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February 17, 2012

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS 5060–P: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Dear Ms. Tavenner:

The Pew Health Group of The Pew Charitable Trusts welcomes the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services' ("CMS"") proposed rule for **Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests.**[1]

The Pew Charitable Trusts is an independent, non-profit organization that applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Based on data, science and non-partisan research, the Pew Health Group ("Pew") works to reduce hidden risks to the health, safety, and well-being of American consumers. The Pew Prescription Project has worked to promote transparency of financial relationships between pharmaceutical and medical device makers and health care providers.

We are pleased CMS is working toward implementing the provisions of the Physician Payments Sunshine Act signed into law as section 6002 of the Patient Protection and Affordable Care Act. The Physician Payments Sunshine Act has the support of consumer and industry groups and leaders within the medical profession. Implementation will bring transparency to the financial

[1] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests. 76 Fed. Reg. 78742 (December 19, 2011).

relationships between physicians and pharmaceutical and medical device companies. The Institute of Medicine has said that these financial relationships "present the risk of undue influence on professional judgments and thereby may jeopardize the integrity of scientific investigations, the objectivity of medical education, the quality of patient care, and the public's trust in medicine."

Pew was closely involved in the development of the Physician Payments Sunshine Act and in working to ensure its inclusion in the Patient Protection and Affordable Care Act. We have also supported the development and implementation of analogous state transparency laws. We look forward to continuing to work with CMS toward a successful implementation of this important new program.

Pew's main goals in commenting on the proposed rule are to ensure timely implementation and to promote the interest of full transparency by ensuring that data is collected, reported, and published in the most complete, consistent and accurate manner possible.

Our first goal is to ensure timely implementation. The statute calls for data collection beginning on January 1, 2012. Although we are not advocating for retroactive data collection, swift implementation of this provision is crucial to meet the aims of the statute.

The purpose of the Physician Payments Sunshine Act is to make information available and understandable to consumers and the public. In the interest of collecting and publishing complete and accurate data, we believe that CMS should (1) carefully define nature of payment categories and remove the proposed "other" category, which could be used to serve as a "catch all" and thereby obfuscate the true nature of payments; (2) provide more clarification on the rules regarding indirect payments, especially indirect research payments; and (3) provide more information regarding how reported data will be presented and accessed from the public website.

II. Provisions of the Proposed Regulations; A. Transparency Reports

Swift implementation of the regulations is crucial to achieving the aims of the Physician Payments Sunshine Act.

In its proposed rule, CMS stated it is seeking comments on the amount of time applicable manufacturers and applicable Group Purchasing Organizations (GPOs) will need following publication of the final rule in order to begin complying with the data collection requirements of section 1128G of the Social Security Act.[2] CMS also stated it is seeking comments on the feasibility of submitting the required information for part of CY 2012 by March 31, 2013.[3]

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[2] 76 Fed. Reg. 78743.
[3] 76 Fed. Reg. 78743.

Section 1128G of the Social Security Act required data collection to begin on January 1, 2012. We believe it is of paramount importance to expedite implementation. We recommend that CMS require applicable manufacturers and applicable GPOs to begin collecting data as soon as possible after the final rule is published, ideally within thirty days, but certainly within ninety days. An initial report of a partial year's data would serve both CMS and manufacturers in preparing them for the first full year of data collection in 2013, for submission in 2014. Having data on as little as three to six months of 2012 will allow for preliminary data analysis, give the agency a chance to assess the report submission system and make necessary changes before the next year's data must be reported to CMS. CMS will have an opportunity to ensure that the submission methods are adequate for the amount of data they will receive. Applicable manufacturers and applicable GPOs will gain insight into the adequacy of their own systems by preparing partial-year reports to better prepare themselves for reporting a full year's data for the next cycle. In addition, implementation starting in 2012 is consistent with the statute and will provide useful information for consumers. For these reasons, we believe that manufacturers should begin collecting data no later than ninety days following publication of the final rule.

To achieve swift implementation, it would be best if a final rule was published between April 1 and July 1, 2012 with data collection to begin between July 1 and October 1, 2012. This timeline will allow for at least one calendar quarter of data to be collected in 2012 and published in 2013, while still allowing manufacturers as long as 90 days to prepare for data collection. In order to allow for faster implementation, we encourage CMS to consider the startup challenges of reporting entities and limit its enforcement actions to cases of intentional failure to comply with the law during the first year.

