ARNOLD & PORTER LLP

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Summary of Proposed Rule to Implement the Physician Payment "Sunshine" Provisions of the Affordable Care Act

I. Introduction

The Centers for Medicare and Medicaid Services (CMS) has released its Transparency Reports and Reporting of Physician Ownership or Investment Interests (Physician Payment "Sunshine" Provisions) proposed rule.[1] Section 6002 of the Affordable Care Act (ACA), which added section 1128G to the Social Security Act (SSA), required CMS to develop reporting procedures by October 1, 2011. Due to the delay in releasing the proposed rule, comments are due by February 17, 2012.

The proposed rule would implement two reporting requirements in SSA §1128G:

(1) Applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or CHIP must track and report annually to the Department of Health and Human Services (HHS) certain payments or "transfers of value" provided to "covered recipients" (physicians and teaching hospitals). (SSA §1128G(a)(1)).

(2) Applicable manufacturers and applicable group purchasing organizations (GPOs) must annually disclose to CMS certain physician ownership or investment interests. (SSA §1128G(a)(2)).

1 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (Dec. 19, 2011) (to be codified at 42 C.F.R. pts. 42 and 43).

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CMS will publish the reported data on a public website and submit annual reports to Congress and each state summarizing the data reported. CMS proposes that these two types of information be reported separately so that the relevant reporting obligations of applicable manufacturers and applicable GPOs are clearly distinguished. CMS seeks comments on this approach.

II. Timing and Relevant Deadlines

CMS hopes to finalize this rule as soon as possible during calendar year (CY) 2012. Due to the timing of the proposed rule's publication, a final rule will not be published in time for manufacturers and GPOs to begin collecting the information on January 1, 2012, as indicated in the statute. CMS will not require manufacturers and GPOs to begin collecting the required information until after the publication of the final rule.

CMS is currently considering a preparation period of 90 days from the date of publication, since the timeline in the statute suggests this was Congress's intent. CMS seeks comment on the amount of time applicable manufacturers and applicable GPOs will need following publication of the final rule and whether 90 days is a sufficient amount of time to begin complying with the data-collection requirements.

Depending on the publication date of the final rule, CMS is considering requiring the collection of data for *part* of 2012, to be reported by the statutory date of March 31, 2013 (the date given in the statute for the first reports). CMS seeks comments on the feasibility of this proposal.

III. Key Provisions that Shape the Obligation to Report "Payments and Other Transfers of Value" Under SSA §1128G(a)(1)

A. Applicable Manufacturers

(1) Manufacturers

SSA § 1128G(a) requires that "applicable manufacturers" disclose certain "payments or other transfers of value" to "covered recipients." Given the Act's definition of a "manufacturer of a covered drug, device, biological, or medical supply"[2] and its clarification that an "applicable manufacturer" is one "operating in the United States, or in a territory, possession, or commonwealth of the United States," CMS proposes that for the purposes of this regulation, "**applicable manufacturer**" be defined 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 and distribution in the United States, or in a territory, possession, or commonwealth of the United States.[3]

Product's Manufacturing Location Does Not Matter: CMS proposes to treat manufacturers the same, whether they are based in the US or internationally. A manufacturer can qualify as an "applicable manufacturer," so long as its products are sold or distributed in the US, "regardless of where the covered drug, device, biological, or medical supply is actually produced or where the entity is actually located or incorporated."[4] CMS explains that the global nature of these industries requires that the manufacturers

2 The SSA defines a "manufacturer of a covered drug, device, biological, or medical supply" as "[a]ny 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). SSA § 1128G(a)

3 76 Fed. Reg. at 78743-44 (emphasis added).

4 *Id.* at 78744.

be treated the same, since "the opportunity for undue influence or inappropriate relationships caused by payments or transfers of value to covered recipients is the same… *regardless of where the product is actually manufactured.*"[5] CMS does not say explicitly that foreign entities under "common control" with a company that sells products in the US must report (if they provide assistance or support with production of the other listed activities), but this seems to be the clear impact of its proposal.[6]

De Minimis Requirement:

CMS clarifies that as long as a manufacturer sells or distributes *at least one* covered drug, device, biological, or medical supply, it meets the definition of applicable manufacturer, *even though it may also manufacture products that do not fall within that category*.[7] CMS proposes that all payments or transfers of value made by an applicable manufacturer to a covered recipient must be reported, regardless of whether the particular payment or other transfer of value is associated with a *covered* drug, device, biological, or medical supply.

Common Ownership:

CMS proposes to define "common ownership" as "when the same individual, individuals, entity, or entities, directly or indirectly, own any portion of two or more entities."[8] CMS states that this definition "would apply to a range of corporate arrangements, including, but not limited to, parent companies, subsidiaries, and brother/sister corporations."[9] Companies that 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 rule's reporting requirements (even if they are not involved in the manufacturing process). *Any* level of common ownership therefore suffices under CMS' proposal.

Alternatively, CMS is considering limiting the common ownership definition to circumstances where the same individual, individuals, entity, or entities own five percent or more of total ownership in two or more entities.[10] CMS seeks comments on its proposed definition, including whether a more specific definition is needed and, if a minimum percentage threshold is adopted, whether five percent is appropriate.

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 CMS proposes that the entities report separately from one another. 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 CMS proposes that the affected entities can choose whether or not to report together.

