in physician offices) would be 1,346,550 (224,425 × 6 hours) for year 1 and 757,436 hours (168,319 × 4.5 hours) for year 2, which averages to 953,807 hours annually for the first 3 years. The total estimated cost for the review and correction period for physicians and the supporting staffs in year 1 is \$55,152,444. For year 2 and annually thereafter, the estimated cost for physician and supporting staffs to conduct review and correction is \$31,023,250. For the first 3 years, the average cost for all physicians review and correction will be \$39,066,314 annually.

For teaching hospitals, as explained, we expect a compliance officer to review the payments and other transfers of value with supporting staff to maintain any necessary records. Since this review could be done by employees with multiple titles, we used the Bureau of Labor Statistics Occupational Employment Statistics reported compensation for Management Occupations at General Medical and Surgical Hospitals in 2010. The hourly average rate for compliance officer in hospitals is \$32.94 or \$43.81 when fringe benefit costs are applied. The average hourly rate for the supporting staff in a teaching hospital is \$16.22 which rises to \$21.57 with 33 percent fringe benefits. For year 1, the total number of hours would be 132,000 (1,100 × 120 hours). For year 2 this would decrease to 99,000 hours (1,100 × 90 hours). For the first 3 years, the average number of hours for teaching hospitals will be 110,000 annually. The total estimated cost for the review and correction period for teaching hospitals is \$3,825,800 for year 1 and \$2,869,350 for year 2 and annually thereafter. On average, the cost for all teaching hospitals will be \$3,188,167 annually for the first 3 years.

We note that Tables 4A and 4B contain revised cost estimates. The original cost estimates were included in the proposed rule (76 FR 78742).

⁸ http://www.bls.gov/oes/current/naics4_621100.htm.

TABLE 4A—YEAR 1 ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	224,425	1.00	\$137	\$137	\$30,746,225
Physicians Support staffs	224,425	5.00	22	109	24,406,219
Compliance officer, Teaching Hospitals	1,100	40.00	44	1,752	1,927,640
Administrative supporting staffs in teaching Hospitals	1,100	80.00	22	1,726	1,898,160
Total					58,978,244

TABLE 4B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS [Annual]

	Estimated number of entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	168,319	0.75	\$137	\$103	\$17,294,751
Physicians Support staffs	168,319	3.75	22	82	13,728,498
Compliance officer, Teaching Hospitals	1,100	30.00	44	1,314	1,445,730
Administrative supporting staffs in teaching Hospitals	1,100	60.00	22	1,294	1,423,620
Total					33,892,600

For purposes of analysis, we also include estimates of the infrastructure costs for physicians and teaching hospitals, which may need to purchase

and maintain equipment for internal tracking purposes. We assume that the combined infrastructure and maintenance costs for teaching hospitals

will be the same as those for GPOs. For physicians, we assume a total cost of \$2 million in the first year, and 10 percent thereafter.

TABLE 5A—YEAR 1 ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	224,425		\$2,000,000
Teaching Hospitals	1,100	2,000	2,200,000
Total			4,200,000

TABLE 5B—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED INFRASTRUCTURE COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Number	Annual cost	Total cost
Physicians	168,319		\$200,000
Teaching Hospitals	1,100	\$200	220,000
Total			420,000

3. Effects of Third Parties

We also received some comments on including estimates for entities that were not included in the proposed rule. We have provided the comment, as well as our response.

Comment: Many commenters suggested that the costs of recordkeeping for third parties, such as contract research organizations or professional associations that receive indirect payments or other transfers of value, should be included in the cost estimation.

Response: In the final rule, we have clarified the requirements for third parties which received payments at the request of, or on behalf of, covered recipients (§ 403.904(c)(10)), as well as the requirements for third parties which receive and make indirect payments to covered recipients (§ 403.904(i)(1)). We believe these revisions will help clarify and minimize any reporting requirements that third parties viewed as burdensome to them, but we maintain that the requirements in section 1128G of the Act do not impose significant burden on third parties,

since they are neither required to report nor review. However, we recognize that some business models may require third parties to report recipients of payments back to applicable manufacturers, so we have included in the final rule estimates on the burden for third parties. We estimate that 58 third parties will incur costs under this final rule. We assume that there will be significantly fewer third parties than applicable manufacturers affected by these provisions, so we reduced the number of applicable manufacturers by 95 percent to obtain the number of third