CMS should clarify that foreign subsidiaries are not required to report, but cannot be used for indirect payments or to avoid reporting.

The proposed rule did not include any language regarding the responsibilities of foreign subsidiaries of applicable manufacturers or applicable GPOs. It would be helpful if CMS would clarify that, although such subsidiaries are not required to submit reports, unless they otherwise independently meet the definition of an "applicable manufacturer," care should be taken to ensure they are not used to make indirect payments in order to avoid reporting. CMS should consider also including guidance on enforcement mechanisms that will be employed to prevent such arrangements.

CMS should require that applicable manufacturers and applicable GPOs report the business address and provider specialty of covered recipients as they appear in the NPPES database.

In its proposed rule, CMS suggested that reporting entities use the NPPES database to find identifying information on covered recipients. We suggest that CMS elevate this suggestion to a requirement in order to ensure consistency of reporting. Many practitioners have multiple business addresses, and if companies do not use a standard address for a practitioner, it may lead to discrepancies that must be reconciled by CMS before information is reported publicly.

CMS should require another unique identifier for physicians who do not have an NPI.

In its proposed rule, CMS requested comments regarding whether it should require that applicable manufacturers report another unique identifier, such as a state license number, for physicians who are identified, but do not have a National Provider Identifier (NPI).[4] CMS also requested comments on whether such information is readily available.[5]

Pew supports the CMS suggestion that that another unique identifier may be required for identification of certain covered recipients. A state medical license number would be an appropriate identifier for covered recipients who do not have an NPI. This information appears to be publicly available in states, and Vermont's payments reporting law explicitly requires manufacturers to include the state license number of health care practitioner covered recipients in payment reports. We believe it is not necessary to require an additional unique identifier for covered recipients who do possess an NPI.

CMS should publish a list of teaching hospitals that are covered recipients.

CMS proposed to publish on its website an annual list of hospitals that qualify as covered recipients.[6] We agree with CMS' proposal to limit the definition of covered "teaching hospitals" to those institutions receiving Medicare direct or indirect graduate medical education (GME) funding and believe that publication of this list is on an annual basis will aid applicable manufacturers in the identification and tracking of payments to these covered recipients.

CMS should require applicable manufacturers to report the name of the entity or individual that receives payment at the request of, or designated on behalf of, a covered recipient.

CMS proposed that applicable manufacturers report the name of the entity or individual that received the payment at the request of or designated on behalf of the covered recipient in addition to reporting the name of the covered recipient who designated the payment.[7]

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[4] 76 Fed. Reg. 78746.
[5] 76 Fed. Reg. 78746.
[6] 76 Fed. Reg. 78746.
[7] 76 Fed. Reg. 78746, see also §403.904(b)(10).

Pew commends CMS for requiring that applicable manufacturers report both the name of the entity or individual that received payment at the request of or on behalf of the covered recipient and the name of the covered recipient making such a request. We also agree with CMS that it would not be feasible to allow a review period for these entities or individuals before the data is published. The purpose of the Physician Payments Sunshine Act is to ensure transparency of relationships between applicable manufacturers and covered recipients. In order to achieve complete transparency, we believe that it is imperative that all parties to a relationship be disclosed.

CMS correctly limited the categories of forms of payment.

CMS requested comments on whether other categories of forms of payment beyond those outlined in the statute are necessary or would be helpful.[8]

Pew supports CMS in its proposal to limit the categories of forms of payment to cash or cash equivalent, in-kind items or services, and stock, stock options, or other ownership interests. We agree that these forms of payment are sufficient to describe the anticipated transfers of value contemplated by the statute.

CMS should publish specific definitions for the various categories regarding nature of payment.

We support CMS' proposal that the nature of payment categories are mutually exclusive and that lump sum payments must be broken into their constituent parts. Minnesota's payments reporting statute resulted in some companies reporting single line item payments that comingle various purposes, demonstrating the need for clear reporting rules that prevent such practices.

However, CMS has proposed that terms identifying the categories describing the nature of payment should be given their dictionary definitions.[9] We believe this would result in inconsistent reporting. Without specific, well-defined categories and clear guidance from CMS, manufacturers may find it difficult to consistently characterize and report payments, and the resulting public data will be confusing or impossible to interpret.

