

CMS-Seeking Comment Physician Payment Sunshine

1. **CMS is seeking 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. CMS is considering a **preparation period of 90 days**, and is **requesting comments** on whether that is a sufficient amount of time.
2. CMS is also **seeking input** on specific challenges that applicable manufacturers and applicable GPOs may face when setting up the necessary data collection and reporting systems.
3. CMS **seeks comments** on the feasibility of submitting the required information for part of CY 2012 by March 31, 2013.
4. CMS **seeks comment** on its interpretation and definition of “applicable manufacturer.”
5. CMS **seeks comment** on its interpretation and definition of “common ownership.”
6. CMS’s **seeks comments** on its proposal 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).
7. **CMS seeks comment on** a proposed additional limitation to the definition in #6 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.
8. **CMS seeks comment** on its proposed definition of “teaching hospital: 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.”
9. **CMS seeks comment on** what other unique identifiers could be used, including whether these unique identifiers are readily obtainable by applicable manufacturers, to identify “covered recipients.”
10. **CMS seeks comments on** its proposal to publish a list of teaching hospital covered recipients (that is, those hospitals that received Medicare direct or indirect GME) on the

CMS website once per year. **CMS proposes** that the list of teaching hospital covered recipients should include the name and address of each teaching hospital.

Payment and Other Transfer of Value Report Content

11. **Date of Payment:** CMS seeks comments on its proposal 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. CMS is also considering requiring manufacturers to report multiple payments in a single consistent manner.
12. **CMS proposes** 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. 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. 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.
13. **CMS seeks comments** on its proposal 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. CMS is **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.

Form of Payment and Nature of Payment

14. **CMS proposes that the categories** within both the form of payment and the nature of payment should be defined as distinct from one another. 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, **CMS proposes** 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. **CMS proposes** 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, **CMS proposes** 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, **CMS proposes** 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. **CMS seeks comment** on the proposal to require reporting payments under a single form of payment and nature of payment.

15. CMS **welcomes comments** about the usefulness of this data as well as any operational issues that applicable manufacturers might face in reporting it. **They 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. **CMS welcomes comments** on the costs and relative advantages and disadvantages of this approach.

Forms of Payments

16. The Act lists the following forms of payment that applicable manufacturers must use to describe payments or other transfers of value: 1) Cash or a 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; 4) Any other form of payment determined by the Secretary. **CMS does not propose** to add any forms of payment beyond those outlined in the statute. **CMS seek comments on whether other categories are necessary or would be helpful.**

Nature of Payment

17. The Act lists the categories for the nature of payment or other transfer of value that applicable manufacturers must use to describe each payment. **CMS proposes** 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, CMS encourages 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, CMS asks applicable manufacturers to make reasonable determinations about the nature of payment reported for the payment or transfer of value. 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.

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- 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 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, CMS 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 CMS believes that applicable manufacturers may want to explain the reasoning behind their categories. Additionally, CMS believes 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 website because they may contain information applicable manufacturers would consider proprietary.

However, based on CMS review and assessment of these assumptions, they may choose to offer further guidance to applicable manufacturers regarding how natures of payment should be classified. CMS recognizes 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. **CMS seeks comments on this proposal**, including whether it should make submission of the assumptions document mandatory instead of voluntary.

18. **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.
19. **Food and Beverage:** CMS proposes that applicable manufacturers should report the value of any food or beverage items provided to covered recipients, over \$10 or \$100 aggregate. However, CMS recognizes 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. **CMS proposes** 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). CMS is considering whether to adopt a **different approach** for these situations, such as counting the number of physicians by department.

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CMS **seeks 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.

20. Additionally, **they 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.
21. **Research:** CMS seeks 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. CMS **proposes** 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. **CMS requests comment on** whether its proposed method is viable and not overly burdensome, and whether an alternative method would be preferable.
22. **CMS proposes 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.
 - a. **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).
 - b. 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.
23. When reporting payments or other transfers of value designated as research, **CMS proposes** that applicable manufacturers must report the payment or other transfer of value as either "**indirect research**" or "**direct research**."
 - a. When reporting indirect or **direct research**, **CMS 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.
 - b. 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).