Third Parties:

In addition to payments or other transfers of value to covered recipients made by applicable manufacturers themselves, applicable manufacturers are 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.[11]

SSA § 1128G(e)(10)(A) excludes the reporting of payments or other transfers of value that a manufacturer "ma[kes] indirectly to a covered recipient through a third party … *where the applicable manufacturer is unaware of the identity of the covered recipient.*"[12] CMS emphasizes that if the *manufacturer is aware of the covered recipient's identity, however, the payment or other transfer of value must be*

5 *Id.* (emphasis added).

6 CMS also clarifies that the "applicable manufacturer" includes entities that hold 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 party. *Id.* It views these entities as being "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply." CMS seeks comment on this interpretation of "applicable manufacturer." *Id.*

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 *Id.*

12 *Id.* at 78750 (emphasis added).

reported, "whether or not the third party is under common ownership with an applicable manufacturer or operating in the U.S."[13]

CMS proposes that "awareness" of the identity of a covered recipient would mean that the manufacturer "has actual knowledge of, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient."[14] The example CMS gives is making a payment designated for the department chairs at a specific hospital; because their identities are publicly available, a manufacturer would be considered to be aware of them.

CMS also proposes that awareness of the identity of the covered recipient by an "agent" of the manufacturer would be attributed to the manufacturer. CMS does not discuss what "agent" would mean in this context—e.g., whether a contract research organization making payments to physicians would be considered an "agent" of the manufacturer.

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

SSA § 1128G(e)(5) defines "covered drug, device, biological, or medical supply" as any drug, biological product, device, or medical supply for which payment is "available" under Medicare, Medicaid, or CHIP. CMS proposes to define "covered" products as those "for which payment is available under [Medicare, Medicaid, or CHIP], 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).[15] 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.[16]

13 *Id.* at 78751 (emphasis added).

14 *Id.* CMS notes that this standard is consistent with the knowledge standard in many fraud and abuse laws, including the False Claims Act. CMS therefore believes that it is a standard with which manufacturers are already familiar.

15 *Id.* at 78745.

16 *Id.* (emphasis added).

CMS proposes to limit drugs and biologicals in this definition to those that, by law, require a prescription to be dispensed, explaining that physicians and teaching hospitals have much less influence over patients' choices of over-the-counter (OTC) products. Similarly, CMS proposes to limit the definition to pertain only to devices and medical supplies that require premarket approval by or notification to the FDA.[17] CMS stated that this could exclude many devices and medical supplies that are so routinely provided in the course of medical care that Congress may not have intended to subject their manufacturers to reporting requirements. CMS seeks comments on this additional limitation.

CMS proposes to define "covered" products so they include those paid separately under Medicare, Medicaid, or CHIP, and those paid for as a part of a composite rate payment system. Payment may be indirect in these systems, but it is still being provided for the bundled drug, device, biological, or medical supply. CMS therefore proposes that payment is considered "available" under Medicare, Medicaid, or CHIP for items included in a composite bundled payment rate.[18]

B. Covered Recipients

SSA § 1128G(1)(1) requires applicable manufacturers 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. The statute defines "covered recipient" as (1) a physician, other than a physician who is an employee of an applicable manufacturer; or (2) a teaching hospital.

Physicians:

The statute adopts the meaning of "physician" in SSA §1861(r), which includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors.[19] CMS does not propose any additions to this definition. Under the statute, manufacturers must report the physician's name, business address, National Provider Identifier (NPI), and specialty.[20] CMS suggests that manufacturers use the

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.* at 78746.

National Plan & Provider Enumeration System (NPPES), which CMS currently maintains on its public website and that includes a database of physician NPIs, to find each individual physician's NPI.[21]

CMS cautions that NPPES may not contain NPI information for every physician and said if a physician is not listed in the NPPES NPI registry, the manufacturers must obtain the physician's individual NPI directly from the physician (if the physician has an NPI).

CMS is considering whether to require manufacturers to report another unique identifier, like a state license number, for physicians who do not have an NPI. CMS seeks comments on what other unique identifiers should be used.

Teaching Hospitals:

"Teaching hospital" is not defined by the statute. CMS proposes to identify "teaching hospitals" by linking the term to Medicare graduate medical education (GME), since (a) GME payments are provided to support the training of medical residents, and (b) hospitals that receive such payments are easily identifiable. CMS thus proposes 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."[22]

To identify teaching hospitals, CMS proposes to publish on its website once a year a list of hospitals that received Medicare direct or indirect GME payments, with the list containing the most recent data available.[23] The list would include the name and address of each teaching hospital.

C. "Payments or Other Transfers of Value"

The statute requires reporting of "payments or other transfers of value"[24]: (1) given to a covered recipient, or (2) given to a third party or "at the request of or designated on behalf of" a covered recipient. "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. CMS proposes that this category would *include* "payments or other transfers of value provided to a physician (or physicians) through a physician group or practice,"[25] which would be reported under the name(s) of the physician covered recipient(s). CMS may be saying that any payment to a physician group or practice is necessarily made "at the request of, or designated on behalf of," one or more of the physicians in the practice, but this is not clear from the proposal.

