DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 402 and 403

[CMS–5060–P]

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: Proposed rule.

SUMMARY: This proposed rule would 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on February 17, 2012.

ADDRESSES: In commenting, please refer to file code CMS–5060–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5060–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5060–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–(800) 743–3951.

I. Background

A. Statutory Background

Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (the Act), which 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.

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 for 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 physicians. Applicable manufacturers must report the required payment and other transfer of value information to CMS in an electronic format by March 31, 2013, and on the 90th day of each calendar year thereafter. Applicable manufacturers and applicable GPOs must report the required information about physician ownership and investment interests, including those held by immediate family members, as well as information on any payments or other transfers of value to such physician owners or investors in the same 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. We are required by statute

to publish the reported data on a public Web site. The data must be downloadable, searchable, and easily 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

Collaboration among physicians, teaching hospitals, and industry manufacturers may contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration is beneficial to the continued innovation and improvement of our health care system, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests 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, legitimate 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 can shed light on the nature and extent of relationships, and may dissuade inappropriate conflicts of interest from developing. Given the intricacies of disclosure and the importance of discouraging inappropriate relationships without harming beneficial ones, we sought to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers. We solicited stakeholder feedback through a CMS Open Door Forum on March 24, 2011 in order to guide our implementation of section 1128G of the Act. The transcript of this Open Door Forum can be found on the regulatory docket on Regulations.gov. In addition to this feedback, we consulted with the Inspector General of the Department of Health and Human Services (HHS), as required by the statute.

II. Provisions of the Proposed Regulations

The following sections outline the agency's proposals concerning implementation of section 1128G of the Act, including clarification of the terms and definitions used in the statute, as well as proposed procedures for the submission, review, and publication of the reported data. For terms undefined by the statute, we sought to provide, where necessary, appropriate definitions, and explanations of how we propose to interpret them. Due to the timing of the publication of this notice of proposed rulemaking, a final rule will not be 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 indicated in the statute. We will not require applicable manufacturers and applicable GPOs to begin collecting the required information until after the publication of the final rule; however, we recognize that some manufacturers and GPOs may begin to collect certain data voluntarily. We seek comment on the amount of time applicable manufacturers and applicable GPOs will need following publication of the final rule in order to begin complying with the data collection requirements of section 1128G of the Act. We are considering a preparation period of 90 days, since we believe that was the time period intended by Congress based on the timeline indicated in the statute and are requesting comments on whether that is a sufficient amount of time. Finally, we also seek input on specific challenges that applicable manufacturers and applicable GPOs may face when setting up the necessary data collection and reporting systems.

We hope to finalize this rule as soon as possible during calendar year (CY) 2012 and, depending on the publication date of the final rule, we are considering requiring the collection of data for part of 2012, to be reported to CMS by the statutory date of March 31, 2013. We seek comments on the feasibility of submitting the required information for part of CY 2012 by March 31, 2013.

A. Transparency Reports

Section 1128G(a) of the Act outlines the transparency reporting requirements and consists of two parts. The first part, 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 part, 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 propose 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 seek comments on this general approach. We 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, or anyone else 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 False Claims Act).

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

a. Applicable Manufacturers

(1) Manufacturers

Section 1128G(a) of the Act requires that applicable manufacturers disclose certain payments or other transfers of value to covered recipients. In defining applicable manufacturer, we sought a comprehensive definition to ensure the full transparency and complete reporting envisioned by the statute. Section 1128G(e)(9) of the Act defines a ''manufacturer of a covered drug, device, biological, or medical supply'' as—:

> Any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity 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).

Section 1128G(e)(2) of the Act clarifies that an ''applicable manufacturer'' of a covered drug, device, biological, or medical supply, is one which is ''operating in the United States, or in a territory, possession, or commonwealth of the United States.''

Given these statutory definitions and relevant considerations, we propose to interpret ''applicable manufacturer'' for the purposes of this regulation as an entity that is:

(1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or

(2) Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or

distribution of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States.

We recognize 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 USC 1396r–8(k)(5)). We note that this proposed definition, which generally tracks the statute, is somewhat more limited than those definitions.

Under this definition, manufacturers of a covered drug, device, biological, or medical supply (under either paragraph (1) or paragraph (2) of the definition) are deemed to be an ''applicable manufacturer'' if their products are sold or distributed in the United States (U.S.), regardless of where the covered drug, device, biological, or medical supply is actually produced or where the entity is actually located or incorporated. Given the global nature of these industries, we believe that any entity manufacturing covered drugs, devices, biologicals, or medical supplies for sale or distribution in the U.S. (or any entity under common ownership which provides assistance or support in the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of such items) should be subject to the requirements of section 1128G of the Act. The opportunity for undue influence or inappropriate relationships caused by payments or transfers of value to covered recipients is the same for manufacturers of drugs, devices, biologicals, or medical supplies sold or distributed in the United States regardless of where the product is actually manufactured, and we, therefore, propose to treat them the same.

We also seek to clarify that any manufacturer that meets the definition of applicable manufacturer by selling or distributing in the United States at least one covered drug, device, biological, or medical supply is considered an applicable manufacturer, even though it may also manufacturer products that do not fall within that category (as defined later in this section). We propose that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported as required under section 1128G of the Act regardless of whether the particular payment or other transfer of value is associated with a covered drug, device, biological, or medical supply. Additionally, we seek to clarify that the proposed definition includes 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 interpret these entities as being ''engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply.'' We seek comment on this interpretation.

As noted previously, section 1128G(e)(9) of the Act states that certain companies which are under ''common ownership'' with an entity that produces, prepares, propagates, compounds, or converts a covered drug, device, biological, or medical supply are also subject to the reporting requirements under this provision, even though they themselves may not be involved in the ''manufacturing'' process. Specifically, this applies to entities under ''common ownership'' with an applicable manufacturer which provide assistance or support to the applicable manufacturer 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 U.S., or in a territory, possession, or commonwealth of the U.S. We propose to define ''common ownership'' as when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities. The common ownership definition would apply to a range of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother/sister corporations.

We are also considering 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 proposed definition described previously, but would only apply to interests of 5 percent of more. We seek comments on our proposed definition of ''common ownership,'' including, whether a more specific definition is needed and, if a minimum percentage threshold is adopted, whether 5 percent is appropriate. We intend to finalize the agency's position on this in the final rule based on comments received.

If two entities are under common ownership with one another, and both individually meet the definition of an applicable manufacturer under paragraph (1) of the definition, then we propose that the entities should report separately under section 1128G of the Act. For example, if company A and company B are both owned by company C, and companies A, B and C all meet the definition of applicable manufacturer under paragraph (1), then all three have to report separately. However, if only one company under common ownership meets the definition of applicable manufacturer under paragraph (1), and the other company is required to report under paragraph (2) of the definition, then we propose that the affected entities can choose whether or not to report together. For example, if only company C meets the definition of applicable manufacturer under paragraph (1) and companies A and B meet the definition of applicable manufacturer under paragraph (2), then the companies can decide whether to report together. If an applicable manufacturer under paragraph (1) reports for itself as well as for entities under common ownership that are required to report under paragraph (2), the report should clearly name all of the entities that are included in the report. Given the various relationships between entities under common ownership, we propose that if an applicable manufacturer under paragraph (1) reports for at least one additional entity under common ownership, the applicable manufacturer may decide whether to identify the payments as those from the entity under common ownership, or whether to combine them with their payments or other transfers of value.

In addition to payments or other transfers of value to covered recipients made by applicable manufacturers themselves, applicable manufacturers (under both paragraphs (1) and (2) of the definition) are also required by statute to report payments and other transfers of value provided indirectly to covered recipients through third parties, if the applicable manufacturer is aware of the identity of the covered recipient. This is addressed in more detail in the discussion of third party payments found later in this preamble.

(2) Covered Drug, Device, Biological, or Medical Supply

The 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. Many drugs, devices, biological, and medical supplies are reimbursed separately under these programs, making payment availability clear. However, others are paid for as a part of a composite rate payment, such as the Medicare hospital inpatient prospective payment system (IPPS), the outpatient prospective payment system (OPPS), or the end-stage renal disease (ESRD) prospective payment system. Since payment, while indirect, is still being provided for the bundled drug, device, biological or medical supply, we propose that payment is considered ''available'' under Medicare, Medicaid or CHIP for items included in a composite payment rate. Therefore, we propose that drugs, devices, biologicals, or medical supplies included in a composite payment rate, as well as those reimbursed separately, are considered to be covered drugs, devices, biologicals, or medical supplies under section 1128G of the Act.

Given these proposals, we propose 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). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

We are proposing 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). We believe this limitation will reduce the number of manufacturers subject to the reporting requirements by excluding those that only manufacturer OTC drugs or biologicals. We believe that this exclusion may be appropriate for manufacturers that manufacture only these products (and not also products which fall within the proposed definition of ''covered drug, device, biological, or medical supply''), since physicians and teaching hospitals have less influence over patients' choice of OTC products. We seek comments on the proposal to limit covered drugs and biologicals to those that require a prescription to be dispensed. In the event we adopt this interpretation, applicable manufacturers who manufacturer only OTC drugs or biologicals (and not also products which fall within the proposed definition of ''covered drug, device, biological, or medical supply''), would not be required to report at all under section 1128G of the Act. However, manufacturers who manufacture both OTC drugs or biologicals 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), as previously explained.

Similarly, we are also proposing 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, 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. Some of these devices and medical supplies are so routinely provided in the course of medical care that the Congress may not have intended to capture manufacturers of such items under these reporting requirements. We believe this limitation may be appropriate for applicable manufacturers, because manufacturers that solely produce these exempt products have not been shown to have extensive relationships with covered recipients. Additionally, we believe this limitation might be appropriate because these financial relationships (to the extent they exist) are less likely to influence patient care. However, we are also concerned that this would be overly limiting for the definition of applicable GPOs, which also incorporates the phrase ''covered drug, device, biological, or medical supply.'' We discuss this more in the applicable GPO definition section. We seek comment on this additional limitation that we are proposing. We note that in the event this interpretation is adopted, applicable manufacturers who manufacture only devices or medical supplies that are exempt from premarket notification requirements (and not also products which fall within the proposed definition of ''covered drug, device, biological, or medical supply''), would not be required to report at all under section 1128G of the Act. However, manufacturers who manufacture both devices or medical supplies that are exempt from premarket notification requirements 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), as previously explained.

b. 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. Section 1128G(e)(11) of the Act defines ''physician'' to have the meaning set forth in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors. ''Employee'' is also defined in section 1128G(e)(7) of the Act to have the meaning set forth in section 1877(h)(2) of the Act, which is defined as follows: ''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).'' We note that these common law rules are discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d) through 1(c).