The terms used for each nature of payment category have varied meanings to the general public. Dictionaries such as the Merriam-Webster Unabridged Dictionary provide multiple meanings for each of the terms and do not provide the meaning within a context suitable for application under the Physician Payments Sunshine Act. In addition, some of the categories contain multiple

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[8] 76 Fed. Reg. 78748.
[9] 76 Fed. Reg. 78748, see also §403.904(d) and (e)

terms, such as "current or prospective ownership or investment interest," making the use of dictionary definitions for the various terms impractical and unclear.

Therefore, we suggest that CMS promulgate more detailed definitions of the various categories describing the nature of payment to ensure that reporting entities have sufficient information to collect and report data. Specifically, we suggest that CMS adopt the following definitions for the purposes of data collection under the Physician Payments Sunshine Act:

1. **Consulting Fee:** fees paid under a written agreement for services that meet the following criteria:[10,11,12]

   (i) a legitimate need for the services clearly identified in advance;

   (ii) a connection between the competence and expertise of the health care practitioner and the purpose of the arrangement;

   (iii) the number of health care practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;

   (iv) the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care practitioner;

   (v) the venue and circumstances of any meeting with the health care practitioner is conducive to the services and activities related to the services are the primary focus of the meeting;

   (vi) the decision to retain a health care practitioner is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel; and

   (vii) compensation is at fair market value.

2. **Compensation for Services other than Consulting:** Payments for services at fair market value that are not made pursuant to a written agreement.
3. **Honoraria:** Payments for services on which custom or propriety forbids a price to be set.
4. **Gift:** Includes but is not limited to promotional items, computers, software, membership fees and dues, subscriptions and journal reprints, textbooks, free services, or any other payment or transfer of value not meeting the criteria for another payment category.

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[10] PhRMA Code of Interactions with Health Care Professionals, at 8. http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf. Accessed Feb. 14, 2012.

[11] AdvaMed Code of Ethics on Interactions with Health Care Professionals, stating that "[c]onsulting agreements should be written and describe all services to be provided. When a company contracts with a consultant to conduct clinical research services, there should also be a written research protocol." at 5-6. http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf. Accessed Feb. 14, 2012.

[12] Massachusetts 105 CMR 970.000: Pharmaceutical and Medical Device Manufacturer Conduct. Under Massachusetts regulations such consulting arrangements are termed "compensation for bona fide services".

5. **Entertainment:** Includes, but is not limited to, provision of tickets or no-cost admission to recreational, cultural, or sporting events that otherwise have a cost.
6. **Food and Beverage:** Includes, but is not limited to, food and beverages, including alcoholic beverages, provided at professional or educational conferences, meetings, or events; meals or beverages provided in an office setting or to teaching hospital physicians or staff; meals or beverages associated with prospective product purchases and demonstrations; meals or beverages provided at marketing or promotional events; and payments to a teaching hospital fund for meals or beverages.
7. **Travel and Lodging:** Includes, but is not limited to contributions to teaching hospital travel funds for conferences and events; or the direct purchase, reimbursement or provision of travel and accommodations associated with speaking at, serving on the faculty of, or attending a professional or educational meeting, conference or event; prospective product purchases and demonstrations; consulting, research, or non-research services; or entertainment.
8. **Education:** Education includes payments and transfers of value to support: graduate medical education events or activities accredited by the Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic Association Commission on Osteopathic College Accreditation (COCA), or the American Dental Association Commission on Dental Accreditation (CODA); or continuing medical education events or activities accredited by the Accreditation Council for Continuing Medical Education (ACCME) or an accrediting organization that has formally adopted ACCME standards for commercial support.
9. **Research:** Research is a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.[13]
10. **Charitable Contribution:** With respect to physicians, a charitable contribution is a payment or transfer of value made on behalf of or at the request or designation of a physician to any entity to which the payment would otherwise meet the definition in section 170(c) of the Internal Revenue Code for "charitable contribution." With respect to a teaching hospital, a charitable contribution is either the provision of financial support to a 501(c)(3) teaching hospital when such financial support is not otherwise described as consulting, compensation for services or a grant; or the in-kind provision of covered products for charity care of patients.
11. **Royalty or License:** Any payment in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the health care provider holds an ownership right.
12. **Current or Prospective Ownership or Investment Interests:** This term should be defined in conformity with IRS and SEC statutes and regulations

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[13] 42 C.F.R. 50.063

13. **Direct Compensation for Serving as Faculty or as a Speaker for Medical Education Program:** Includes compensation for speaking as part of a non-accredited program, including activities often termed "speakers bureaus."
14. **Grant:** Funds provided under a grant agreement for purposes other than research, education, or compensation for serving on the faculty or as a speaker for a medical education program.