When a covered recipient requests a manufacturer to provide a payment or other transfer of value to another individual or entity (instead of being provided directly to the covered recipient), the payments should be reported under the name of the covered recipient.[26] CMS proposes that the manufacturer also report the name of the entity or individual that *received* the payment, saying this would "allow end users to discern whether a covered recipient actually received the payment, and if not, where the payment went."[27]

CMS does not think it is feasible to provide a review period for such parties before data is made public on the CMS website, but CMS believes that review by the covered recipient will suffice.

D. Payment and Other Transfer of Value Report Content

The statute lists the specific categories of information to be reported for each payment or transfer of value provided to a covered recipient.[28] CMS explained how it proposes that some of this information be reported.

21 *Id.*

22 *Id.* at 78745-46.

23 *Id.* at 78746.

24 This is defined broadly in SSA § 1128G(e)(10)(A) as "a transfer of anything of value."

25 76 Fed. Reg. at 78746.

26 *Id.*

27 *Id.*

28 SSA §1128G(a)(1)(A).

Identifying Information:

CMS proposes that manufacturers report the full name, specialty, and NPI for physician covered recipients and the full street address of the business address for all covered recipients. For physicians, the physician's primary practice location address would be reported. If a physician has multiple specialties, only a single specialty need be reported.[29]

Date of Payment:

Since some payments or transfers are provided over multiple dates, CMS proposes that manufacturers could either report the total payment on the date of the first payment as a single line item, or report each individual payment as a separate line item. However, CMS is also considering requiring manufacturers to report multiple payments in a single consistent manner. CMS seeks comments on these proposals.

Associated Covered Drug, Device, Biological, or Medical Supply:

If a payment is "related to marketing, education, or research of a particular covered drug, device, biological, or medical supply," manufacturers must report the name of that product.[30] Recognizing that not every financial relationship between a manufacturer and a covered recipient is explicitly linked to a particular product, CMS proposes that 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.[31] (E.g., if a manufacturer sales representative takes a physician out to dinner to discuss a new device product, then the name of the new product should be reported in connection with the dinner.)

Second, CMS proposes that the applicable manufacturers report only *one* covered product as related to a payment or other transfer of value, even though it recognizes that there may in fact be multiple products related to payment. As an alternative approach, CMS is considering allowing applicable manufacturers to report *multiple* covered products as related to a single payment or other transfer of value. CMS believes this may be easier for the manufacturers (since many financial relationships are not specific to one product), but would make aggregating payments by product very difficult. CMS seeks comments on this approach.

CMS proposes that manufacturers report products using the name under which they are marketed, as this is most recognizable to the consumer, or report the scientific name if a covered product "does not yet have a marketed name."[32] (It would seem unusual if a product that does not yet have a marketed name was already covered by Medicare, Medicaid, or CHIP, but CMS did not discuss this point. The text of the statute indicates that a product must be a "covered drug, device, biological, or medical supply" before it must be reported in connection with related payments or transfers.)

E. Form of Payment and Nature of Payment

The statute requires that the reported information on each payment or other transfer include the "form" of the payment and its "nature."[33] CMS proposes that the categories within both the form of payment and the nature of payment be defined as distinct from one another, feeling that overlap would decrease the utility of the information. But since reporting multiple categories to describe a single payment or transfer of value may be confusing for end users, CMS proposes that for each payment or other transfer reported, manufacturers only report a single nature of payment and a single form of payment. The hope is that this will lead to greater consistency in the database. CMS seeks comments and especially welcomes comments about the usefulness of the data as well as any operational issues that manufacturers might face in reporting it.

29 CMS proposes using specialties listed in the "provider taxonomy" field in NPPES.

30 SSA § 1128G(a)(1)(A)(vii).

31 76 Fed. Reg. at 78747.

32 *Id.*

33 The "form" is cash, stock, etc. and the "nature" is usually the purpose of the payment or transfer (e.g., "consulting fees") or a designation like "entertainment" or 'travel."

Forms of payments that must be reported are: 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; and "any other form of payment determined by the Secretary."[34] CMS believes that the forms listed are sufficient and declines to add any additional forms of payment (but asks for comments on whether other categories are necessary or would be helpful).

The "nature of payment or other transfer of value" categories are as follows:

- 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)

CMS believes that these terms should be defined by their "dictionary definitions," but does offer more detailed explanations for charitable contributions, food and beverage, research, and direct compensation for serving as a faculty member or as a speaker for a medical education program.[35] CMS also proposes[36] a catch-all category ("other") for all payments or other transfers of value that do not fit into one of the listed natures of payment.[37]

Charitable Contributions:

CMS would define a charitable contribution as any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986 that is not described more specifically by one of the other nature or payment categories.[38]

Food and Beverage:

CMS proposes that manufacturers report the value of any food or beverage items provided to covered recipients, subject to the statutorily required US$10 minimum threshold for reporting (discussed further in the "Exclusions from Reporting" section).[39] This can become burdensome and difficult in group settings and CMS tries to address this issue. CMS proposes that when group meals are provided in group settings, manufacturers report the cost per covered recipient receiving the meal, even *if* some covered recipients do not partake of the meal. A US$25 group lunch served at a solo practitioner's office would be above the US$10 threshold[40] while a US$25 group lunch served at a five-physician group practice would fall below the threshold (25 divided by 5), even if some of the physicians did not eat. CMS recognizes that scenarios are not always as clear-cut as the example above, and is considering whether to adopt a different approach for these group scenarios, such as "counting the number of physicians by department."[41] CMS seeks comments on these proposals and whether there is a more equitable, but not overly burdensome, way to report these payments or other transfers of value. CMS also proposes that manufacturers would not need to report food or beverages served at "booths at conferences or other similar events," where it would be difficult to establish definitively who accepted the manufacturer's offerings.