The term ''teaching hospital'' is not explicitly defined in section 1128G of the Act or elsewhere in the Act. One possible way to define the term ''teaching hospital'' is by linking it to Medicare graduate medical education (GME). We believe this is an appropriate way to identify teaching hospitals because GME payments are provided to support the training of medical residents, and hospitals that receive such payments are easily identifiable. Therefore, we propose to define a teaching hospital as any institution that received payments under section 1886(d)(5)(B) of the Act (IPPS Indirect Medical Education (IME)), section 1886(h) of the Act (direct GME), or

section 1886(s) of the Act (psychiatric hospitals IME) during the most recent year for which such information is available. While we recognize that this definition may not capture hospitals with accredited resident programs that do not receive IME or GME payments, we are unable to include these hospitals since we cannot readily identify them based on Medicare payment data. We seek comment on this proposed definition.

c. Identification of Covered Recipients

In order to accurately distinguish covered recipients, section 1128G of the Act requires that applicable manufacturers report the covered recipient's name and business address, and for physician covered recipients, report the physician's National Provider Identifier (NPI), and specialty. The collection of this information is necessary for applicable manufacturers, in order to distinguish individual covered recipients when reporting to CMS. Similarly, it is also important for CMS when aggregating the data. However, it is not simple given the number of covered recipients. In order to identify physicians covered recipients, we suggest that applicable manufacturers use the National Plan & Provider Enumeration System (NPPES), which CMS currently maintains and updates on its public Web site. The NPPES Web site includes a database of physician NPIs and has an NPI Registry function which allows applicable manufacturers to look up individual physician's NPIs.[1] Similarly, the full database can be downloaded from the CMS Web site.[2] The NPPES system is updated frequently and NPIs do not generally change over time, so we believe this is the best source of information for applicable manufacturers to obtain physician NPIs. We realize that the NPPES system may not contain NPI information for every physician covered recipient as defined in this provision. However, we believe that NPPES represents the most comprehensive listing of physicians available. If a physician is not listed in the NPPES NPI registry, the applicable manufacturer will be responsible for obtaining the physician's individual NPI directly from the physician, to the extent that the physician has an NPI.

We are also considering whether we should require, under the authority granted in section 1128G(a)(1)(A)(viii) of the Act, that applicable manufacturers report another unique identifier, such as State license number, for physicians who are identified, but do not have an NPI. We seek comments on what other unique identifiers could be used, including whether these unique identifiers are readily obtainable by applicable manufacturers.

With respect to teaching hospitals, we propose to publish a list of hospital covered recipients (that is, those hospitals that received Medicare direct or indirect GME) on the CMS Web site once per year. We believe publication of this list is necessary because it may not be immediately apparent to applicable manufacturers whether a particular hospital meets our proposed definition of a teaching hospital, and there is no currently published database that includes this information. The list for the reporting year would include the most recent data available. We propose that the list of teaching hospital covered recipients should include the name and address of each teaching hospital. We seek comments on this proposal.

d. Payments or Other Transfers of Value

''Payment or other transfer of value'' is defined broadly in section 1128G(e)(10)(A) of the Act as ''a transfer of anything of value.'' This includes all payments or other transfers of value given to a covered recipient, regardless of whether the covered recipient specifically requested the payment or other transfer of value. In addition, payments or transfers of value made to an individual or entity at the request of or designated on behalf of a covered recipient must be reported under the name of the covered recipient. We propose that this includes payments or other transfers of value provided to a physician (or physicians) through a physician group or practice. We propose 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).

In addition, there may be other situations when a covered recipient may request that a payment or other transfer of value be transferred by the applicable manufacturer to another individual or entity instead of being provided directly to himself/herself or the hospital itself. As required in section 1128G(a)(1)(A) of the Act, these payments should be reported under the name of the covered recipient since they are made at the request of, or designated on behalf of, a covered recipient. Additionally, we propose that applicable manufacturers report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient. Reporting the entity or individual paid will 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. We do not believe it is feasible to provide a review period for these entities or individuals before the data is made publicly available on the CMS Web site. Instead, we believe that review by the covered recipient is sufficient. We welcome comment on this approach. We believe that the collection of this information is within the discretion provided in section 1128G(a)(1)(A)(viii) of the Act to require reporting of additional categories of information regarding a payment or other transfer of value.

e. Payment and Other Transfer of Value Report Content

The specific categories of information required to be reported for each payment or transfer of value provided to a covered recipient are set forth in section 1128G(a)(1)(A) of the Act. We have provided the following explanations and details on how we propose that applicable manufacturers report some of this information to CMS.

(1) Name

When reporting the name of physician covered recipients, we propose reporting the first name, last name, and middle initial for physician covered recipients.

(2) Business Address

We propose that applicable manufacturers report the full street address. For teaching hospital covered recipients, we propose using only the address included in the CMS-published list of teaching hospitals. For physician covered recipients, we propose that applicable manufacturers report the physician's primary practice location address since this is more easily recognizable to end users of the data. The practice location can be found in NPPES as the ''provider business practice location.''

(3) Specialty and NPI

Applicable manufacturers are also required to report specialty and NPI for physician covered recipients. If using NPPES, we suggest using the ''provider taxonomy'' field when reporting the physician specialty. We propose that applicable manufacturers only report a single specialty for each physician covered recipient. We propose that applicable manufacturers use only the specialties available for the ''provider

[1] NPI Registry can be found at *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.*

[2] Database can be downloaded at *http://nppes.viva-it.com/NPI_Files.html.*

taxonomy'' field in NPPES; details on these terms are available online.[3] As explained previously, for NPI, we propose that applicable manufacturers report the physician's individual NPI, rather than any group NPI, with which the physician may be associated.

(4) Date of Payment

Applicable manufacturers must provide the date upon which a payment or transfer of value was provided to the covered recipient. Some payments or transfers of value may be provided over multiple dates, such as a consulting agreement with monthly payments. We propose that applicable manufacturers use their discretion over 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. Under this proposal, either approach would comply with these regulations. We are also considering requiring manufacturers to report multiple payments in a single consistent manner. We seek comments on these proposals.

(5) Associated 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 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. However, 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. For example, if a sales representative takes a physician to dinner to explain the benefits of the applicable manufacturer's new product, the name of the product must be included since it was associated with the dinner. We propose that the applicable manufacturer should report a related covered drug, device, biological, or medical supply (if there is one) using 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, the applicable manufacturer should report the scientific name. Additionally, we propose that applicable manufacturers 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 products related to the payment. We are considering, 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. Allowing the 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 would make aggregating payments by product difficult. We seek comment on this approach. Finally, if an applicable manufacturer is not reporting the name of the drug, device, biological, or medical supply as appropriate, then the applicable manufacturer may be subject to penalties under section 1128G(b) of the Act.

(6) 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 define additional categories, if necessary. These categories are described in more detail later in this section.

We propose that the categories within both the form of payment and the nature of payment should be defined as distinct from one another. We believe that any overlap among the categories will decrease the overall utility of the information submitted to CMS. For example, a payment for activities under the nature of payment category ''education'' should be separate from activities under the nature of payment category ''research.'' 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 propose 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. However, we believe that reporting multiple categories to describe a single payment or transfer of value may be confusing for end users, so we propose 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 propose 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 these lump sum payments or other transfers of value, we propose that the applicable manufacturer break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment. This approach should be easier for users to understand since they will know the totals for each form of payment, and each nature of payment, rather than totals for various combinations of categories, which may differ across applicable manufacturers. In addition, this should lead to greater consistency within the database because applicable manufacturers will separate all payments, rather than each applicable manufacturer combining payments differently. We seek comment on the proposal to require reporting payments under a single form of payment and nature of payment. We welcome comments about the usefulness of this data as well as any operational issues that applicable manufacturers might face in reporting it.

We also solicit 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. This approach may be more compatible with existing business processes, but it might also make the public disclosure database more confusing for end users. We welcome comment on the costs and relative advantages and disadvantages of this approach.

f. Forms of Payments

Section 1128G(a)(1)(A)(v) of the Act lists the following forms of payment that applicable manufacturers must use to describe payments or other transfers of value:

- 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.

[3] Health care provider taxonomy codes are available through a link on the NPPES Web site: *https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.instructions.*

- Any other form of payment determined by the Secretary.

We do not propose to add any forms of payment beyond those outlined in the statute because we believe what is provided in the statute is sufficient to describe payments and other transfers of value. We seek comments on whether other categories are necessary or would be helpful. Additionally, we believe that these terms are understandable as written and propose that each form of payment be defined by the term's dictionary definition. 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.

g. 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. As explained previously, we propose that each of these categories should be distinct and that only one nature of payment can be indicated for each individual payment or other transfer of value reported. When selecting natures of payment, we encourage 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 ask applicable manufacturers to make reasonable determinations about the nature of payment reported for the payment or transfer of value. Section 1128G(a)(1)(A)(vi) of the Act lists the following categories for nature of payment:

- 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 (as defined by the Secretary).

We believe that these terms have meanings to the general public that are familiar to the industry and propose defining each nature of payment category by its dictionary definition. To ensure consistency in the reporting and selection of categories, we will allow applicable manufacturers to submit with their data a document describing the assumptions used when categorizing the natures of payments. Submission of the assumptions document will not be mandatory, but we believe that applicable manufacturers may want to explain the reasoning behind their categories. Additionally, we believe that the information may be useful for CMS to monitor how applicable manufacturers are reporting data and whether significant differences among applicable manufacturers exist. The assumptions documents will not be posted on the public Web site because they may contain information applicable manufacturers would consider proprietary. However, based on our review and assessment of these assumptions, we may choose to offer further guidance to applicable manufacturers regarding how natures of payment should be classified. We recognize that many of these categories are similar, so the assumptions document can also help us understand the assumptions made by applicable manufacturers when classifying payments or other transfers of value. We seek comment on this proposal, including whether we should make submission of the assumptions document mandatory instead of voluntary.

We are providing some explanation of the following categories to provide additional context: Charitable contribution, food, research, and direct compensation for serving as faculty or as a speaker for a medical education program. These explanations are not exhaustive (unless specified as such), but rather are intended to provide guidance to applicable manufacturers when they are categorizing payments.

(1) Charitable Contributions

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 that is not more specifically described by one of the other nature or payment categories. Payments that do not meet this requirement made to, at the request of, or designated on behalf of a covered recipient must be reported in another appropriate category.