Additionally, we support CMS' suggestion that manufacturers submit assumptions used in determining how to categorize the nature of various payments. Even with more detailed definitions of the categories, there will be some ambiguity and CMS could later improve upon the definitions based on the assumption documents provided by manufacturers.

Finally, some in industry believe that it would be helpful to be able to provide "context" for payment reports where they provide additional information about the circumstances of a particular payment. Therefore, CMS should consider adding an optional, short, free-form data field where applicable manufacturers may include context information in connection with each reported payment.

CMS should take additional steps to ensure that indirect payments made via third parties for accredited continuing medical education (CME) are reported in cases where the manufacturer directs the payment to a specific end recipient.

We urge CMS to acknowledge that payments to entities that receive grants from applicable manufacturers for CME activities are subject to disclosure in certain cases. ACCME regulates industry support of CME via its Standards for Commercial Support.[14] The following three aspects of ACCME policy allow applicable manufacturers to suggest specific speakers, allow CME speakers to receive direct promotional and research payments from CME supporters, and allow industry supporters to become aware of the identity of the covered recipient receiving funding from industry educational grants.

1. Applicable manufacturers may "suggest" CME speakers. While ACCME Standard 1.1 requires that the industry supporter cannot control the selection of faculty members, Standard 3.2 allows industry supporters to suggest specific faculty members, as long as the third party is not "required" to follow that advice. Thus, third party entities may, at their discretion, select physician faculty who are recommended by the commercial supporter. In such cases, the applicable manufacturer (in cooperation with the third party entity) "designates" payment to a specific covered recipient.

[14] ACCME. Standards for Commercial Support. http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support Accessed Feb 15, 2012.

2. CME speakers may receive CME funding and direct promotional funding from the same applicable manufacturer, on the same educational topics. ACCME's Standards for Commercial Support allow CME faculty to receive funding from the same applicable manufacturer via two mechanisms: first, via an educational grant provided through a third party entity, and second, via direct funding from the same manufacturer for other, non-CME activities, such as promotional speaking and research grants. Therefore, companies are in a situation in which they have already identified and directly paid covered recipients for non-CME activities and then can identify and suggest these same speakers to third party CME entities.

3. ACCME regulations virtually guarantee applicable manufacturer awareness of the identity of CME speakers whom they indirectly support. According to ACCME Standard 6.1, all learners must be provided with the following information before the CME program begins: The name of the faculty member, the name of the commercial interest, and the nature of the relationship the faculty has with each commercial interest. These regulations mean that applicable manufacturers need only access the educational brochure to become aware of the identity of the covered recipient receiving funds via their educational grant.

According to the latest ACCME annual report, applicable manufacturers have paid $830 million to support CME programs in 2010. We are concerned that unless CME payments to covered entities are explicitly included as reportable transfers of value, a significant proportion of company-initiated physician payments will go unreported, undermining the intent of the Physician Payments Sunshine Act.

However, unrestricted grants to support CME should not be reported if the applicable manufacturer provides no suggestion of faculty and is unaware of the physician recipient. Some medical centers have established blinded CME funds that receive contributions from multiple entities,[15] and if there are strong institutional policies that prohibit the applicable manufacturer from providing any guidance to the teaching hospital on CME speaker selection or education topic, then it is not necessary to report the payment as an indirect CME payment.

CMS should clarify the rule for reporting the name of an associated drug, biological, or device in cases where payments are made related to marketing, education, or research.

The proposed rule provides little detail regarding the requirements for reporting the name of an associated drug, biological, or device in cases where payments are made related to marketing, education, or research.

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[15] Steinbrook R. Future directions in industry funding of continuing medical education. Arch Intern Med. 2011 Feb 14;171(3):257-8.