34 SSA § 1128G(a)(1)(A)(v).

35 76 Fed. Reg. at 78748-50.

36 Under the discretion provided in SSA § 1128G(a)(1)(A)(vi)(XV).

37 76 Fed. Reg. at 78750.

38 *Id.* at 78748.

39 *Id.*

40 CMS would not count staff members who are not covered recipients; the dollar amount of the meal would only be allocated across covered recipients. *Id.*

41 *Id.*

Research:

CMS seeks to limit the research-related provisions 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."[42] We discuss the proposed definition of research and related terms below in the section on delayed publication (at pages 14-15).

CMS proposes to sub-divide the classification of research payments to clarify whether the payment or other transfer of value went directly or indirectly to the covered recipient.[43] Manufacturers would have to report a payment or other transfer of value as either "direct research" or "indirect research."

CMS also proposes 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 (whether the payments are direct or indirect), "assuming the applicable manufacturer is aware of the identity of the principal investigator(s)."[44] If the payment is reported as indirect research, the manufacturer also should include the name of the entity or individual that received the payment or other transfer of value.

CMS does not want to establish different reporting requirements for physician covered recipients acting as principal investigators at teaching hospitals versus other research institutions. CMS therefore proposes 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), as a direct research payment and indirect research payment, respectively.

CMS believes that reporting the total research payment amount will provide additional transparency. CMS understands that reporting the amount of the payment or other transfer of value may be difficult because neither the applicable manufacturer nor the contract research organization (CRO) generally know how the research payment is distributed and CMS does not believe the total costs should be fully attributed personally to a principal investigator, for example, even though it recognizes that it would be burdensome for manufacturers to determine the exact amounts different physicians received. Given these considerations, CMS proposes that for both direct and indirect research, manufacturers must report the entire payment amount for each research payment, rather than the specific amount that was provided to the covered recipient. CMS would report the payment amount separately on the public website, however, and would not aggregate it into the total for physician covered recipients. CMS seeks comments on these proposals.

CMS recognizes that its proposed reporting requirements on research payments may not cover all relevant circumstances. CMS seeks comments on whether its proposed method concerning research payments is viable and not overly burdensome, and whether an alternative method would be preferable. CMS also seeks comments about which existing nature of payment category would apply to these other types of research, whether the scope of the "research" nature of payment should be broadened, and whether another nature of payment category should be added to address research.

Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program:

CMS proposes that this category be interpreted broadly to encompass all instances in which manufacturers pay physicians to serve as speakers, and not just those situations involving "medical education programs."[45] Alternatively, CMS is considering adding another nature of payment category to describe situations where a covered recipient provides

42 *Id.* at 78749.

43 *Id.* 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. 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 and that organization in turn pays the physician covered recipient(s) serving as principal investigator(s).

44 *Id.*

45 *Id.* at 78750. CMS believes that this interpretation is consistent with the authority granted in SSA § 1128G(a)(1)(A)(vi)(XV) to add additional nature of payment categories.

speaking services that are outside of medical education programs, though it recognizes that having fewer categories is preferable. CMS believes that having only one category for speaker fees is preferable, because it minimizes potential inconsistencies in how manufacturers categorize payments. CMS welcomes comments on this proposal and the appropriate distinction between this category and other categories, such as honoraria.

CMS will allow manufacturers to submit an optional document describing the assumptions used when categorizing the natures of payments.[46] These documents will allow manufacturers to "explain the reasoning behind their categories." These documents will not be posted on the public website since they may contain proprietary information. (CMS does not discuss the extent to which such documents could be obtained under FOIA.) CMS seeks comments on this proposal, including whether it should make submission of the assumptions document mandatory.

F. Exclusions from Reporting

SSA § 1128G(e)(10)(B) excludes certain types of payments and other transfers of value from the reporting requirements.[47] CMS proposes that manufacturers use the "dictionary definitions" for the exclusions, but offers guidance on how to apply some of them.

Transfers of Value Less Than US$10:

Manufacturers need not report any payments or other transfers of value less than US$10, unless the total annual value of payments or other transfers of value provided to a covered recipient exceeds US$100. Once the US$100 threshold is reached, then manufacturers should report the total amounts by "nature of payments" category.[48] Examples of small-payment scenarios are provided in the proposed rule (at page 36) to ensure that the exclusion is applied consistently. Since the statute requires that 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, CMS proposes publishing the updated threshold amounts annually on its website.

Educational Materials that Directly Benefit Patients or are Intended for Patient Use:

CMS emphasizes that "educational materials" are limited to *materials*, including those that are written and electronic.[49] CMS does not consider educational materials to include services or other items. CMS is considering whether certain materials provided by manufacturers to educate *the covered recipients themselves* and that are never given to patients (e.g., medical textbooks) should be interpreted as educational materials that "directly benefit patients." CMS seeks comments on whether such materials should fall within this exclusion and, if so, which types of educational materials that are given to the covered recipients only would "directly benefit patients."