(2) Food and Beverage

We propose that applicable manufacturers should report the value of any food or beverage items provided to covered recipients, subject to the minimum threshold as discussed in more detail in section II.A.1.h.(1). of this proposed rule. This would be more straightforward in circumstances where covered recipients who partake in the meal are easily identifiable (for example, when a sales representative takes a specific number of physician covered recipients to a restaurant). However, we recognize that in instances where group meals are being provided in group settings (for example, buffet-style food in a physician's office), it may be more difficult to keep track of which covered recipients are partaking in the food and beverage. We propose that in this type of scenario, applicable manufacturers should report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal). For example, if once during the calendar year, a sales representative from an applicable manufacturer brings $25 worth of bagels and coffee to a solo physician's office for a morning meeting, regardless of the number of individuals who partake (such as non-covered recipient staff members), the per covered recipient cost is $25. Since this falls above the $10 minimum threshold for reporting a payment or other transfer of value, which is statutorily required and discussed in detail in section II.A.1.h.(1). of this proposed rule, this meal must be reported. However, if the practice group includes five physicians, then the per-covered recipient cost is $5 (regardless of whether all five physicians actually consumed any of the food provided), so the payment would not need to be reported. We recognize that this may be difficult for large group practices or hospital-based physicians, where an applicable manufacturer may be bringing bagels for a meeting with two specialists. We are considering whether to adopt a different approach for these situations, such as counting the number of physicians by department. We seek comment on these proposals and whether there is a more equitable, but not overly burdensome, way to report these payments or other transfers of value. Additionally, we propose 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.

(3) Research

We seek to limit the research category to bona fide research activities, including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research, as well as a research protocol. We propose to use this method to distinguish the research nature of payment category from other natures of payment categories because this method is also used to identify payments or other transfers of value eligible for delayed publication to protect the proprietary interests of applicable manufacturers. More details and an explanation of the written agreement and research protocol, as well as a definition of clinical investigation, are discussed more fully in the section of this preamble regarding delayed publication.

We recognize that reporting payments or other transfers of value for research activities may be complicated, since many research activities include large payment amounts which are spread across numerous activities and parties. Additionally, the payments are often not provided directly to a covered recipient, but to a clinic, hospital, or institution administering the research that is often led by a physician-covered recipient(s) as the principal investigator(s). This situation is further complicated because many applicable manufacturers use contract research organizations (CROs), as defined in 21 CFR 312.3(b), or other similar entities, such as site management organizations (SMOs) to manage their clinical research activities. Due to the complexities in the flow of research payments, we have outlined a proposed method for reporting research payments. However, we request comment on whether our proposed method is viable and not overly burdensome, and whether an alternative method would be preferable.

We propose 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. Indirect research would be used when a research payment is made to a clinic, hospital (other than a teaching hospital), or institution conducting the research (either by an applicable manufacturer or a CRO entity) and that organization in turn pays the physician covered recipient (or multiple physician covered recipients) serving as a principal investigator(s). Conversely, direct research would be used when a research payment or other transfer of value was provided directly to a physician covered recipient or teaching hospital covered recipient by an applicable manufacturer or CRO entity. When reporting payments or other transfers of value designated as research, we propose that applicable manufacturers must report the payment or other transfer of value as either ''indirect research'' or ''direct research.''

When reporting indirect or direct research, we propose that the payment or other transfer of value should be reported individually under the names and NPIs of physician covered recipients serving as principal investigators. For indirect payments, this includes 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). This is consistent with section 1128G(a)(1)(B) of the Act, which requires payments to an entity or individual at the request of or designated on behalf of a covered recipient to be disclosed under the name of the covered recipient. Payments or other transfers of value reported as indirect research should also include the name of the entity or individual that received the payment or other transfer of value.

Teaching hospitals are also defined as covered recipients, and may conduct research led by a physician covered recipient(s) acting as (a) principal investigator(s). While these payments could be reported as direct research to the teaching hospital covered recipient, we do not want to establish different reporting requirements for physician covered recipients acting as principal investigators at teaching hospitals versus other research institutions. To maintain consistency, we propose that research payments provided to teaching hospitals and ultimately to physician covered recipients must be reported for both the teaching hospital covered recipient, and the physician covered recipient(s). The payment or other transfer of value to the teaching hospital covered recipient should be reported as a direct research payment; whereas the payment or other transfer of value for the principal investigator(s) (physician covered recipient(s)) should be reported as indirect research.

We understand that reporting the amount of the payment or other transfer of value may be difficult because neither the applicable manufacturer nor the CRO generally know how the research payment is distributed because the payment includes all items and activities associated with the research project, not only the physician's time and services. This is particularly important for indirect research, since a principal investigator(s) may be receiving his/her usual salary from the institution for conducting the study. Additionally, we do not believe the total costs should be attributed personally to the principal investigator(s). However, we do believe it would be burdensome for applicable manufacturers to accurately determine the exact amount a physician covered recipient received. Finally, we also believe that reporting the total research payment amount provides additional transparency to end users about the applicable manufacturers' total research payments.

Based on these considerations, we propose 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. However, we propose that on the public Web site, we would report the payment amount separately and would not aggregate it into the total for physician covered recipients. For teaching hospitals, we believe end users would understand that the research payment covered all aspects of the research, so we believe it is appropriate to aggregate this into the teaching hospital's total payment amount. However, for physician covered recipients we believe attributing the full research payment to the physician could be misleading, due to the nature of research payments as described. We seek comment on these proposals.

We are also considering attributing the total payment to the covered recipient for direct research. We believe this may be necessary because in direct research, the covered recipient is individually receiving the payment, so the specific amount the covered recipient is receiving is clearly defined and available to the applicable manufacturer.

We recognize that the proposed reporting requirements for research payments and transfers of value may not cover all circumstances in which applicable manufacturers make payments or other transfers of value to covered recipients for research-related activities (for example, post-marketing research or other research or studies not conducted pursuant to a written contract between the applicable manufacturer and the organization conducting the research, and those studies without a research protocol). We

solicit comments about which existing nature of payment category (previously described) would apply to these other types of research, whether the scope of the ''research'' nature of payment should be broadened, and/or whether another nature of payment category should be added to address such research. Finally, we note that some of the reporting requirement will duplicate requirements already required under FDA regulations at 21 CFR part 54.

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

We propose that this category be interpreted 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 believe that this interpretation is consistent with the authority granted in section 1128G(a)(1)(A)(vi)(XV) of the Act to add additional nature of payment categories. Alternatively, we are considering adding another nature of payment category to describe situations when a covered recipient provides speaking services that are outside of medical education programs; however we believe that fewer categories for nature of payment is preferable. Additionally, it is simpler to only have one category for speaker fees to minimize potential inconsistencies in how applicable manufacturers categorize payments. We welcome comment on this proposal and the appropriate distinction between this nature of payment category and other categories, such as honoraria.

We realize that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. We are considering, and welcome comments on, whether to limit this category to CME-accredited speaking engagements and report other speaking engagements in another category, such as compensation for services other than consulting, or additional category.

(5) Other

Under the Act, all payments or transfers of value from applicable manufacturers to covered recipients (other than those excluded under section 1128G(e)(10)(B) of the Act) must be reported. For simplicity, and under the discretion provided in section 1128G(a)(1)(A)(vi)(XV) of the Act, we propose the addition of a nature of payment category to serve as a catch all for all payments or other transfers of value that do not fit into one of the listed natures of payment. Any payments or transfers of value that are not specifically excluded, and do not fit into another category should be reported with a nature of payment of ''other.''

h. Exclusions

Section 1128G(e)(10)(B) of the Act excludes the following types of payments and other transfers of value from the reporting requirements:

- 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.
- Product samples that are not intended to be sold and are intended for patient use.
- Educational materials that directly benefit patients or are intended for patient use.
- The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.
- Discounts, including rebates.
- In-kind items used for the provision of charity care.
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.
- Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient.

We anticipate that the public may inquire about the treatment of payments or other transfers of value between individuals who happen to have existing personal relationships. It is not our intent to capture 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). We welcome suggestions on how to incorporate this into the codified language of the final rule.

We propose that applicable manufacturers use the dictionary definitions for the exclusions. However, we are providing some clarification on how we propose applying the following types of exclusions:

(1) Transfers of Value Less Than $10

Small payments, 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 defined in 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 for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. We propose to publish the updated threshold amounts annually on the CMS Web site. We propose 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. This would simplify reporting for applicable manufacturers and prevent the reporting of payments less than $10 individually. We have provided a few examples to ensure that this exclusion is applied consistently.

- *Example 1:* An applicable manufacturer takes a physician out to lunch four times during the year and each lunch costs $9. The applicable manufacturer has no other relationships with the physician. Since the aggregate cost of the four meals is $36 for the year, these payments would not need to be reported.
- *Example 2:* An applicable manufacturer provides a physician with five meals, each worth $9, a speaker fee of $150, and pens worth $5. The aggregate amount is greater than $100 so all the payments need to be reported. The speaker fee should be reported as $150 under ''direct compensation for serving as faculty or as a speaker for a medical education programs,'' the meals

would be reported together as food for $45, and the pens would be reported as gifts for $5.

(2) Educational Materials That Directly Benefit Patients or Are Intended for Patient Use

Educational materials must consist of materials (such as pamphlets) that directly benefit patients or are intended for patient use. We want to clarify that this exclusion is limited to ''materials'' (including, but not limited to, written or electronic materials) and does not include services or other items. We are considering whether certain materials provided by applicable manufacturers to covered recipients to educate the covered recipients themselves, but which are not actually given to patients (for example, medical textbooks), should be interpreted as educational materials that ''directly benefit patients.'' We seek comments on whether such materials should be included in this exclusion and, if so, which types of educational materials provided to covered recipients should be deemed to ''directly benefit patients.'' We intend to finalize the agency's position on this in the final rule based on comments received.

(3) 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. Discounts and rebates are common in the industry and may be beneficial to payers (including Federal health care programs) and beneficiaries. We remind manufacturers of their obligations to appropriately report discounts and rebates for purposes of the Medicare and Medicaid programs and to comply with fraud and abuse laws, including the Federal Anti-Kickback statute.

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

We recognize the extensive philanthropic activities of many applicable manufacturers, such as the provision of supplies (both in the U.S. and abroad) to provide care for those who are unable to pay. We propose defining ''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 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). For example, the donation of an imaging machine to a covered recipient that would be for the use of both paying and non-paying patients would not be excluded under this category, even if the covered recipient is a charitable organization. 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.

(5) Indirect Payments 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 when 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.

This exclusion hinges on whether an applicable manufacturer is ''unaware'' of the identity of the covered recipient. To ensure that payments via third parties are reported, where appropriate, we propose that an applicable manufacturer is aware of the identity of a covered recipient if the applicable manufacturer has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient. For example, if an applicable manufacturer provides a payment through a third party to the department chairs at a specific hospital, this payment would need to be reported because even though the applicable manufacturer did not name the recipients, their identities are publicly available. This standard is consistent with the knowledge standard set forth in many fraud and abuse laws, including the False Claims Act, and we believe it is one with which applicable manufacturers are already familiar. In addition, we propose that awareness of the identity of the covered recipient by an agent of the applicable manufacturer will be attributed to the applicable manufacturer.

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. There is significant overlap between the requirements under section 1128G(a)(1) and (a)(2) of the Act. We note the areas of overlap and, when necessary, refer to the sections of this proposed rule that apply.

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 required to include any 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.'' Many hospitals and other types of health care providers rely on GPOs to lower their acquisition costs for supplies, devices, and services. We note that Congress gave the Secretary authority to define a GPO for purposes of reporting under section 1128G of the Act, 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. We thus interpret 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. This would include, for example, physician owned distributors (PODs) of covered drugs, devices, biologicals, and medical supplies. We propose 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 propose 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 covered drugs, devices, biologicals, or medical supplies for resale or distribution to others. We solicit comments on this proposal.