CMS should clarify that when a payment or transfer of value is associated with marketing, education, or research, the brand name, generic name, and associated National Drug Code (NDC) of the relevant covered drug or biological must be reported and published. Use of an NDC number will facilitate subsequent analysis of the data by, for example, allowing CMS and other stakeholders to easily assess aggregate spending by drug class. However, medical devices lack a system of identifiers comparable to the NDC. CMS should require a payment associated with marketing, research or education related to a medical device to name the specific product. Where multiple models belong to a single product family, it would be acceptable to list only the product family.

CMS should allow manufacturers to report multiple drugs, biologics, or devices in cases where payments are made related to marketing, education, or research.

CMS proposed that 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.[16] CMS is considering as an alternative, however, allowing manufacturers to report multiple products as related to a single payment. CMS notes that the alternative may be easier for manufacturers, but make aggregating payments by product difficult. Under the Vermont disclosure regulations, manufacturers can disclose up to five products most relevant to each allowable expenditure or permitted gift. We support allowing applicable manufacturers to report a limited number of related products when the transfer of value is related to more than one product or component.

CMS should not exempt any food or beverage from the reporting requirements and should require applicable manufacturers to report the food and beverage based on actual consumption whenever possible.

CMS proposed that in the case of meals provided in a group setting, applicable manufacturers should report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal).[17] CMS also has proposed 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 to definitively establish the identities of the individuals who accept the offerings.[18]

We recommend that manufacturers have the option of (1) attributing the cost per covered recipient receiving the meal (for example, when lunch is provided to the staff of a medical practice associated with a single covered recipient, the entire cost should be attributed to that

[16] 76 Fed. Reg. 78747.
[17] 76 Fed Reg. 78748
[18] 76 Fed Reg. 78748

covered recipient) or (2) to report the cost per covered recipient or (3) report the adjusted cost per covered recipient by tracking or estimating actual consumption (for example, if five covered recipients receive a meal and a sixth is present but does not partake, the manufacturer should have discretion not to attribute a portion of the cost to that sixth covered recipient).

CMS should not exempt from reporting buffet style meals or beverages provided to covered recipients. We note that, in response to existing state disclosure laws, some manufacturers already have in place systems to track identifying information on physicians before providing food and beverage at these conferences and other events. We suggest that all applicable manufacturers should be able to set up similar systems.

CMS should require more detailed reporting regarding indirect research payments.

In its proposed rule, CMS laid out special rules for reporting indirect research payments.[19] While physician-industry research collaboration is necessary and beneficial, payments for research still create conflicts of interest that have long been recognized. For example, persons serving on FDA advisory committees must disclose research support. The National Institutes of Health also requires transparency and disclosure of investigators' significant financial interests resulting from industry research support.[20] We note that the public reports resulting from this provision may serve as a compliance mechanism for other institutions charged with reporting or managing such conflicts. For example, in June 2008, a Congressional investigation by Senator Grassley found that a prominent physician at a major teaching hospital had received $1.4 million in outside income from makers of antipsychotic medicines while conducting extensive research on these medicines.[21,22] Had section 1128G been in place at the time, the total amount and the nature of these multiple payments by industry to this investigator would have been disclosed and the hospital would have been able to audit the investigator's disclosures to the institution.

Pew supports CMS' proposal to capture indirect payments via third parties when the applicable manufacturer knows the principal investigator is a physician under the indirect payment rules. We suggest that CMS allow applicable manufacturers to include more detail regarding the specific amount a principal investigator receives in the context field of the report. For example, a principal investigator may receive a large research grant. The full amount of the grant should be reported, but the context field could clarify the proportion that goes to the investigator and the portion used to pay direct study costs.

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[19] 76 Fed. Reg. 78749, see also §403.904(e).
[20] 76 Fed Reg. 53256
[21] Levin, EC and Parry, PI. Conflict of Interest as a Possible Factor in the Rise of Pediatric Bipolar Disorder. Adolescent Psychiatry 2011, 1. 61-66.
[22] U.S. Senator Grassley (IA). "Payments to Physicians." Congressional Record 154:91 (June 4, 2008) p. S5029.

While the full amount of transfers of value to support research must be disclosed, applicable manufacturers should be permitted to provide context to these payments in a separate text field. In this field manufacturers may voluntarily provide insight into how the payment is broken down by trial costs versus salary of the primary investigator, for example. The proposed rule does not require applicable manufacturers to set up systems to identify non-principal investigator physicians being paid through indirect research monies. Manufacturers should include the names of other physician investigators who receive a portion of the research payment indirectly in a separate "indirect payment" field. Finally, we suggest that an applicable manufacturer must report the identity of a covered recipient as soon as possible if the applicable manufacturer becomes aware of the covered recipient's identity at a later date.