24. 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, **CMS does 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, **CMS 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)**.
- a. The payment or other transfer of value to the **teaching hospital** covered recipient should be reported as a **direct research payment**;
 - b. Whereas the payment or other transfer of value for the **principal investigator(s)** (physician covered recipient(s)) should be reported as **indirect research**.
25. Based on these considerations, **CMS proposes 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, on the public website, CMS would report the payment amount separately and would not aggregate it into the total for physician covered recipients. **CMS seeks comment on these proposals.**
26. CMS is also considering attributing the total payment to the covered recipient for direct research. CMS believes 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. **CMS solicits 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.
27. **Direct Compensation for Serving as a Faculty or as a Speaker for a Medical Education Program: CMS proposed that this category** of payment 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."
28. Alternatively, CMS is 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 CMS believes that fewer categories for nature of payment is preferable. **CMS welcomes comment on this proposal and the appropriate distinction between this nature of payment category and other categories, such as honoraria.**
29. CMS realizes that this interpretation does not allow for differentiation between continuing medical education (CME) accredited speaking engagements, and all other speaking engagements. **CMS is 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.

30. **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. CMS wants 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. **CMS is 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."
31. CMS **seeks 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." CMS intends to finalize the agency's position on this in the final rule based on comments received.
32. **Indirect Payments through a Third Party:** 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, **CMS proposes** 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.
33. 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**.
34. CMS proposes that awareness of the identity of the covered recipient by an agent of the applicable manufacturer will be attributed to the applicable manufacturer.

Exclusions

35. 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.

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- 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.

CMS said it is not their 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). They **welcome suggestions** on how to incorporate this into the codified language of the final rule.

CMS proposes that applicable manufacturers use the dictionary definitions for the exclusions. However, they provided some clarification.

36. **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. **CMS proposes** to publish the updated threshold amounts annually on the CMS website.
37. **CMS proposes 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.

38. **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. CMS reminded 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.
39. **In-kind Items for the Provision of Charity Care:** CMS proposed 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 nonpaying 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.

Report Submission and Correction

40. **Prior to Submission:** CMS seeks comments on a way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS.
41. **Report Submission:** CMS seeks comment on the proposed timing of the registration and submission process.
- a. **CMS proposes** 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.
 - b. **CMS is 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.
 - c. **CMS proposes** that applicable manufacturers and applicable GPOs register with CMS prior to submission of data for the current reporting cycle to facilitate communication. This registration process would require the applicable manufacturer or applicable GPO to designate a point of contact, which CMS would use for communications related to the submitted data. **CMS proposes** that applicable manufacturers or applicable GPOs must register prior to the submission.

42. **Alternatively, CMS is 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.
43. However, CMS **is seeking input** on whether requiring registration for all entities and an attestation from entities with no reportable information **would be more burdensome than beneficial. CMS seeks 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.**
44. **CMS proposes** 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. **CMS seek comments** on the appropriateness of the CSV format for data submission, and suggestions for alternative formats.
45. Additionally, **CMS proposes** 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.

Report Format

46. **CMS seeks comment** on the proposed requirements regarding the data elements that should be submitted and plans to finalize them in the final rule based on comments received.
- 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.

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- 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)

45-Day Review Period

47. 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 CMS has received the data, it 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, CMS plans to notify all applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors about the procedures for the review.
48. **CMS proposed notice a few ways:** 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, notify physicians and hospitals through CMS' list serves and posting the information publicly CMS is considering a posting either on the CMS website or on the **Federal Register**, and **seeks comment** on which would be most useful to physicians and teaching hospitals. **CMS proposes 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, CMS is considering that covered recipients and physician owners and investors would sign in to a secure website to see the information reported about them.
49. CMS is also **considering an alternative method**, in which CMS 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. CMS **seeks comment** on the proposed method of notification, as well as the alternative method provided, and **solicit comments** on other ways that CMS, applicable manufacturers, or applicable GPOs can provide timely, adequate, and costeffective notice to covered recipients and physician owners or investors of their opportunity to review the collected data.
50. **Dispute Resolution:** CMS is working on identifying a streamlined and automated process for reporting disputes between applicable manufacturers or applicable GPOs and

covered recipients. **CMS proposes** 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. CMS proposes that at least one of any entity involved 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.

51. 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 CMS proposes** 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 website.
52. CMS is 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. CMS is seeking **comment on this proposal** and suggestions for how best to handle instances where there are outstanding disagreements.
53. Finally, **CMS proposes** 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, **CMS proposes** that neither applicable manufacturers, applicable GPOs, covered recipients, nor physician owners or investors would be permitted to amend the data for that calendar year.
54. **CMS proposes** 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, **CMS proposes** that it would have the option to make changes to the data at any time (for example, to correct mathematical mistakes).
55. **CMS also proposes** that only the current and previous year would be available for review and correction. CMS **seeks 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.
56. Under the statute, CMS is required to publish on a publicly available website the data reported by applicable manufacturers and applicable 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 public website 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." **CMS request comments on how to structure this website for ultimate usability.**

57. As required in the Act, CMS proposes that the following information on payments and other transfers of value would be included on the public website in a format that is searchable, downloadable, understandable and able to be aggregated:

- Applicable manufacturer 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.