As discussed in the section on covered drug, device, biological, and medical supply, we are proposing limiting the definition to only those drugs and biologicals that, by law, require a prescription to be dispensed and to only those devices (including medical supplies) that require premarket approval by or notification to FDA. We believe the device limitation may be appropriate for defining the universe of applicable manufacturers, but are considering that it may be overly limiting for the definition of applicable GPOs, since GPOs often purchase, arrange for, or negotiate the purchase of routine devices and medical supplies. We seek comment on whether to include the proposed limitation on devices and medical supplies in the definition of covered drug, device, biological, or medical supply.

b. Physicians

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,'' 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. Similarly, ownership and investment interests of immediate family members of physicians must also be reported under this provision. As required by section 1128G(a)(2) of the Act, we propose to define ''immediate family member'' as it relates to a person 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.

c. Ownership or Investment Interests

We propose 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 propose to define an ownership or investment interest as one that may be direct or indirect, and through debt, equity, or other means. 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 or revenue. As required by statute, 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, ownership or investment interest shall not include the following:

(i) 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;

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

(iii) An unsecured loan subordinated to a credit facility.

We also note that ''ownership and investment interests'' is listed in section 1128G(a)(1)(A)(vi)(XII) of the Act as a nature of payment for transparency reports on payments and other transfers of value. We would like to clarify that any payments or other transfers of value of an ownership or investment interest made to a covered recipient (as defined) must be reported under section 1128G(a)(1) of the Act. Additionally, all ownership and investment interests held by a physician must also be reported under section 1128G(a)(2) of the Act, which also requires reporting of payments or other transfers of value to physician owners or investors. In order to prevent the duplicative reporting, we propose that if an ownership or investment interest is required to be reported under section 1128G(a)(1) of the Act and under section 1128G(a)(2) of the Act, then the applicable manufacturer need only to report under section 1128G(a)(1) and should not re-report the provision of the ownership or investment interest under the reporting requirements in section 1128G(a)(2)(C) of the Act.

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)). We propose that the applicable manufacturer or applicable GPOs should report the name, address, NPI, and specialty of the physician owner or investor, as required in section 1128G(a)(2) of the Act. In cases when the ownership or investment interest is held by an immediate family member of a physician, we propose that applicable manufactures 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 are considering whether to require the reporting of the immediate family member's relationship to the physician, as well as the immediate family member's name, in order to bring additional transparency to the nature of the relationship. We believe this would provide additional details on the nature of the relationship; however, we wonder whether this information is worth the additional collection of information, particularly since we believe, due to privacy concerns, that the name of the immediate family member should not be made public. We seek comment on whether to report the relationship and/or the name of the immediate family member holding the ownership and 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 propose that applicable manufacturers and applicable GPOs follow the procedures outlined in this preamble for reporting payments and other transfers of value. Given this overlap, we are concerned about duplicative reporting, since applicable manufacturers must submit both reports and there may be overlap between physicians holding an ownership or investment interest and physicians being considered covered recipients for the purposes of reporting payments or transfers of value. We propose that applicable manufacturers submit one file 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 propose that applicable manufacturers report the payments or other transfers of value to physician owners or investors (regardless of whether the physician owner is a covered recipient) in the section for all 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. This would prevent double counting of payments or other transfers of value to physicians that meet the definition of a covered recipient and are a physician owner or investor of the applicable manufacturer.

Since applicable GPOs are not subject to the reporting requirements in section 1128G(a)(1) of the Act, we propose that applicable GPOs are only required to submit a report on physician ownership or investment interests. However, in the event that an applicable GPO has payments or other transfers of value to report for their physician owners or investors, we propose that applicable GPOs use the data elements outlined in the preamble section on payments and other transfers of value report contents for payments or other transfers of value, but that they would only be required to report payments to physician owners or investors.

B. Report Submission and Correction

The statute requires the Secretary to establish procedures for applicable manufacturers and applicable GPOs to submit the required information. We recognize that these regulations would require applicable manufacturers and applicable GPOs to collect and submit large amounts of new data, so we strive to be as flexible as possible about the data collection and submission methods. However, we believe that we also need standardization to ensure that we can aggregate the data correctly and efficiently to make it publicly available. Given these considerations, we plan to work with applicable manufacturers and applicable GPOs to create the best system for all parties involved. Based on our stakeholder outreach and analysis of the data systems available, we are proposing a potential system for the submission of data to CMS. We seek comments on the proposed approach and whether an alternative system would be preferable.

1. Prior to Submission

We are considering ways to ease the post-submission review process of this information and facilitate early resolution of conflicts between applicable manufacturers, applicable GPOs, covered recipients and physician owners or investors. We seek comments on a way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS, thus lessening potential changes during the statutory review and correction period, and thereby strengthening the accuracy of the data. One way to achieve this is for applicable manufacturers, prior to submitting data to CMS, to provide each covered recipient with information regarding the payments or other transfers of value that the applicable manufacturer plans to report to CMS as having made to the covered recipient. Similarly, applicable manufacturers and applicable GPOs could provide to each physician owner or investor the information they plan to report regarding the ownership and investment interests held by the physician owner or investor. While CMS is not proposing to require this type of pre-review, we recommend that applicable manufacturers and applicable GPOs provide for a ''pre-submission review,'' and we seek comment on whether a pre-review of this nature would be useful.

2. Report Submission

Applicable manufacturers and applicable GPOs are statutorily required to submit their reports electronically to CMS on March 31, 2013 and on the 90th-day of each calendar year thereafter. We propose 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 propose 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. If an applicable manufacturer neither made any payments or other transfers of value required to be reported nor had any physician owners or investors in the previous calendar year, it need not submit a report to CMS. Similarly, only applicable GPOs with physician owners or investors are required to submit information.

For applicable manufacturers and applicable GPOs that do have information to disclose, we propose that applicable manufacturers and applicable GPOs register with us prior to submission to facilitate communication. This 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. We propose that applicable manufacturers or applicable GPOs must register prior to the submission of data for the current reporting cycle. We do not limit the time prior to the submission of data, so an applicable manufacturer or applicable GPO could choose to submit the data immediately after registration. We are proposing 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. The first opportunity for registration and the data submission would be January 1, 2013. We seek comment on the proposed timing of the registration and submission process.

Alternatively, we are considering requiring that all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they have information to report. If an applicable manufacturer or applicable GPO had no payments or transfers of value and/or ownership or investment interests to report, the chief executive officer, chief financial officer or chief compliance officer would be required to submit an attestation that, to the best of

his or her knowledge and belief, there were no reportable payments or transfers and value and/or ownership or investment interests during the previous calendar year. We believe this may help us better understand the extent of these relationships (including which types of entities have financial relationships with covered recipients and physician owners and investors and which do not). Additionally, we believe such a requirement would ensure that applicable manufacturers and applicable GPOs perform a more thorough evaluation to determine whether they have any reportable information. However, we are seeking input on whether requiring registration for all entities and an attestation from entities with no reportable information would be more burdensome than beneficial. We seek comment on both the benefits and burdens of this consideration and intend to finalize the agency's position on this in the final rule based on comments received. We propose that applicable manufacturers and applicable GPOs submit their data electronically in a comma-separated value (CSV) format. 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 the applicable manufacturer or applicable GPO may submit as many files as necessary to provide the entirety of its data. We seek comments on the appropriateness of the CSV format for data submission, and suggestions for alternative formats. Additionally, we propose 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 truth, correctness, and completeness of the data submitted to the best of the signer's knowledge and belief. Such attestations must be signed by the chief executive officer, chief financial officer or chief compliance officer.

3. Report Format

We have outlined the fields of information to be included when reporting payments or other transfers of value and physician ownership and investment interests . The asterisks indicate the additional information, which we propose to require under the discretion provided by the statute. The justification for the submission of these additional data requirements is provided throughout the preamble. In the Addendum to this proposed rule, we have provided a sample of the reporting template, and we will place a spreadsheet in the regulatory docket on Regulations.gov. We note that this is a mock up table (not in CSV format) to demonstrate how we expect this data to be reported. This is not an official reporting document, but only an example for the purposes of the proposed rule.

For each payment and other transfer of value, we are proposing that the following information is required:

- Applicable manufacturer or applicable GPO name.
- Covered recipient's or physician owner's (as applicable)—

++ Name (for physicians include first and last name, and middle initial);

++ Specialty (physician only);

++ Business street address (practice location);

++ NPI (physician only);

- 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 of the associated covered drug, device, biological, or medical supply, as applicable.
- 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)
- 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 or applicable GPO name.
- Ownership or investment physicians'—

++ Name (for physicians include first and last name, and middle initial)

++ Specialty;

++ Business street address (practice location);

++ NPI;

- 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.
- For applicable GPOs only: 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 of the associated covered drug, device, biological, or medical supply, as applicable.

We seek comment on our proposed requirements regarding the data elements that should be submitted and plan to finalize them in the final rule based on comments received.

4. 45-Day Review Period for Applicable Manufacturers, Applicable GPOs, and Covered Recipients

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. After the due date has passed, and we have received the data from the applicable manufactures and applicable GPOs, we will aggregate the data by individual covered recipient and physician owner or investor, across applicable manufacturers and applicable GPOs. Once the data aggregation is complete, we plan to notify all applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors about the procedures for the review. We recognize it may be difficult for CMS to contact covered recipients and physician owners or investors, since they do not actively participate in the data submission process with CMS prior to their review, so we propose to notify covered recipients and physician owners or investors in a few ways. We propose 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 propose to notify physicians and hospitals through CMS' list serves and posting the information publicly. We are considering a posting either on the CMS Web site or on the **Federal Register**, and

seek comment on which would be most useful to physicians and teaching hospitals. We propose that these notifications would be provided annually to announce the covered recipient and physician owner and investor review and correction period, and would include the specific instructions for performing this review. For example, we are considering that covered recipients and physician owners and investors would sign in to a secure Web site to see the information reported about them. We are also considering 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 seek comment on our proposed method of notification, as well as the alternative method provided. We solicit comments on other ways that CMS, applicable manufacturers, or applicable GPOs can provide timely, adequate, and cost-effective notice to covered recipients and physician owners or investors of their opportunity to review the collected data.

In addition, we believe 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. However, we are working on identifying a streamlined and automated process for reporting disputes and changes to ensure that the review and correct process is as smooth as possible. We plan to provide more information on the details of this process once it has been fully developed, but provide general guidelines for comment at this time. We propose that covered recipients, and physician owners or investors may request from CMS 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 try to resolve the dispute with the applicable manufacturer or applicable GPO. We propose 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 at the end of the 45-day review period.