Discounts and Rebates:

SSA §1128G(e)(10)(B)(vii) excludes discounts and rebates for covered drugs, devices, biologicals, and medical supplies provided by applicable manufacturers to covered recipients.

46 *Id.* at 78748.

47 The exclusions are as follows: (1) Transfers of value less than US$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds US$100 in a calendar year; (2) product samples that are not intended to be sold and are intended for patient use; (3) educational materials that directly benefit patients or are intended for patient use; (4) 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; (5) 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; (6) 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; (7) discounts, including rebates; (8) in-kind items used for the provision of charity care; (9) a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund; (10) 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; (11) 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 nonmedical professional services of the licensed non-medical professional; (12) 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; (13) 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. *Id.* at 78750.

48 *Id.*

49 *Id.* at 78751.

CMS does not expand on this exclusion but reminds 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."[50]

In-Kind Items for the Provision of Charity Care:
Items provided as charity care to covered recipients are excluded from reporting. CMS proposes 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."[51] CMS states that the exception does not include providing in-kind items to a covered recipient for the care of *all* of the covered recipient's patients (both those who can and cannot pay). This holds true even if the covered recipient is a charitable organization. It thus appears that charity care items must only benefit patients who cannot pay for a particular item; others, including patients who *can* pay, cannot receive benefit. CMS does not discuss whether manufacturers must document the fact that an item was given to a covered recipient for the exclusive benefit of patients who cannot pay for the item.

IV. Key Provisions Shape the Obligation to Report "Physician Ownership and Investment Interests" under SSA §1128G(a)(2)

A. Reporting Entities

SSA § 1128G(a)(2) applies to "applicable manufacturers" and "applicable GPOs." It requires them to report annually to HHS certain information on: (1) ownership and investment interests held by physicians (or immediate family members) in the manufacturer or GPO; and (2) payments or other transfers of value to their physician owners or investors. As CMS notes, in the case of "applicable manufacturers" it overlaps significantly with §1128G(a)(1). "Applicable manufacturers" has the same definition that it has for purposes of reporting payments and other transfers of value under SSA § 1128G(a)(1).

Applicable GPOs are defined by SSA §1128G(e)(1)[52] but Congress also gave the Secretary authority to define a GPO for purposes of section 1128G. CMS proposes to interpret the statute to encompass not only 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. CMS proposes to define "applicable GPO" 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.[53]

CMS does not consider this definition to include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals; its intention is to capture entities that purchase covered products for resale or distribution to others. Physician-owned distributors are included in this definition. CMS seeks comments on this proposal.

As discussed in the section on covered drugs, devices, biologicals, and medical supplies, CMS proposes limiting the definition to those drugs and biologicals that, by law, require a prescription, and to those devices that require premarket approval by or notification to FDA. CMS is concerned, however, that the device limitation may limit the definition of applicable GPOs too much, since GPOs often purchase, arrange for, or negotiate the purchase of routine devices and medical supplies. CMS therefore seeks comments on whether to include the proposed limitation on devices and

50 *Id.*

51 *Id.*

52 SSA § 1128G(e)(1) defines an applicable GPO 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."

53 76 Fed. Reg. at 78752.

medical supplies in the definition of covered drug, device, biological, or medical supply.

B. Physicians

Unlike SSA §1128G(a)(1), §1128G(a)(2) does not use the term "covered recipient." Instead, it uses the term "physician," as defined in SSA §1861(r). Based on this definition, applicable manufacturers and applicable GPOs must report *any* physician's ownership and investment interests (except excluded interests noted below), even if the physician is an employee of the manufacturer or GPO.[54]

Ownership and investment interests of immediate family members of physicians must also be reported. As required by SSA § 1128G(a)(2), CMS proposes to define "immediate family member" as a person's 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; or spouse of a grandparent or grandchild.[55]

C. Ownership or Investment Interests

CMS proposes to define an ownership or investment interest as "one that may be direct or indirect, and through debt, equity, or other means."[56] It may include stock, partnership shares, or bonds, among other things, but excludes an ownership or investment interest in a publicly traded security or mutual fund.[57] The proposal also excludes:

> (1) An interest … that arises from a retirement plan offered by [an]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;
>
> (2) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity; or
>
> (3) An unsecured loan subordinated to a credit facility.[58]

CMS states that: (1) "any payments or other transfers of value of an ownership or investment interest made to a covered recipient … must be reported under section 1128G(a)(1);" and (2) "all ownership and investment interests held by a physician must also be reported under section 1128G(a)(2)" (which "also requires reporting of payments or other transfers of value to physician owners or investors").[59] To prevent duplicative reporting, CMS proposes that if an ownership or investment interest is required to be reported under *both* sections, then the manufacturer need only report under § 1128G(a)(1).[60]

D. Content of the Physician Ownership or Investment Report

Physician Information and Immediate Family Member Information:

Manufacturers and GPOs must report information about each ownership or investment interest held by physicians (or their immediate family members). For physicians, CMS proposes that the name, address, NPI, and specialty of the physician owner or investor be reported. For ownership or investment interests held by an immediate family member, CMS proposes that the manufacturer or GPO report the required information for the physician *and* the fact that the ownership or investment interest is held by an immediate family member of the physician. However, CMS is also considering requiring the reporting of the immediate family member's name and relationship to the physician, in order to promote greater transparency. CMS is concerned, however, about immediate family members' privacy and about whether this additional collection of information is worth the burden. The proposed rule does not address how manufacturers or GPOs would know that an individual is an immediate family member of a physician. Presumably there

54 *Id.*

55 *Id.* SSA § 1128G(a)(2) defines "immediate family member" by reference to SSA § 1877(a) (part of the Stark law); CMS' proposed definition of immediate family member is based on regulations of 42 CFR § 411.351 that implement the Stark law.