58. In addition, as required by statute, **CMS proposes** that the website 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.

59. Beyond the information required by statute, **CMS proposes** that the website clearly state that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing. **CMS welcomes comment** regarding the details and format for how this information should be displayed on the website.

Delayed Publication for Payments made Pursuant to Product Research or Development

60. **CMS proposed** 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 website.

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61. In addition, **CMS proposes** 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.
62. Further, **CMS proposes** 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. **CMS seeks comment** on these proposals.
63. **CMS proposes** 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, **CMS proposes** 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.**
64. 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." **CMS proposes** 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.
65. If an applicable manufacturers contracts with CROs, to facilitate their clinical research, as long as the applicable manufacturer has a written agreement with the CRO, **CMS proposes** that the CRO may have the written research agreement with the covered recipient, rather than the applicable manufacturer.
66. 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. **CMS proposes** to consider "medical technology" broadly as any drug, device, biological, or medical supply. **CMS proposes** this interpretation because it believes 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.
67. **Alternatively, CMS is considering** defining "medical technology" more narrowly as a subset of drugs, devices, biologicals, and medical supplies. **CMS seeks comments** on both approaches, including suggestions for a narrower definition of "medical technology."

68. Alternatively, CMS is considering defining "medical technology" more narrowly as a subset of drugs, devices, biologicals, and medical supplies. **CMS seeks comments** on both approaches, including suggestions for a narrower definition of "medical technology."
69. The statute also distinguishes between the scope of delayed publication permitted for payments related to "research" versus payments related to "development" or "clinical investigations."
- a. 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,
 - b. Whereas, delayed publication for **development and clinical investigations** are limited solely to new drugs, devices, biologicals, and medical supplies.
 - c. 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, **CMS proposes** to treat them similarly in this provision.
70. However, CMS is also considering the possibility of assigning different meanings to "research" and "development," and **seeks comments** on this approach and suggestions for meaningful distinctions for the two terms. With regard to clinical investigations, CMS believes 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.
71. Given 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.
72. Conversely, **CMS proposes** 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. **CMS seeks comment** on these proposals and **solicit comments** 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.

Penalties

73. In determining the amount of the civil money penalty (CMP), **CMS proposes** and **seeks comments on** factors to be considered, which 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.

74. In addition, **CMS also proposes** 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.

75. 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.

76. **CMS proposes** 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 website. CMS believes 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. **CMS seeks comments** on these proposals.

Collection of Information Requirements

77. 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**. CMS estimates 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. **CMS seeks comment** on whether there are any other sources of data available.

78. **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 CMS consulted that are expert in the overall cost of existing reporting systems.

79. **CMS welcomes more detailed and disaggregated information** that would help them improve the overall estimate or better craft the final rule to deal with specific problems or time-saving options.
80. CMS is 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.**
81. **CMS welcomes 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.** In total, CMS estimated 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.

ICRs Regarding Review and Correction by Physicians and Teaching Hospitals

82. **No recordkeeping requirement for physicians and teaching hospitals. CMS seeks 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.
83. **CMS welcomes 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 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. 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.
84. Based on the assumptions presented here, CMS anticipates 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.
- a. CMS estimates 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, CMS anticipates that there would be a further reduction in the number of physicians reviewing the data because they would be familiar with the information, so CMS reduced the number of physicians reviewing by another 25 percent, to 250,875 physicians. CMS estimates 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.

- b. CMS believes that teaching hospitals would have to review more payments or other transfers of value and have more complex relationships, so CMS estimates 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.

Regulatory Impact Analysis

- 85. **CMS solicit comments** on all assumptions and estimates in this regulatory impact analysis.
- 86. For purposes of the RFA, CMS estimates 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. **CMS seeks comment** on assumptions and estimations regarding the RFA.
- 87. **CMS 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.**
- 88. **CMS solicits comments** on the assumptions, data, estimates, and anticipated effects
- 89. **CMS seeks comment on this interpretation and whether there is a more precise way to quantify these estimates**
- 90. 45 day review period: Here **CMS 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?
- 91. They also request **comments on** any approach that minimizes costs or improves accuracy of the information with respect to applicable manufacturers and applicable GPOs being required to inquire of covered recipients and physician owners or investors of their opportunity to review the data.
- 92. They also want **comments on** or information on the likely frequency of cases in which additional communication methods would be necessary, useful, costly, inexpensive, or otherwise better or worse.