If an applicable manufacturer or applicable GPO, and covered recipient, or physician owner or investor have contradicting information that cannot be resolved by the parties involved, then we propose that 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 recognize that publishing disagreements in this manner may make it difficult to aggregate the data and report it in a meaningful way to the public and are considering how to best aggregate reports that note contested information but do not double count payments or other transfers of value or ownership and investment interests. Given these concerns, we are considering that in these cases (when a dispute over the data cannot be resolved by the parties), the individual payment would be flagged as contested, but the contradictory data, as corrected by the covered recipient or physician owner or investor, would be used for aggregated totals for the physician, as necessary. We believe that this is preferable since the covered recipient and physician owner or investor stakeholders have expressed concern about the accuracy of information submitted by the applicable manufacturer or applicable GPO. However, we are also considering aggregating the original information, as submitted by the applicable manufacturer and applicable GPO. We seek comment on this proposal and suggestions for how best to handle instances where there are outstanding disagreements.

Finally, we propose 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 CMS has made or noted them all, we propose 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 believe that allowing continual changes would be operationally difficult for CMS to handle and would reduce the utility of the data set. We propose that applicable manufacturers, applicable GPOs, covered recipient, or physician owners or investors alert CMS as soon as possible regarding any errors or omissions, but these changes may not be made until the data is refreshed for the following reporting year. At that time, all parties would once again have an opportunity to review and amend the data. However, we propose that we would have the option to make changes to the data at any time (for example, to correct mathematical mistakes). We also propose that only the current and previous year would be available for review and correction. For example, during the 45-day review period in 2014, applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors would be able to review and amend the data submitted for 2012 and 2013. However, during the 2015 review, only 2013 and 2014 would be available for changes. We seek comments on the procedures outlined for data submission and the 45-day review period, particularly the best way to contact covered recipients and physician owners or investors to ensure they receive notification of the review period.

C. 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. The public Web site must be searchable, understandable, downloadable, and easily aggregated on various levels, as stated in the statute. In addition, 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 request comments on how to structure this Web site for ultimate usability.

As required in section 1128G(c)(1)(C)(ii) of the Act, we propose that 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 name.
- Covered recipient's—
  - ++ Name;
  - ++ Specialty (physician only); and
  - ++ 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 of the covered drug, device, biological, or medical supply, when applicable.
• Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly.

For physician ownership and investment interests, 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 or applicable GPO name.
• Physician owner's—
++ Name;
++ Specialty; and
++ 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, 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 of the covered drug, device, biological, or medical supply, as applicable.

In addition, as required by statute, we propose 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, as required under section 1128G(c)(1)(C) of the Act. Beyond the information required by statute, we propose that the Web site 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 welcome comment regarding the details and format for how this information should be displayed on the Web site.

D. Delayed Publication for Payments Made Pursuant to 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 product research or development agreements or clinical investigations. The granting of delayed publication aims to maintain confidentiality for proprietary information relating to development of new drugs, devices, biologicals, and medical supplies. The statute outlines several statutorily required instances when publication of a payment or transfer of value should be delayed in the context of a product research or development agreement or clinical investigation.

The statute 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. For example, if in April of 2013 an applicable manufacturer provides a research grant to a teaching hospital for an initial trial of a new product under a product research or development agreement, the applicable manufacturer would be required to report this payment to us under section 1128G(a)(1) of the Act by March 31, 2014. However, the payment would not be published on the public Web site in 2014 since the product had not yet been granted FDA approval, licensure or clearance. If the product is granted FDA approval, licensure or clearance in October of 2015, then we would publish the payment by the applicable manufacturer to the covered recipient as part of the public release of CY 2015 data in 2016. If the product had not been approved or cleared by the FDA by the beginning of 2018 (4-calendar years after the payment date in 2013), we would publish the 2013 payment during the data release in 2018.

We propose that applicable manufacturers should indicate on their reports whether or not a payment or other transfer of value should be granted a delay in publication on the public Web site. In the absence of notification by an applicable manufacturer that a payment or other transfer of value is subject to delayed publication, we would have no way of knowing that such a payment or other transfer of value should not be published. In addition, we propose 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 propose 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. Failure to indicate to CMS in a timely fashion that a payment or other transfer of value should no longer be granted a delay in publication, due to FDA approval, licensure or clearance, may be subject to penalties under section 1128G(b) of the Act. Finally, 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. For example, in 2019, all payments or transfers of value with a payment date in 2014 (which were initially submitted to CMS in 2015) would be published in the public database in 2019. With an annual publication, it is difficult to grant each payment an exactly 4-year delay and we recognize that payments made early in the year would be granted more than a full 4-year delay period under this proposal. We believe that this method is preferable because it allows all payments, even those made late in the year, a full 4 year delay. We seek comment on these proposals.

We propose that payments or other transfers of value granted delayed publication are limited to relationships for bona fide research or investigation activities, which, if made public, would damage the manufacturers' competitive and/or proprietary interests. In order to ensure that the payments or other transfers of value granted a delay are for bona fide research, we propose that the ''product research or development agreement'' referenced in the statute include a written statement or contract between the applicable manufacturer and covered recipient, as well as a written research protocol. Additionally, the Act defines ''clinical investigation'' in section 1128G(e)(3) of the Act as ''[a]ny experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.'' We propose that in the context

of this definition, a clinical investigation is limited to one which is memorialized in a written research protocol between the covered recipient and the applicable manufacturer.

We realize that many applicable manufacturers contract with CROs, to facilitate their clinical research. In these cases, as long as the applicable manufacturer has a written agreement with the CRO, we propose that the CRO may have the written research agreement with the covered recipient, rather than the applicable manufacturer.

The statute provides for delayed publication of payments for services furnished in connection with research on ''medical technology'' with regard to both research on potential new medical technologies and new applications of existing medical technologies. In contrast, the statute provides for delayed publication for services furnished in connection with the development of, or a clinical investigation for, a new drug, device, biological, or medical supply (as opposed to a new application of an existing drug, device, biological, or medical supply as well). However, given the close relationship and significant overlap among the phrases ''medical technology'' and ''drug, device, biological, and medical supply,'' we propose to consider ''medical technology'' broadly as any drug, device, biological, or medical supply. We propose this interpretation because we believe that the rationale underlying the statutory inclusion of the delayed publication provision—protecting an applicable manufacturer's legitimate proprietary and competitive interests in research and development—should apply to all applicable manufacturers under this statute. Moreover, it is difficult to fairly carve out certain applicable manufacturers or certain products for differing standards of delayed publication. Alternatively, we are considering defining ''medical technology'' more narrowly as a subset of drugs, devices, biologicals, and medical supplies. We seek comments on both approaches, including suggestions for a narrower definition of ''medical technology.''

The statute also distinguishes between the scope of delayed publication permitted for payments related to ''research'' versus payments related to ''development'' or ''clinical investigations.'' Delayed publication is allowed for payments or other transfers of value for research-related services for both new medical technologies and new applications of existing medical technologies, whereas, delayed publication for development and clinical investigations are limited solely to new drugs, devices, biologicals, and medical supplies. It is difficult to meaningfully separate research and development due to the overlap in the activities associated with them, and the fact that they are commonly used synonymously. Given this close association between the terms, we propose to treat them similarly in this provision. However, we are also considering the possibility of assigning different meanings to ''research'' and ''development,'' and we seek comments on this approach and suggestions for meaningful distinctions for the two terms. With regard to clinical investigations, we believe they have a distinct meaning as set forth in section 1128G(e)(3) of the Act, which is separate from both ''research'' and ''development'' for the purposes of the Act. Specifically, section 1128G(e)(3) provides that clinical investigations involve human subjects or materials derived from human subjects. We note that this definition may differ from those that applicable manufacturers may be familiar with in 21 CFR 312.3 and 812.3.

Given these interpretations, we propose 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 propose limiting delayed publication for payments in connection with clinical investigations for *new* drugs, devices, biologicals, or medical supplies, and not new applications of existing drugs, devices, biologicals, or medical supplies. We seek comment on these proposals and solicit comment on whether there are better ways to distinguish among these categories for the purposes of delayed publication, including treating payments and transfers of values made in connection with clinical investigations the same as those made in connection with research and development.

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.

E. 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 our regulations. If an applicable manufacturer or applicable GPO fails to submit the required information, then the applicable manufacturer or applicable GPO may 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 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 CMP with respect to each annual submission for a knowing failure to report is $1,000,000. The term ''knowingly'' is given the meaning from the False Claims Act, 31 U.S.C. 3729(b).

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 propose that the procedures in 42 CFR part 402 subpart A would apply with regard to imposition and appeal of CMPs.

As noted previously, applicable manufacturers and applicable GPOs may be subject to a CMP for a failure to report information timely in accordance with our regulations. This proposed rule interprets the statute to require the submission of information that is accurate and complete. Therefore, we propose that a CMP may be imposed for failure to report information in a timely, accurate, and complete manner. As set forth in section 1128G(c)(1)(C)(ix) of the Act, applicable manufacturers and applicable GPOs are allowed 45-days prior to publication to review their data. Outside this period, any additions or oversights would be considered late and subject to penalties. Together with the annual submission of data, an authorized representative from each applicable manufacturer and applicable GPO would be required to submit a signed attestation certifying the truth, correctness, and completeness of the data submitted to the best of the signer's knowledge and belief.

In determining the amount of the CMP, we propose that 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.

We seek comments on these proposals.

In addition, we also propose that the Secretary, CMS, OIG or their designees may audit, evaluate, or inspect applicable manufacturers and applicable GPOs for their compliance with timely, complete and accurate submission of information required in section 1128G of the Act and the implementing regulations. Access to this information is implicit in the statute in order to enforce the requirements outlined. To facilitate this review, 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 propose 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. We believe that 5 years from the date of publication is sufficient for all audit, inspection, or evaluation activities. The requirements set forth in this proposed 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. We seek comments on these proposals.

F. Annual Reports

We are required to submit annual reports to Congress and the States. The Report to Congress is due annually on April 1st beginning in 2013 and shall include aggregated information on each applicable manufacturer and applicable GPO for the preceding calendar year, as well as any enforcement action taken and any penalties paid. 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 propose that we report to Congress information submitted by applicable manufacturers and applicable GPOs during the preceding year. Similarly, we must report to States annually by September 30, 2013 and June 30 for each year thereafter. The 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 propose that the reports would include data collected during the previous calendar year which was submitted in the current year. These reports would not 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.

G. 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. Such agencies 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. However, this exception does not apply to State or local reporting requirements related to information on payments or other transfers of value included in section 1128G of the Act.