56 76 Fed. Reg. at 78752.

57 As publicly traded securities and mutual funds are described in SSA § 1877(c).

58 76 Fed. Reg. at 78752.

59 *Id.* (emphasis added).

60 *Id.*

is no obligation to seek out such information, but the point is not discussed.

Avoiding Duplicative Reporting:

Manufacturers and GPOs must report all the information required in SSA §1128G(a)(1)(A) for those physicians who hold ownership or investment interests. CMS proposes that manufacturers and GPOs follow the same procedures for reporting payments and other transfers of value that apply under SSA § 1128G(a)(1). Then CMS states that: "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) … we propose that applicable manufacturers report 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 there that the individual is also a physician owner or investor. This would prevent double counting of payments and other transfers of value to physicians [who are "covered recipients and owners/investors]."[61]

V. Submission and Correction of Reports Required By SSA § 1128G(a)(1) and (2)

A. Report Submission Requirements

The statute requires that reports be electronically submitted to HHS on March 31, 2013 and on the 90th day of each subsequent calendar year.

Registration:

For manufacturers and GPOs that have no information to disclose, no report needs to be submitted. For those that do have information to disclose, CMS proposes that the manufacturer or GPO register with CMS prior to submission, to facilitate communication. Entities would need to designate a point of contact and register before submitting data for the current reporting cycle. The registration process would open at the beginning of the calendar year (which would make January 1, 2013 the first opportunity for registration and data submission).

In the alternative, CMS is considering requiring all applicable manufacturers and applicable GPOs to register with CMS, *regardless of whether they have information to report*. If they had nothing to report, CMS would require submission of an attestation to that affect.[62] CMS believes that this could give it a better understanding of financial relationships and encourage manufacturers and GPOs to perform a more thorough evaluation of whether they have any reportable information.[63] CMS seeks comments on whether this would be more burdensome than beneficial.

Format and Content:

CMS proposes that manufacturers and GPOs submit their data electronically in a "comma-separated value (CSV)" format, and seeks comments on the appropriateness of this format. CMS proposes a list of required information to be included in the report, reprinted in the appendix to this memo.

Attestation of Truth, Correctness, and Completeness:

CMS proposes that following the submission of data each year, the CEO, CFO, or Chief Compliance Officer for each manufacturer and GPO submit a signed attestation "certifying the truth, correctness, and completeness of the data submitted to the best of the signer's knowledge and belief."[64]

B. 45-Day Review Period

The statute provides a 45-day period for manufacturers, GPOs, and covered recipients to review and submit

61 *Id.* at 78753 (emphasis added).

62 *Id.* at 78753-54.

63 *Id.* at 78754.

64 *Id.*

corrections to reported information before it is made public.[65] CMS seeks comments on a way for manufacturers and GPOs to make necessary corrections before submission to CMS, to reduce potential changes during the 45-day statutory review and correction period and improve the accuracy of the data. CMS suggests that manufacturers and GPOs could provide each covered recipient or each physician owner or investor with the relevant information they plan on reporting before actually submitting it to CMS.[66] CMS does not propose that this type of "pre-submission review" be *required*, but it recommends that manufacturers and GPOs adopt such a procedure and seeks comments on its utility.

CMS plans to notify all manufacturers, GPOs, covered recipients, and physician owners or investors once data aggregation is complete, but CMS says it may be difficult to contact covered recipients and physician owners and investors. CMS proposes two ways to contact them:

(1) CMS would 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.[67] CMS would also notify physicians and hospitals through CMS' listservs and by posting the information that aggregated data is ready for review, either on the CMS website or in the Federal Register. These notifications would include specific instructions for performing review. CMS is also considering a requirement that covered recipients and physician owners and investors sign in to a secure website to see the information reported about them.

(2) CMS would require manufacturers and 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.[68]

CMS seeks comments on these proposed methods of notification and suggestions for other ways that CMS, manufacturers, or 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.

Dispute Resolution During the 45-Day Period: CMS does not think that it should be actively involved when disputes arise between manufacturers or 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. CMS is working on developing a streamlined and automated process for reporting disputes.[69] The general proposed guidelines for the process are as follows:

- In the event of a potential dispute over the reported data, covered recipients and physician owners or investors may request from CMS the contact information for a specific manufacturer or GPO, but it would then be their responsibility to contact that manufacturer or GPO and try to resolve the dispute.
- At least one of the entities involved must report to CMS that there is a dispute, and the results of that dispute at the end of the 45-day review period.
- If there is contradictory information that cannot be resolved by the parties involved, CMS proposes that the data be identified as contradictory and both the original submission (from the manufacturer or GPO), and the modified information (provided by the covered recipient, or physician owner or investor) appear on the final publicly available website.[70]
- CMS is considering how best to aggregate reports without double counting any reported information. CMS is considering that the individual payment be flagged as contested, but the contradictory data, as corrected by the covered recipient or physician owner or investor, be used for aggregated totals for the physician. CMS is also considering aggregating the original information, as submitted by the

65 SSA § 1128G(c)(1)(C)(ix).
66 76 Fed. Reg. at 78753.
67 *Id.* at 78754.
68 *Id* at 78755.
69 *Id.*
70 *Id.*

manufacturer and GPO. CMS seeks comment on this proposal and suggestions for how best to handle outstanding disagreements.