parties as 5 percent the number of applicable manufacturers. Given the range of entities that could be third parties, we believe it is difficult to estimate the hourly rate for these entities. We assume that the role will be similar to that of compliance officers in applicable manufacturers and applicable GPOs, since it may require them to track similar relationships. Therefore, we estimate the hourly rate for third parties will be \$47.55 (\$35.75,

plus a 33 percent increase for fringe benefits), which is the same hourly rate described in section IV.C.1. the final rule for a compliance officer at an applicable manufacturer or applicable GPO. As described, we do not believe these requirements set significant burden on third parties, since they are neither required to report nor review. We estimate that third parties may need to spend 40 hours in year 1 on tasks that are associated with the reporting

requirements. Similarly to other estimates, we decreased this estimate by 25 percent in year 2 (for a total of 30 hours) to account for increased familiarity with the systems. In total, third parties will dedicate 2,320 hours in year 1 and 1,740 hours in year 2 with a total cost of \$110,316 in year 1 and \$82,737 in year 2.

In summary, the first year and subsequent year annual costs are presented in the following tables.

TABLE 6A—TOTAL YEAR 1 ESTIMATED COSTS

	Labor costs (\$)	Infrastructure costs (\$)	Total cost (\$)
Applicable Manufacturers	183,119,560	11,500,000	194,619,560
Applicable GPOs	9,917,544	840,000	10,757,544
Third-Parties	110,316	110,316
Physicians	55,152,444	2,000,000	57,152,444
Teaching Hospitals	3,825,800	2,200,000	6,025,800
Total	252,125,664	16,540,000	268,665,664

TABLE 6B—TOTAL COSTS, YEAR 2, AND SUBSEQUENT YEARS
[Annual]

	Labor costs (\$)	Infrastructure costs (\$)	Total cost (\$)
Applicable Manufacturers	137,339,670	1,150,000	138,489,670
Applicable GPOs	7,438,158	84,000	7,522,158
Third-Party Recordkeeping	82,737	82,737
Physicians	31,023,250	200,000	31,223,250
Teaching Hospitals	2,869,350	220,000	3,089,350
Total	178,753,165	1,654,000	180,407,165

4. Effects on the Medicare, Medicaid, and CHIP

Although the Department proposes to administer this program through the CMS, the final rule would have no direct effects on the Medicare, Medicaid, and CHIP. Reporting is required for physicians and teaching hospitals regardless of their association with Medicare, Medicaid, or CHIP. Manufacturers are identified by whether the company has a product eligible for payment by Medicare, Medicaid or CHIP, but this does not affect whether or not the product may be covered under titles XVIII, XIX, or XXI of the Act. We will incur some costs in administering the program. However, as required by statute, we will be able to use any funds collected from the CMPs assessed under this rule to support the program, decreasing the agency funding required.

5. Benefits

We outlined numerous benefits in the proposed rule and received numerous

comments supporting these benefits. We appreciate these comments. Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. While collaboration is beneficial to the continued innovation and improvement of our health care system, some payments from manufacturers to physicians and teaching hospitals can introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and lead to increased program costs. It is important to understand the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency, and to permit patients to make better informed decisions when choosing health care professionals and making treatment decisions. Additionally, it is important to develop

a system that encourages constructive collaboration, while also discouraging relationships that threaten the underlying integrity of the health care system.

Both the Institute of Medicine and other experts, such as MedPAC, have noted the recent increases in both the amount and scope of industry involvement in medical research, education, and clinical practice has led to considerable scrutiny and recommended enhanced disclosure and transparency to discourage the inappropriate use of financial incentives and lessen the risk of such incentives interfering with medical judgment and patient care. We recognize that disclosure is not sufficient to differentiate beneficial, legitimate financial relationships from those that create a conflict of interest or are otherwise improper. However, transparency can shed light on the nature and extent of relationships, and

discourage inappropriate conflicts of interest.⁹

We have no empirical basis for estimating the frequency of such problems, the likelihood that transparent reporting will reduce them, or the likely resulting effects on reducing the costs of medical care. Although a few States do have similar reporting requirements, determining the benefits based on their experiences is difficult. Transparency does not identify which relationships are conflicts of interests or whether public reporting dissuaded a relationship from forming, making it difficult to assess the benefits of public reporting. We plan to continue considering methods to use the data collected to identify any changes in these relationships as a result of public reporting. However, we observe, that the costs for preparing reports are small in relation to the size of the affected industry sectors.