In addition, State and local governments may require reporting of information other than that required under this provision, including the types of information excluded by section 1128G(e)(10)(B) of the Act, with the exception of payments that fall below the $10 individual or $100 aggregate threshold in section 1128G(e)(10)(B)(i).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on the following requirements:

A. ICRs Regarding Reports of Payments or Other Transfers of Value and Physician Ownership and Investment Interests (§ 403.904, § 403.906 and § 403.908(a) Through (g))

Proposed § 403.904 would require 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). Applicable manufacturers and applicable GPOs would also be required 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. Covered recipients and physician owners or investors must be provided with the opportunity to review and, if necessary, correct the information before it is posted publicly. When reporting the burden of this provision, we considered the impact in the first year of the program when applicable manufacturers and applicable GPOs must build reporting systems, and covered recipients and physician owners or investors are becoming accustomed with the review and correction requirements, as well as year 2 and annually thereafter. We anticipate that the burden will be reduced by roughly 25 percent in year 2 and remain the same annually thereafter.

The burden associated with these requirements is the time and effort spent by applicable manufacturers and applicable GPOs collecting the data, compiling reports to send to CMS, as well as the processes for registering and submitting the data, and any corrections, if necessary, to CMS. We estimate that approximately 1,150 applicable 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, and the number of device manufacturers is based on reporting in Massachusetts, since Minnesota and Vermont do 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. For device manufacturers, we used data from the FDA to identify the total number of manufacturers to use as a ceiling for our estimate. We seek comment on whether there are any other sources of data available.

It is difficult to establish with precision the number of GPOs, as proposed, because the definition of GPO includes 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. 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 judgmental estimates, from 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 believe that larger companies that manufacture more products may have a greater number of financial relationships with a more diverse group of covered recipients. 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 proposed in this proposed 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), obtain NPI and other information from the NPPES 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 certain disputed information (if necessary). 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 the potentially substantial time savings that would accrue to them as registrants through the ability to query CMS, and receive informal guidance through a listserv or other methods of providing technical assistance and useful information on low cost methods of compliance. As a technical point, we note that we propose a 5-year records retention requirement. We believe the costs of this are negligible for electronic recordkeeping, but solicit comment on this approach. Additionally, the estimates also include the time of employees, such as sales representatives, who have direct relationships with covered recipients and physician owners or investors. These employees would have to record the details of each relationship with the covered recipient, or physician owner or investor for reporting purposes.

This overall estimate is based primarily on the judgmental estimates of persons we have consulted that are expert in the overall cost of existing reporting systems. We welcome more detailed and disaggregated information that would help us improve the overall estimate or better craft the final rule to deal with specific problems or time-saving options. We are particularly interested in the burden of collecting and recording information for each payment or transfer of value by the staff and identifying whether individuals with ownership or investment interests have physicians as immediate family members.

We estimate that on average, smaller applicable manufacturers will have to dedicate 50 percent of a full time equivalent (FTE) employee (mainly in the range of zero to one), whereas larger applicable manufacturers may have to dedicate 5 to 15 FTE employees to comply with the reporting requirements (we assume 10 on average). Large manufactures are often multinational enterprises that employ tens of thousands of people worldwide, whereas many small manufacturers only have a few products and employ significantly fewer people. Since there are many more small companies, we estimate that on average, 1.74 FTE employees would be needed for each applicable manufacturer in the first year (150 larger firms times 10 FTE and 1000 smaller firms times 0.5 FTE). We appreciate that this is considerable simplification of a far more complex distribution of firms, but we think that it captures the skewness of 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 dollar 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.

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 1.3 FTEs 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 welcome comments that can provide empirical data on the costs to implement the requirements in firms of varying sizes and product portfolios, on the extent to which systems already in place meet the proposed requirements in firms of various kinds and sizes, and on the extent to which firms would modify their practices to avoid reporting costs.

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. Once again, this includes time of many individuals, particularly the ones who are in direct contact with the physician and are required to record the details of the interaction. 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 employee to reporting under this section for year 1, followed by 7.5 percent for year 2 and annually thereafter. We welcome any comments or data that would improve this estimate.

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 a compliance officer. According to the Bureau of Labor Statistics Occupational Employment Statistics, in 2010, the annual compensation for a compliance officer in the pharmaceutical and medicine manufacturing field was $73,380. We applied a 33 percent increase to this amount to account for fringe benefits and overhead, making the total annual cost of a compliance officer $97,595. The total number of hours for applicable manufacturers during year 1 would be 4,186,000 (1,150 applicable manufacturers × 70 hours (1.74 FTEs) × 52 weeks). For year 2 and subsequent years, we estimate a total of 3,110,000 hours (1,150 applicable manufacturers × 52 hours (1.3 FTEs) × 52 weeks). On average, this equals 3,460,000 hours annually for all applicable manufacturers for the first 3 years. The total number of hours for applicable GPOs for year 1 would be 87,400 (420 applicable GPOs × 4 hours (0.10 FTE) × 52 weeks) and for year 2 would be 65,500 hours (420 applicable GPOs × 3 hours (0.075 FTE) × 52 weeks). For the first 3 years, in total applicable GPOs will spend on average 72,800 hours annually.

The following tables provide our total cost estimates for applicable manufacturers and applicable GPOs to collect and submit the information required in section 1128G of the Act for year 1 and year 2. In total, we estimate that for applicable manufacturers and applicable GPOs required to report, it will cost $199,387,000 for year 1 and will cost $148,979,000 for year 2 and annually thereafter. For the first 3 years, this averages to a cost of $165,781,000 annually. All estimates are in 2010 dollars.

TABLE 1—YEAR 1 ESTIMATED BURDEN FOR APPLICABLE MANUFACTURERS AND APPLICABLE GPOS

	Estimated reporting organizations	Average FTE per reporting organization	Average annual rate (with 33% fringe/overhead)	Average total cost per organization	Total burden
Applicable Manufacturers	1,150	1.74 FTE (70 hrs × 52 wks)	$97,595	$169,815	$195,288,000
Applicable GPOs	420	0.10 FTE (4 hrs × 52 wks)	97,595	9,759.54	4,098,990

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

	Estimated reporting organizations	Average FTE per reporting organization	Average annual rate (with 33% fringe/overhead)	Average total cost per organization	Total cost
Applicable Manufacturers	1,150	1.3 FTE (52 hrs × 52 wks)	$97,595	$126,874	$145,905,000
Applicable GPOs	420	0.075 FTE (3 hrs × 52 wks)	97,595	7,320	3,074,000

B. ICRs Regarding Review and Correction by Physicians and Teaching Hospitals (§ 403.908(h))

An additional burden associated with section 1128G of the Act is the time and effort spent by covered recipients, and physician owners or investors reviewing, and if necessary, correcting the data before it is reported publicly. Neither the statute, nor this proposed rule, contains a recordkeeping requirement for physicians or teaching hospitals. Therefore, while we evaluated the burden associated with the review and correction process, we do not include an estimate of the burden for keeping records. We seek comments on this assumption, and on the extent to which physicians and teaching hospitals will keep records in the absence of a requirement to do so. While this would not be considered an information collection under the Paperwork Reduction Act, this will be helpful information to consider at the final rule stage related to the overall costs of this regulatory action.

The statute uses the definition of physician in section 1861(r) of the Act, which includes doctors of medicine and osteopathy, dentists, 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 892,000 physicians. However, we believe that not all physicians will have relationships with applicable manufacturers or applicable GPOs. Based on feedback we received from stakeholders, we estimate that 25 percent of physicians have no relationships with applicable

manufacturers or applicable GPOs, which reduces our universe of affected physicians to approximately 669,000. 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 669,000 physicians will review the report, which reduces our universe of affected physicians to 334,500 for year 1. For year 2, we anticipate that there would be a further reduction in the number of physicians reviewing the data because they would be familiar with the information, so we reduced the number of physicians reviewing by another 25 percent, to 250,875 physicians. 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.

Each physician and teaching hospital would be only allowed to review the information attributed to them by all applicable manufacturers and applicable GPOs. We estimate that on average, physicians would need one hour 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. We believe that teaching hospitals would 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 from a teaching hospital 10 hours to review the submitted data, ranging from 3 hours for small teaching hospitals that receive few payments or other transfer of value, to 60 hours for teaching hospitals that have lengthy disputes. We welcome comment and data on these estimates, and particularly welcome data from physicians and institutions in States that have required similar reporting in the past.

The Bureau of Labor Statistics Occupational Employment Statistics publishes data on hourly compensation for Healthcare Practitioners and Technical Occupations in physicians' offices. Although this category is broader than the provider types listed in the definition of physician in section 1861(r) of the Act, we believe that many physicians would delegate their review responsibilities to their nurses and office assistants. Given this expectation, we believe that the Healthcare Practitioners and Technical Occupations cost estimate is appropriate for this calculation. The average hourly rate for Healthcare Practitioners and Technical Occupations is $54.53 in physician offices (see *http://www.bls.gov/oes/current/oes290000.htm*), which rises to $72.52 with 33 percent fringe benefits and overhead costs. This average includes physicians, who account for about half of the employment in this category. The total number of hours for physicians (including physician offices) would be 334,500 for year 1 and 188,156 hours (250,875 × 0.75 hours) for year 2, which averages to 236,938 hours annually for the first 3 years. The total estimated cost for the review and correction period for physicians in year 1 is $24,258,000. For year 2 and annually thereafter, the estimated cost for physician review and correction is $13,645,000. For the first 3 years, the average cost for all physicians review and correction will be $17,190,000 annually.

For teaching hospitals, we expect a manager to review the payments and other transfers of value. 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 Management Occupations is $48.88, or $65.01 when fringe and overhead costs are applied. For year 1, the total number of hours would be 11,000 (1,100 × 10 hours) at $65.01 per hour. For year 2 this would decrease to 8,250 hours (1,100 × 7.5 hours) at $65.01 per hour. For the first 3 years, the total number of hours for teaching hospitals will be 9,167 annually. The total estimated cost for the review and correction period for teaching hospitals is $715,000 for year 1 and $536,332 for year 2 and annually thereafter. On average, the cost for all teaching hospitals will be $595,925 annually for the first 3 years.

TABLE 3—YEAR 1 ESTIMATED BURDEN FOR PHYSICIANS AND TEACHING HOSPITALS

	Estimated entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total burden
Physicians	334,500	1.0	$72.52	$75.52	$24,258,000
Teaching Hospitals	1,100	10.0	65.01	650.10	715,000

TABLE 4—YEAR 2 AND SUBSEQUENT YEAR ESTIMATED COSTS FOR PHYSICIANS AND TEACHING HOSPITALS

	Estimated entities reviewing	Estimated hours for review	Hourly rate	Average total cost per entity	Total cost
Physicians	250,875	0.75	$72.52	$56.64	$13,645,000
Teaching Hospitals	1,100	7.5	65.01	487.57	536,000

Based on the assumptions presented here, we anticipate that the total estimated burden of section 1128G of the Act for year 1 is 4,619,000 hours, at a cost of $224,360,000. For year 2 and annually thereafter, the total estimated burden is 3,372,000 hours, at a cost of $163,087,390. Annualized over 3 years, the total number of hours per year is 3,788,000 with a cost of $183,560,000.