— CMS proposes that the 45-day review period is the primary opportunity to correct errors or contest the data submitted by manufacturers and GPOs. Once this period has passed, and the parties have identified all changes or disputes and CMS has made or noted them all, CMS would not permit any party to amend the data for that calendar year. CMS proposes that the parties alert CMS as soon as possible regarding any errors or omissions, but these changes would not be made until the data is refreshed for the following reporting year.[71]

C. Public Availability

The statute requires CMS to publish, on a publicly available website, the data reported by manufacturers and GPOs for CY 2012 by September 30, 2013. For each year thereafter, CMS must publish the data for the preceding calendar year by June 30th. The format must be searchable, downloadable, understandable, and able to be aggregated. CMS requests comments on how to structure the website for ultimate usability.

CMS proposes a list of information from the collected data that would be included on the website.[72] CMS also proposes that the website include (1) information on any enforcement activities taken under SSA § 1128G for the previous year, (2) background or other helpful information on relationships between the drug and device industry and physicians and teaching hospitals, and (3) information on payments or other transfers of value that were granted delayed reporting. CMS welcomes comments regarding the details and format for how this information should be displayed on the website.

71 CMS additionally proposes, however, that it has the option to make changes to the data at any time to, for example, correct mathematical mistakes. *Id.*

72 *Id.* at 78755-56. A list of information is provided, which includes, for example, names, addresses, amounts of payments or transfers, dollar amounts of investments, and, where applicable, the name of the covered drug, device, biological, or medical supply. *Id.*

D. Delayed Publication for Payments made Pursuant to Product Research or Development Agreements and Clinical Investigations

The statute provides for delayed publication of payments or other transfers of value from manufacturers to covered recipients made pursuant to product research or development agreements or clinical investigations.[73] Publication is delayed until the earlier of: (1) the date of FDA approval or clearance of the covered product; or (2) four years after the date the payment or other transfer of value was made. CMS proposes that manufacturers should indicate on their reports whether a payment or other transfer of value should be granted a delay in publication on the public website. In the absence of such notification, CMS states that it would have no way of knowing that such a payment or other transfer of value should not be published.[74]

CMS further proposes that payments or other transfers of value subject to delayed publication need to be reported each year with a continued indication that publication should remain delayed, along with any updated information, as necessary. Following FDA approval, licensure or clearance, CMS proposes that 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.[75] Finally, CMS proposes that if a report includes a date of payment four years prior to the current year, then the payment or other transfer of value would be automatically published, regardless of whether the manufacturer indicates that the payment should be delayed.

Limiting Applicable Research and Investigation Activities:

CMS proposes that payments or other transfers of value granted delayed publication be limited to relationships for "bona fide" research or investigation activities that, if made public, would damage the manufacturers' competitive or proprietary interests. CMS proposes that the "product

73 SSA § 1128G(a)(1)(E).

74 76 Fed. Reg. at 78756.

75 *Id.*

research or development agreement" referenced in the statute must include a written statement or contract between the manufacturer and covered recipient, as well as a written research protocol. The statute defines "clinical investigation" 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."[76] CMS proposes that in the context of this definition, a clinical investigation is limited to one that is memorialized in a written research protocol between the covered recipient and the manufacturer (or between the covered recipient and a contract research organization if the manufacturer uses a CRO).[77]

Defining Terms:

The statute provides for the delayed publication of (a) payments for services furnished in connection with research on "medical technology" (both new technologies and new applications of existing technologies), and (b) services furnished in connection with the development of, or a clinical investigation for, a new drug, device, biological, or medical supply.[78] CMS proposes considering "medical technology" broadly as any drug, device, biological, or medical supply, because of the "significant overlap" between the phrases.[79] Alternatively, CMS is considering defining "medical technology" more *narrowly* as an unspecified "subset" of drugs, devices, biologicals, and medical supplies. CMS seeks comments on both approaches.

CMS proposes treating payments related to "research" and payments related to "development" the same, because of the overlap in the activities associated with them.[80] CMS is also considering assigning different meanings to "research" and "development." CMS seeks comments on this approach and suggestions for meaningful distinctions between the two terms.

CMS believes that "clinical investigations" has a distinct meaning as set forth in section 1128G(e)(3) of the SSA, which is separate from both "research" and "development."[81]

Based on these interpretations, CMS proposes 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. However, CMS proposes limiting delayed publication to payments in connection with "clinical investigations" to investigations concerning new drugs, devices, biologicals, or medical supplies, and *not* new applications of existing products. CMS seeks comments on whether there are better ways to distinguish among these categories, including treating payments and transfers of value made in connection with clinical investigations the same as those made in connection with research and development.