Finally, section 1128G(d)(3) of the Act preempts State laws requiring the reporting of the same type of information as required by section 1128G(a) of the Act. Applicable manufacturers and applicable GPOs subject to State requirements would not have to comply with multiple State requirements, and instead would only have to comply with a single Federal requirement with regard to the types of information required to be reported under 1128G(a) of the Act. This benefits applicable manufacturers and applicable GPOs by allowing them to comply with a single set of reporting requirements for this information, lessening the potential for multiple, conflicting State requirements. This benefit may also lead to potential cost-savings, since a single reporting system for reporting this information is less burdensome than multiple programs.

D. Alternatives Considered

Reporting under section 1128G of the Act is required by law, which limits the other policy options available. Section 1128G of the Act encourages transparency of financial relationships between physicians and teaching hospitals, and the pharmaceutical and device industry. Although, many of these relationships are beneficial, close relationships between manufacturers and prescribing providers can lead to conflicts of interests that may affect clinical decision-making. Increased transparency of these relationships tries to discourage inappropriate

relationships, while maintaining the beneficial relationships. Public reporting and publication is the only statutorily permissible option for obtaining this transparency and achieving the intentions of this provision. In developing this final rule, we tried to minimize the burden on reporting entities by trying to simplify the reporting requirements as much as possible within the statutory requirements and in response to public comment.

The statute is prescriptive as to the types of information required to be reported, and the ways in which it is required to be reported; however wherever possible we tried to allow flexibility in the reporting requirements. For example, we note the following:

- We did not require the submission of an assumptions document for nature of payment categories, but allow applicable manufacturers and applicable GPOs to submit this voluntarily.
- The Secretary is allowed discretion to require the reporting of additional information, but we tried to use this discretion as sparingly as possible, in large part because of the strong desire expressed by stakeholders that we not expand reporting categories. For example, we considered asking applicable manufacturers and applicable GPOs to report the method of preferred communication and email address for physicians and teaching hospitals with which they have relationships, but based on the comments that this would be burdensome, we did not finalize it. In order to reduce the burden further, we could have not added any additional reporting categories (such as requiring State professional license number or NDC (if any)); however, we believe that all the additional reporting elements are necessary for the successful administration of the program and have tried to provide sufficient explanation of each decision.

- We limited the definition of covered drug, device, biological, and medical supply to reduce the number of entities meeting the definition of applicable manufacturer and applicable GPO. We proposed limiting covered drugs and biologicals to those that require a prescription to be dispensed and limiting covered devices (including medical supplies that are devices) to those that require premarket approval by or notification to the FDA. The comments strongly supported these limitations, so we have finalized them in the final rule.

- In the proposed rule, we defined “common ownership” as covering any

ownership portion of two or more entities, but are finalizing an alternate interpretation that would limit the common ownership definition to circumstances where the same individual, individuals, entity, or entities own 5 percent or more of total ownership in two or more entities. Additionally, we provided further guidance on the phrase “assistance and support” in order to limit the number of entities under common ownership reporting. We could have employed a higher threshold of common ownership to further lower the burden; however, as explained in section II.B.1.a.(3) of this final rule, we believe that 5 percent is a standard threshold.

- In the proposed rule, we considered whether we should require that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified but do not have an NPI. Such an approach would provide additional information by which to cross-reference physicians who do not have an NPI, but the approach could also cause confusion if the additional information is not captured in a consistent manner. We received numerous comments on this provision and finalized the reporting of State professional license number for all physician covered recipients. The comments and rationale for this decision is discussed in section II.B.1.d.(1) of the preamble to this final rule.

- The Congress gave the Secretary authority to define a GPO and also specified that such organizations would include organizations that purchase covered drugs, devices, biologicals, and medical supplies, as well as organizations that arrange for or negotiate the purchase of covered drugs, devices, biologicals, and medical supplies. Therefore, we interpret the statute to encompass entities that purchase covered drugs, devices, biological, and medical supplies for resale or distribution to groups of individuals or entities. This would include physician owned distributors (PODs) of covered drugs, devices, biological, and medical supplies. We received numerous comments on this proposal and finalized the definition as proposed (see section II.B.2.a.(2) of the preamble of this final rule).

- We also finalized limitations that will reduce the reporting requirements for applicable manufacturers that only manufacture a few covered products. Applicable manufacturers with less than 10 percent of revenues from covered products do not need to report all payments or other transfers of value as proposed. This will greatly reduce the

⁹ Information on the IOM recommendations may be found here: <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>.

burden of reporting for these entities, allowing them greater flexibility. We could have lowered the burden by including additional limitations to reporting by certain applicable manufacturers, but believe that the statute did not provide much flexibility to do so.