TABLE 5—ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 403.904 and § 404.908(a)–(g)—Applicable Manufacturer Data Collection and Reporting.	0938–New ..	1,150	1,150	3,009	3,460,427	$46.92	$162,365,548	$0	$162,365,548
§ 403.906 and § 404.908(a)–(g)—Applicable GPO Data Collection and Reporting.	.....	420	420	173	72,800	46.92	3,415,825	0	3,415,825
§ 403.908—Physician Review and Correction Period.	.....	278,750	278.750	0.85	236,938	72.52	17,182,708	0	17,182,708
§ 403.906—Teaching Hospital Review and Correction Period.	.....	1,100	1,100	8.33	9,167	65.01	595,925	0	595,925
Total	.....	281,410	281,410	13.43	3,779,331	48.57	183,560,006	0	183,560,006

We emphasize that these estimates are, by necessity, uncertain, and that we particularly solicit comments providing us a better basis for final estimates.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–5060–P.

Fax: (202) 395–5806; or

Email: OIRA_submission@omb.eop.gov.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed 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 group purchasing organizations (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 Medical Payments Advisory Commission (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.'' [4]

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 solicit comments on all assumptions and estimates in this regulatory impact analysis. As is standard practice in meeting these various requirements for regulatory analysis, this section of the preamble addresses all of them together. Other parts of the preamble, together with this analysis, meet all statutory and Executive Order requirements.

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

[4] All quotes from pages 315–316 of ''Public reporting of physicians' financial relationships'' at *http://www.medpac.gov/chapters/Mar09_Ch05.pdf.*

organizations or governmental jurisdictions with a population of less than 50,000. 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. We seek comment on our assumptions and estimations regarding the RFA. According to the Small Business Administration size standards [5] 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 proposed rule, we propose 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 $50,000 in the first year (average annual wage rate of $97,595 times 0.5 FTE) 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 $50,000 would be about one-fourth of 1 percent of revenues. Firms this small would potentially face costs considerably less than $50,000, 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 the great majority of individual physicians and/or their office staff one hour or less to perform annually and 10 hours or less annually for teaching hospitals, on average. 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.'' Moreover, the amount of time spent on such reviews is entirely discretionary. 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, 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 603 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. We do not believe that any of the affected teaching hospitals are small rural hospitals. Therefore, we have determined that this proposed 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 2011, that threshold is approximately $136 million. The estimates presented in this section of this proposed 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 proposed rule. Reporting under section 1128G of the Act is required by law, so we are limited in another policy avenue for achieving the expected benefits. Section V.D. of this proposed 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 proposed 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 section II.G. of this proposed 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 proposed rule. As a reminder, we estimate a total cost of about $224 million for the first year of reporting, followed by about $163 million in the second year and annually thereafter. Because of a paucity of existing data on which to base these estimates they are very uncertain. We solicit comments on the assumptions, data, estimates, and anticipated effects described throughout this analysis and section III. of this proposed rule.

1. Effects on Applicable Manufacturers and Applicable GPOs

Only applicable manufacturers that made reportable payments or other transfers of value, or have physicians (or immediate family members of physicians) holding ownership and investment interests, would 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 manufacturers (150 drug and biologic manufacturers and 1,000 device and medical supply manufacturers) and 420 applicable GPOs would submit reports. Across applicable manufacturers we estimate that, on average, fewer than two FTE employees would be needed for each applicable manufacturer submitting a report, and that for smaller manufacturers the effort would be on average about half of an FTE employee. For applicable GPOs, we estimate that

[5] *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

on average an applicable GPO would dedicate 10 percent of an FTE employee to reporting under section 1128G of the Act. The rationale for these estimations is included in section III.A. of this proposed rule and Tables 1A and 1B provide our total cost estimates for applicable manufacturers and applicable GPOs to collect and submit the information required in section 1128G of the Act.

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 so 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 to comply with the requirements in section 1128G of the Act, so the burden of these requirements may be lower for these companies. 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 the lessened burden for entities already reporting. We seek comment on this interpretation and whether there is a more precise way to quantify these estimates. Further, we estimate that applicable manufacturers and applicable GPOs may face significant first year costs in scaling and staffing up to meet the reporting requirements. However, once systems are in place and reporting becomes routine, such costs would decrease in subsequent years. Therefore we estimate that the cost for year 2 would be approximately 25 percent less for applicable manufacturers and applicable GPOs.

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. We estimated the number of physicians as defined in the statute, which includes a number of provider types, including doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors. We also reduced these numbers to adjust for physicians with no financial relationships and those who would not review and correct the data submitted on their behalf. See the Table 6 for a breakdown of this calculation. Roughly 1,100 teaching hospitals meet the proposed definition of teaching hospital and would need to review the data submitted during the 45-day review period.

TABLE 6—NUMBER OF PHYSICIANS BY TYPE

Physician type	Number
Doctor of Medicine/Doctor of Osteopathy	660,000
Doctor of Dental Medicine	150,000
Doctor of Podiatric Medicine	12,000
Doctor of Optometry	35,000
Licensed Chiropractors	*35,000
Total	892,000
Adjustment for physicians with no reports (reduction by 25%)	669,000
Adjustment for physicians who do not review reports (year 1—reduction by 50%)	334,500
Adjustment for physicians who do not review reports (year 2—reduction by 25%)	250,875

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

We estimate that it would take on average one hour for physicians or their office staffs to review the information reported. For teaching hospitals, we estimate that, on average, it would take a representative from a teaching hospital 10 hours to review the submitted data, ranging from 3 hours for small teaching hospitals that receive few payments or other transfer of value, to 60 hours for teaching hospitals that have lengthy disputes. Further we estimate that as physicians and teaching hospitals become accustomed to receiving these reports that the amount of time they spend reviewing them and interacting with applicable manufacturers and applicable GPOs would decrease in year 2 and subsequent years of reporting. These assumptions are described in more detail in section III.B. of this proposed rule. Additionally, more detailed information regarding these costs is provided in Tables 3 and 4 of this proposed rule.

3. Effects on the Medicare, Medicaid, and CHIP

Although the Department proposes to administer this program through the Centers for Medicare and Medicaid Services, the proposed rules would have no direct effects on the Medicare, Medicaid, and CHIP. Reporting is required for all 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.

4. Benefits

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.

Recent increases in both the amount and scope of industry involvement in medical research, education, and clinical practice has led to considerable scrutiny. Both the Institute of Medicine and other experts, such as the Medicare Payment Advisory Commission (MedPAC), have 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.[6]

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.

[6] 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.*

However, we observe that the costs of the proposed rule 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 a single set of reporting requirements with which to comply, lessening the potential for multiple, conflicting State requirements. We do not have a basis for estimating the amount of savings that manufacturers would realize through immediate elimination of duplicative reporting, but these could be substantial. Future savings from the preemption could be far greater, since manufacturers were facing potentially dozens of State-mandated reporting systems, all differing in reporting requirements and detail.

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 identified option for obtaining this transparency and achieving the intensions of this provision. In developing this proposed 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.

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 do not propose to require the submission of an assumptions document for nature of payment categories, but allow applicable manufacturers and applicable GPOs to submit this voluntarily; and
- 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 have solicited comment on whether this would be useful or additionally burdensome.

These examples demonstrate our effort to minimize the regulatory burden of this proposed rule and we solicit comments on all the alternatives considered in this section or elsewhere in the preamble.

Throughout this preamble we have identified alternatives that are possible within the statutory framework. While we do not have precise cost estimates for these, our qualitative assessment of each is as follows.

- We are considering not including the two proposed limitations on the definition of covered drug, device, biological, and medical supply. We propose limiting covered drugs and biologicals to those that require a prescription to be dispensed and limiting covered devices (including medical supplies) to those that require premarket approval by or notification to the FDA. These limitations may reduce the number of entities meeting the definition of applicable manufacturer and applicable GPO. However, we do not expect that removing these limitations would significantly change the regulatory burden because we do not expect many companies that manufacture only these exempt products to have significant relationships with physicians and teaching hospitals. As a result, if the companies were included as applicable manufacturers, they would likely not be required to file a report, or would only have a few relationships to report, thus minimizing the burden. We request information on the potential cost and transparency implications of including these products.
- We propose to define ''common ownership'' as covering any ownership portion of two or more entities, but are also considering 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. We solicit information on the potential implications of this option or of variations for ease of implementation, scope of covered entities or transparency implications.
- We are also considering 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 it may be confusing to interpret if it is not captured in a consistent manner. Instead, we are proposing that applicable manufacturers may leave the NPI blank for physicians that do not have an NPI. We seek comments on this alternative.
- 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. We therefore 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 welcome comment on this interpretation and on whether there is some variation that would reasonably distinguish entities according to potential for improper influence.
- We are proposing, 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. As discussed earlier in the preamble, there are some complexities involved, especially regarding the latter two groups. We request comments on alternative time periods and, especially, on possible alternatives to this approach that might better serve the interest of all concerned in publication of accurate information. For example, should there be a two-step process, in which the information when first released is labeled provisional, and ''final'' data is labeled as such after a second opportunity for correction? As

previously discussed, what about mail or email options? Should applicable manufacturers and applicable GPOs be required to inquire of covered recipients and physician owners or investors of their opportunity to review the data? We welcome comments on any approach that minimizes costs or improves accuracy of the information. We also would welcome information on the likely frequency of cases in which additional communication methods would be necessary, useful, costly, inexpensive, or otherwise better or worse.

As these alternatives suggest, we welcome ideas on how to improve the quality and utility of the program, while minimizing unnecessary costs. We particularly welcome comments that can provide not only better methods, but also ways to quantify the potential savings from those methods.

E. Accounting Statement (Table 7)

The Office of Management and Budget, in Circular A–40, requires an accounting statement for rules with significant economic impacts. The table that follows shows the costs we have estimated by the first year, the second year, and annualized over 10 years. We assume that future outlay costs may be similar to those costs experienced in year two. 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. However, we welcome information on the burden in these future years and seek comment on our assumptions for the burden beyond year two.

TABLE 7—ACCOUNTING STATEMENT

Category	Costs
CY 2013 Monetized Costs	Estimated increase in expenditures of $224 million for year one for the implementation of section 1128G of the Act.
CY 2014 Annualized Monetized Costs	Estimated increase in expenditures of $163 million for year two and beyond for the implementation of section 1128G of the Act.
CY 2013–CY 2022 Annualized Monetized Costs.	Estimated increase in expenditures of $170 million at discount rate of 3% or $171 million at discount rate of 7%.
From Whom To Whom?	Increased costs for manufacturers and GPOs of covered drugs, devices, biologicals, and medical supplies, as well as physicians and teaching hospitals.
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 $224 million for the first year of reporting, and $163 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 solicit comments on the analysis and assumptions provided throughout this preamble and in the alternatives section of the regulatory impact analysis in particular.

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 proposes to amend 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) of the Act—Any applicable manufacturer or applicable group purchasing organization that fails to report information to CMS as required under Part 403 Subpart I.