VI. Penalties for Failure to Report

The statute authorizes the imposition of civil monetary penalties (CMPs) for failures to report required information on a timely basis. CMS interprets the statute to require the submission of information that is accurate and complete, and therefore states that a CMP may be imposed for failure to report information in a timely, accurate, and complete manner.[82] For failure to submit the required information, a manufacturer or GPO may be subject to a CMP of at least US$1,000, but no more than US$10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required.[83] The maximum annual CMP with respect to failure to report is US$150,000. For knowing failure to submit required information in a timely manner, a manufacturer or GPO will be subject to a CMP of at least US$10,000, but no more than US$100,000, for each payment or other transfer of value, or ownership or

76 SSA § 1128G(e)(3).
77 76 Fed. Reg. at 78756-57.
78 SSA § 1128G(c)(1)(E)(i).
79 76 Fed. Reg. at 78757
80 *Id.*
81 *Id.* SSA § 1128G(e)(3) provides that clinical investigations involve human subjects or materials derived from human subjects.
82 76 Fed. Reg. 78757.
83 *Id.*

investment interest not reported as required.[84] The maximum annual CMP with respect to knowing failure to report is US$1,000,000.

CMS proposes that the procedures in 42 CFR § 402(a), on civil money penalties, would apply with regard to imposition and appeal of CMPs. In determining the amount of the CMP, CMS proposes to consider the following noncomprehensive list of factors:

- The length of time the manufacturer or GPO failed to report, including the length of time it knew of the payment or other transfer of value, or ownership or investment interest.
- The amount of the payment or other transfer of value, or the value of the ownership or investment interest the manufacturer or 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.[85]

Audits:

CMS proposes that the Secretary, CMS, Office of Inspector General, or their designees may audit, evaluate, or inspect manufacturers and GPOs for their compliance with the regulations. CMS states that "[a]ccess to this information is implicit in the statute in order to enforce the requirements outlined."[86] CMS proposes that manufacturers and GPOs must maintain books, records, documents, and other materials for a period of at least five years from the date that the payment or other transfer of value, or ownership or investment interest is published on the website. CMS does not directly address those manufacturers and GPOs that may not maintain such materials under the mistaken belief that they are not applicable manufacturers or applicable GPOs.

84 The term "knowingly" is given the meaning from the False Claims Act, 31 U.S.C. 3729(b).

85 *Id.* at Fed. Reg. 78757-58.

86 *Id.* at 78758.

VII. Annual Reports

CMS is required to submit annual reports to Congress (by April 2013 and each later year) concerning the information submitted to CMS "during the preceding year."[87] Since CMS will not receive data for the prior year until the 90th day of the next year, CMS proposes to report to Congress information submitted by manufacturers and GPOs during the *preceding year*. CMS also reports to states; since the state reports are due later in the year than the Report to Congress (September 30, 2013 and June 30 for each subsequent year), CMS proposes that the reports include data collected that was submitted to CMS in the current year.[88]

VIII. State Law Preemption

The proposed rule has a very short discussion of preemption.

SSA §1128G(d)(3) 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 manufacturers to covered recipients. CMS states that 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 the Physician Payment "Sunshine" Provisions, *unless* such information is being collected by a federal, state, or local governmental agency for public health purposes or health oversight.[89] However, CMS also says that "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."[90] This suggests that section 1128G(d)(3) still preempts any state and local laws requiring reporting information on payments or transfers of value by manufacturers to covered recipients.

87 SSA § 1128G(d)(1)(A).

88 76 Fed. Reg. at 78758.

89 *Id.* 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. *Id.*

90 *Id.* (emphasis added).

CMS notes that the statute does not preempt state or local laws on reporting of information not required under section 1128G (including reporting of exempted items, except those that fall below the US$10/$100 threshold).[91]

If you have any questions regarding this proposal, please feel free to contact your Arnold &Porter attorney, or any of the following attorneys:

Daniel A. Kracov
+1 202.942.5120
Daniel.Kracov@aporter.com

Jeffrey L. Handwerker
+1 202.942.6103
Jeffrey.Handwerker@ aporter.com

Allison W. Shuren
+1 202.942.6525
Allison.Shuren@aporter.com

Alan E. Reider
+1 202.942.6496
Alan.Reider@aporter.com

Keith M. Korenchuk
+1 202.942.5817
Keith.Korenchuk@aporter.com

Kirk Ogrosky
+1 202.942.5330
Kirk.Ogrosky@aporter.com

Rosemary Maxwell
+1 202.942.6040
Rosemary.Maxwell@aporter.com

Paul Rudolf
+1 202.942.6426
Paul.Rudolf@aporter.com

Jeffrey R. Ruggiero
+1 212.715.1089
Jeffrey.Ruggiero@aporter.com

Lauren R. Robbins*
+1 202.942.5551
Lauren.Robbins@aporter.com

*Admitted only in New York; practicing law in the District of Columbia during the pendency of her application for admission to the DC Bar and under the supervision of lawyers of the firm who are members in good standing of the DC Bar.

91 *Id.*

Appendix

Required Information in Reports, as proposed by CMS:[92]

- 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); and
  - NPI (physician only).
- Amount of payment or other transfer of value in US 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); and
  - 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 US 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.

92 *Id.* at 78754. Asterisked items are proposed based on CMS discretion; they are not required by the statute.