• We have finalized, as required by statute, a 45-day review period during which applicable manufacturers and GPOs, covered recipients, and physician owners or investors can review the data before it is made available to the public. In response to the comments, we have considered the best methods to administer this review, as well as any dispute resolution processes. We have

finalized a dispute resolution system which will allow covered recipients and physician owners or investors to more easily review the information submitted on their behalf and a more streamline process to initiate disputes, as necessary.

Finally, it is important to evaluate and monitor if the changes reflected in this rule achieve the goal of improving transparency and accountability between health care providers and drug manufacturers. We will evaluate over time, and encourage others to evaluate, the effects of this rule on Medicaid enrollment, on Federal, State, and enrollee costs, and on health outcomes.

E. Accounting Statement

The Office of Management and Budget, in Circular A–4, requires an accounting Statement for rules with significant economic impacts. The table that follows shows the estimated costs annualized over a 10-year period. The estimated costs are \$269 million in year 1 and \$180 million in year 2. We assume that future outlay costs may be similar to those costs experienced in year 2. We envision that the number of financial relationships required to be reported will remain similar, so the cost of reporting the information will not change significantly.

TABLE 7—ACCOUNTING STATEMENT

Category	Primary estimate	Year dollars	Discount rate (percent)	Period covered
Annualized Monetized Costs	\$192	2011	7	2013–2022
	190	2011	3	2013–2022
Benefits	Public reporting of the extent and nature of relationships between physicians, teaching hospitals, and industry manufacturers through increased transparency will permit patients to make better informed decisions when choosing health care professionals and making treatment decisions, and deter inappropriate financial relationships.			

F. Conclusions

Section 1128G of the Act requires applicable manufacturers to report annually to CMS certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable GPOs are required to report annually certain physician ownership interests. We estimate that the impact of these reporting requirements will be about \$269 million for the first year of reporting, and \$180 million for the second year and annually thereafter. As we have indicated throughout, these are rough estimates and subject to considerable uncertainty. Better estimates might well be 25 percent higher or lower. Nonetheless, we believe that the public comment period offers an excellent opportunity for all stakeholders to consider alternatives and to present quantitative or qualitative information that will enable us to both improve the effectiveness and lower the costs of the final rule. Therefore, we solicited comment on the analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.

Many of the comments received discuss our assumptions for the costs of collecting this information. Because this rule involves the collection of data, the

vast majority of the financial impact is included in the collection of information requirements. Therefore earlier in the preamble of this final rule, we summarize and respond to the comments regarding our cost assumptions.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 402

Administrative practice and procedure, Medicaid, Medicare, Penalties.

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

■ 1. The authority citation for part 402 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 402.1 is amended as follows:

■ A. In paragraph (c) introductory text, by removing the reference “(c)(33)” and adding the reference “(c)(34)” in its place.

■ B. Adding a new paragraph (c)(34). The addition reads as follows:

§ 402.1 Basis and scope.

* * * * *

(c) * * *

(34) Section 1128G (b) (1) and (2)—Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

* * * * *

■ 3. Section 402.105 is amended as follows:

■ A. In paragraph (a), by removing the reference to “paragraphs (b) through (g)” and adding the reference “paragraphs (b) through (h)” in its place.

■ B. Adding paragraphs (d)(5) and (h). The additions read as follows:

§ 402.105 Amount of penalty.

* * * * *

(d) * * *

(5) CMS or OIG may impose a penalty of not more than \$10,000 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to failures to report in an annual submission of information will not exceed \$150,000.

* * * * *

(h) \$100,000. CMS or OIG may impose a penalty of not more than \$100,000 for each knowing failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to knowing failures to report in an annual submission of information will not exceed \$1,000,000.

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 4. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 5. A new subpart I is added to part 403 to read as follows:

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

Sec.

403.900 Purpose and scope.

403.902 Definitions.

403.904 Reports of payments or other transfers of value.

403.906 Reports of physician ownership and investment interests.

403.908 Procedures for electronic submission of reports.

403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

403.912 Penalties for failure to report.

403.914 Preemption of State laws.

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value

provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

§ 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

(1) Operates in the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor

expects to receive, payment because of the patient's inability to pay.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered device means any device for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that, by law, requires premarket approval by or premarket notification to the Food and Drug Administration (FDA).

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a—

(1) Drug or biological, by law, requires a prescription to be dispensed; or

(2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Covered recipient means— (1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be “employed by” or an “employee” of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of

section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

- (1) Spouse.
- (2) Natural or adoptive parent, child, or sibling.
- (3) Stepparent, stepchild, stepbrother, or stepsister.
- (4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.
- (5) Grandparent or grandchild.
- (6) Spouse of a grandparent or grandchild.

Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).

Know, knowing, or knowingly—(1) Means that a person, with respect to information—

- (i) Has actual knowledge of the information;
- (ii) Acts in deliberate ignorance of the truth or falsity of the information; or
- (iii) Acts in reckless disregard of the truth or falsity of the information; and
- (2) Requires no proof of a specific intent to defraud.

NPES stands for the National Plan & Provider Enumeration System.

Operating in the United States means that an entity—

- (1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or
- (2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.

Ownership or investment interest—(1) Includes, but is not limited to the following:

- (i) Stock, stock option(s) (other than those received as compensation, until they are exercised).
- (ii) Partnership share(s);
- (iii) Limited liability company membership(s).
- (iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.
- (2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

- (i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.
- (ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.
- (iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.
- (iv) An unsecured loan subordinated to a credit facility.
- (v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the

applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

- (i) Street address.
- (ii) Suite or office number (if applicable).
- (iii) City.
- (iv) State.
- (v) ZIP code.

(3) *Identifiers for physician covered recipients.* In the case of a covered recipient who is a physician, the following identifiers:

- (i) The specialty.
- (ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual 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.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or

other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other transfer of value.

(i) For drugs and biologicals, applicable manufacturers must report the name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.

(ii) For devices and medical supplies, applicable manufacturers must report at least one of the following:

(A) The name under which the device or medical supply is or was marketed.

(B) The therapeutic area or product category for the device or medical supply.

(iii) If the payment or other transfer of value is not related to a covered drug, device, biological or medical supply, but is related to a specific non-covered product, applicable manufacturers must indicate "non-covered product."

(iv) If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate "none."

(v) If the payment or other transfer of value is related to at least one covered drug, device, biological, and medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological or medical supply (as required by paragraphs (c)(8)(i) and (ii) of this section) and may indicate "non-covered products" in addition.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value

was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate "individual" (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, stock option, or any other ownership interest.

(4) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xvii) of this

section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

- (i) Consulting fee.
- (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
- (iii) Honoraria.
- (iv) Gift.
- (v) Entertainment.
- (vi) Food and beverage.
- (vii) Travel and lodging (including the specified destinations).
- (viii) Education.
- (ix) Research.
- (x) Charitable contribution.
- (xi) Royalty or license.
- (xii) Current or prospective ownership or investment interest.
- (xiii) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- (xiv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- (xv) Grant.
- (xvi) Space rental or facility fees (teaching hospital only).

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a physician covered recipient, all of the following must be provided:

- (1) The physician's name as listed in the NPPES (if applicable).
- (2) National Provider Identifier.
- (3) State professional license number(s) (for at least one State where

the physician maintains a license) and State(s) in which the license is held.

(4) Specialty.

(5) Primary business address of the physician(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any.

(v) Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(iii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for payments or other transfers of value related to continuing education programs.* (1) Payments or other transfers of value provided as compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:

(A) The Accreditation Council for Continuing Medical Education.

(B) The American Academy of Family Physicians.

(C) The American Dental Association's Continuing Education Recognition Program.

(D) The American Medical Association.

(E) The American Osteopathic Association.

(ii) The applicable manufacturer does not pay the covered recipient speaker directly.

(iii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category "Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program."

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category "Compensation for serving as a faculty or as a speaker for a unaccredited and non-certified continuing education program."

(iii) Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category "Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program."

(h) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(i) *Exclusions from reporting.* The following are excluded from the

reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (i)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than \$10 in CY 2013 (or less than the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the \$100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the \$10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which

are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

- (i) Street address.
- (ii) Suite or office number (if applicable).
- (iii) City.
- (iv) State.
- (v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

- (i) The specialty.
- (ii) National Provider Identifier (if applicable and as listed in NPPES).
- (iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in

§ 403.904(c) through (i). The terms “applicable manufacturer and applicable group purchasing organization” must be substituted for “applicable manufacturer,” and “physician owner or investor” must be substituted for “covered recipient” in each place they appear.

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician’s immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician’s immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the

information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using an online posting and notifications on CMS’s listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review

data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the

Web site at least once annually with corrected information.

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new

application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed \$150,000.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than \$10,000, but not more than \$100,000, for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed \$1,000,000.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

- (1) Aggregated separately;
- (2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of \$1,150,000.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in

accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State

that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 23, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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