* * * * *

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 to report timely, accurately, and completely a payment or other transfer of value, or each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, and completely an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to each 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 to report timely, accurately and completely a payment or other transfer of value, or each knowing failure of an applicable manufacturer or an applicable group purchasing organization to report timely an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to each 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. 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 to physicians and teaching hospitals, 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.

§ 403.902 Definitions.

Applicable group purchasing organization means an entity that—

(1) Operates in the United States, or in a territory, possession or commonwealth of the United States; and

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

Applicable manufacturer means an entity that is—

(1) Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or

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

Charity care means services provided by a covered recipient specifically for a patient who cannot pay, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

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.

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

Common ownership means entities that are owned, in whole or in part, by the same individual, individuals, entity, or entities, directly or indirectly. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

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, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). This definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

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, as part of a fee schedule payment, or as part of a composite payment rate (for example, the hospital inpatient prospective payment system or the hospital outpatient prospective payment system). With respect to a drug or biological, this definition is limited to those drug and biological products that, by law, require a prescription to be dispensed. With respect to a device or medical supply, this definition is limited to those devices (including medical supplies) that, by law, require premarket approval by or premarket notification to the Food and Drug Administration.

Covered recipient means—

(1) Any physician, except for a physician who is an employee (as defined in section 1877(h)(2) of the Act) of an applicable manufacturer; or

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

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.

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.

Ownership or investment interest. (1) Includes, but is not limited to—

(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; and

(3) Must not include an ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act, nor any of the following:

(i) 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.

(ii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iii) An unsecured loan subordinated to a credit facility.

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

§ 403.904 Reports of payments or other transfers of value.

(a) *General rule.* Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer) must be reported to CMS by the applicable manufacturer on an annual basis.

(b) *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. If the payment or other transfer of value was provided to another individual or entity at the request of (or designated on behalf of) any covered recipient, the payment or transfer of value must be disclosed in the name of that covered recipient.

(2) Business address of the covered recipient, including street address, suite or office number (if applicable), city, state, and ZIP code.

(3) In the case of a covered recipient who is a physician, the specialty and National Provider Identifier (if applicable) of the covered recipient.

(4) Amount of each payment or other transfer of value to the covered recipient.

(5) Date of each payment or transfer of value to the covered recipient.

(6) Form of each payment or other transfer of value, as described in paragraph (c) of this section.

(7) Nature of each payment or other transfer of value, as described in paragraph (d) of this section.

(8) If a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name under which the covered drug, device, biological, or medical supply is marketed. If the marketed name has not yet been selected, applicable manufacturer must indicate the scientific name. Applicable manufacturers may only report a single covered drug, device, biological or medical supply for each payment or other transfer of value.

(9) The applicable manufacturer must indicate that a payment or other transfer of value is subject to delayed publication, if the payment or other transfer of value is made under any of the following arrangements:

(i) In accordance with a product research or development agreement for services furnished in connection with research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological or medical supply.

(ii) In connection with a clinical investigation regarding a new drug, device, biological, or medical supply.

(10) If the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other individual or entity that receives the payment or other transfer of value.

(11) Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(c) *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, using the designation that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value. Each of the following terms has its dictionary definition:

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

(d) *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.

(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, in one of the categories listed in this paragraph (d)(2), 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. Each of the following terms has its dictionary definition:

(i) Consulting fee.

(ii) Compensation for services other than consulting.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging.

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interests.

(xiv) Direct compensation for serving as a faculty or as a speaker for a medical education program.

(xv) Grant.

(xvi) Other.

(e) *Special rules for research payments.* (1) Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research.

(i) Direct research, is a payment or other transfer of value provided to a covered entity directly by an applicable manufacturer or through a contract research organization (or similar entity).

(ii) Indirect research, is a payment or other transfer of value provided by an applicable manufacturer (including through a contract research organization or similar entity) to a clinic, hospital, or other institution conducting the research, and that clinic, hospital, or

other institution conducting the research in turn pays the physician covered recipient (or multiple physician covered recipients) serving as the principal investigator(s).

(2) All payments or other transfers of value designated as research (direct or indirect) must be subject to a written agreement and research protocol. Direct or indirect research payments (whether made directly by an applicable manufacturer or through a clinical research organization or similar entity) must be reported as follows:

(i) For indirect research, individually under the name(s) and NPI(s) (if applicable) of the physician covered recipient principal investigator(s). The total amount paid to the clinic, hospital or other institution conducting the research, must be reported for each principal investigator.

(ii) For direct research, individually under the name(s) and NPI(s) (if applicable) of the covered recipient. The total must indicate the amount the covered recipient received.

(3) If payment is made to a teaching hospital, the payment to the teaching hospital must be reported as follows:

(i) Direct research under the name of the teaching hospital.

(ii) Indirect research under the name(s) and NPI(s) (if applicable) of the physician covered recipient serving as principal investigator(s).

(4) For direct or indirect payments provided to physician covered recipients, CMS reports the total payment amount separately from other payments or transfers of value.

(f) *Exclusions from reporting.* The following types of payments or other transfers of value are excluded from the reporting requirements specified in this section:

(1) Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient.

(2)(i) For CY 2012, transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2013 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (f)(2)(i) of this paragraph must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(3) Product samples that are not intended to be sold and are intended for patient use.

(4) Educational materials that directly benefit patients or are intended for patient use.

(5) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(6) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

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

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

(11) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership or investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding year.

(b) *Identifying information.* Reports on physician ownership or investment interests must include the following identifying information:

(1) Name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician.

(2) Business address of physician, including street address, suite or office number (if applicable), city, State, and ZIP code.

(3) The physician owner's specialty and NPI (if applicable). If the ownership or investment interest is held by the immediate family member of a physician, the physician's specialty and National Provider Identifier must be reported.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) For any payment or other transfer of value provided to a physician holding 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 or investment interest), an applicable manufacturer or applicable group purchasing organization must report the information requested in § 403.904(b). The same exclusions from reporting in § 403.904(f) apply to payments or other transfers of value made by applicable manufacturers and applicable group purchasing organizations to physician owners or investors under this section.

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted as comma separated value (CSV) files to CMS by March 31, 2013, 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.* Any applicable manufacturer or applicable group purchasing organization that is required to report under this subpart must register with CMS before March 31,

2013. During registration, applicable manufacturers and applicable group purchasing organizations must name a point of contact with appropriate contact information.

(d) *Other rules.* (1) An applicable manufacturer under paragraph (1) of the definition of ''applicable manufacturer'' in § 403.902 and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of ''applicable manufacturer'' may, but are not required to, file a consolidated report of payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(2) If an applicable manufacturer and an entity (or entities) under common ownership choose to file a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers. It is up to the discretion of the applicable manufacturer and entity (or entities) under common ownership whether or not specific payments need to be identified to the entity that provided the payment.

(3) If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(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) *Errors or omissions.* If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon discovery of the error or omission.

(f) *Attestation.* Each report, including any subsequent corrections to a filed report, must include a certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.

(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 point of contact the applicable manufacturer or applicable group purchasing organization identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using a CMS' list serve and through a posting.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date of this notification, but in no case may the 45-day review period begin later than August 16, 2013, or May 16 of any subsequent year.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient, and a physician owner or investor may log into a secure Web site where each applicable manufacturer, applicable group purchasing organization, covered recipient, and physician owner is able to view the information reported specific to it.

(ii) 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.

(4) *Data disputes.* (i) Upon request by a covered recipient, physician owner or investor, CMS provides the point of contact information for the applicable manufacturer or applicable group purchasing organization in the event that the covered recipient or physician owner disputes the reported data.

(ii) The covered recipient or physician owner or investor must directly contact the applicable manufacturer or applicable group purchasing organization to attempt to resolve any dispute regarding a reported payment or other transfer of value or an ownership or investment interest.

(iii) At the discretion of the parties involved, one entity must notify CMS that a specific payment or other transfer of value, or ownership or investment interest is disputed and the outcome of the dispute at the end of the 45-day review period.

(iv) If the dispute is not resolved by the end of the 45-day review period, CMS publicly reports both the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, as well as the covered recipient's or physician owner's version of the payment or other transfer of value, or ownership or investment interest data.

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

(a) *General rule.* In the case of payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement, or in connection with a clinical investigation, payments may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement and research protocol between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments must be reported to CMS on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* It is the responsibility of the applicable manufacturer to notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, with which the payment is associated, is approved by the FDA.

(1) An applicable manufacturer must indicate on its 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 results 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 of the new drug, device, biological or medical supply, with which the payment is associated, is pending.

(3) 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.

(4) 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.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported.

(2) The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization under this subpart with respect to each 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 accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported.

(2) The total amount of civil monetary penalties imposed on an applicable manufacturer or group purchasing organization for knowing failure to report under this subpart with respect to each annual submission of information will not exceed $1,000,000.

(c) *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 and applicable GPO 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.

(d) *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 accurately and completely submit information in a timely manner in accordance with the rules established under this subpart.

(ii) The items described in paragraph (d)(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, and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules established under this subpart.

(3) The record retention and audit requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

§ 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: November 9, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 13, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

This Addendum will not appear in the Code of Federal Regulations.

ADDENDUM: SAMPLE REPORTING TEMPLATE
TABLE A: PAYMENT OR OTHER TRANSFER OF VALUE TEMPLATE

Notes:

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file

Recipient = Covered Recipient or Physician Owner or Investor
Form of payment must be 1) cash or cash equivalent, 2) in-kind items or services, 3) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Nature of payment must be 1) Consulting fee, 2) Compensation for services other than consulting, 3) Honoraria, 4) Gift, 5) Entertainment, 6) Food and beverage, 7) Travel and lodging, 8) Education, 9) Direct Research, 10) Indirect Research, 11) Charitable contribution, 12)Royalty or license, 13) Current or prospective ownership of investment interests, 14) Direct compensation for serving as a faculty or as a speaker for a medical education program, 15) Grant, or 16) Other.

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Amount of Payment (US dollars)	Date of Payment	Form of Payment	Nature of Payment	Name of Associated Drug, Device, Biological, or Medical Supply *if necessary	Entity Paid Name	Physician Owner or Investor (y/n)	Delayed Publication (y/n)

[FR Doc. 2011–32244 Filed 12–14–11; 4:15 pm]
BILLING CODE 4120–01–C

TABLE B: SAMPLE PHYSICIAN OWNERSHIP OR INVESTMENT INTEREST TEMPLATE

Notes:

This is a sample template for illustrative purposes, and is subject to changes.

Please submit this template as a Comma Separated Value (CSV) file.

Owner = Physician Owner or Investor.

All payments or other transfers of value provided to physician owners or investors must be reported on the Payment & Transfer of Value tab and designated as that to a physician owner or investor.

Reporting Entity	Recipient Name	Recipient Business street address	Recipient Specialty *physician only	Recipient National Provider Identifier (NPI) *physician only	Interest Held by Immediate Family Member (y/n)	Dollar Amount Invested	Value of Interest	Terms of Interest