CMS should not exclude educational materials that are not actually given to patients, such as medical textbooks, from Physician Payments Sunshine Act reporting requirements.

CMS requests comments on whether educational materials such as medical textbooks should be included in the exclusion for educational materials that directly benefit patients or are intended for patient use and if so, which types of educational materials provided to covered recipients should be considered to directly benefit patients.[23]

Educational materials such as medical textbooks, when provided to covered recipients by applicable manufacturers, are principally a benefit to the recipient and are not intended for patient use. Educational materials that directly benefit patients are appropriate when the purpose is to advance patient learning and health. Medical textbooks are clearly intended for use by physicians, and may only indirectly benefit patients. Such materials may be of substantive value, and should be reported consistent with the intent of the law. Therefore, educational materials intended for physician use are clearly not within the exception for "educational materials that directly benefit patients or are intended for patient use" and should be reported.

CMS should take additional steps to ensure that indirect payments made via third parties are reported and that regulations do not create loopholes.

CMS proposed that applicable manufacturers are "aware of the identity of a covered recipient" if they have actual knowledge of the identity of the recipient or if they act in deliberate ignorance or reckless disregard of the identity of the recipient. We support CMS's proposal that awareness of the identity of the covered recipient by an agent of the applicable manufacturer be attributed to the applicable manufacturer.

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[23] 76 Fed. Reg. 78751.

In many contexts, awareness or knowledge can include both an entity's actual knowledge, and their 'constructive knowledge' (i.e. "knowledge that one using reasonable care or diligence should have, and therefore that is attributed by law to a given person").[24]

We recommend that the rules state that a manufacturer be deemed to be constructively aware of recipient identities in cases where the manufacturer directs a third party's payments under circumstances where the manufacturer could easily determine the identities of the recipients. Furthermore, rules should define "unaware" in this context to be an ongoing requirement, such that the manufacturer must not later become actually aware of the identity of a recipient through any action by the third party or the recipient. For instance, if the third party communicates to the manufacturer which covered recipients received payments or transfers of value funded by that manufacturer, the manufacturer would then have actual awareness of these identities, and thus have to report these payments.

Moreover, it is essential that this provision not be used to construct new kinds of third-party payment mechanisms to avoid reporting of financial relationships that would otherwise be reportable.

We are concerned that without clarifying rules, this language could create a loophole that would undermine the comprehensiveness of the reporting of payments to physicians. For instance, if a manufacturer were to instruct a third party to host a conference and pay for the travel and accommodations for doctors described as 'the top 50 prescribers of Drug X' or 'leaders of departments of psychiatry at academic medical centers' in a particular area, this would be a discrete set of individual recipients whose identity a manufacturer could easily determine.

II. Provisions of Proposed Regulations; B. Report Submission and Correction

CMS should require reporting entities to provide their payment reports directly to covered recipients for pre-review prior to submitting reports to CMS.

CMS requested comments on a way for applicable manufacturers and applicable GPOs to make necessary corrections prior to submission to CMS.[25]

We recommend that CMS require that manufacturers should provide their payment reports directly to individual covered recipients for pre-review prior to submitting reports to HHS. Errors would thereby be minimized and the pre-review process required by HHS would be satisfied before public disclosure. Applicable manufacturers must report the name and business address of the covered recipients to whom it made payments in order to comply with reporting

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[24] Blacks Law Dictionary, Second Pocket Edition, 2001, p 394.
[25] 76 Fed. Reg. 78753.

requirements. It would impose very little additional burden to provide relevant payment reports directly to the covered recipients who have an interest in reviewing the reports prior to publication.

CMS should require all applicable manufacturers and applicable GPOs to register with CMS.

CMS proposed that applicable manufacturers and applicable GPOs register with CMS prior to submission to facilitate communication.[26]

Pew supports a pre-registration requirement. We suggest that CMS require all applicable manufacturers and applicable GPOs register with CMS, regardless of whether they believe they have information to report, in order to streamline the process of reporting. Massachusetts, which operates a transparency program akin to the Physician Payments Sunshine Act, has successfully implemented a mandatory manufacturer registration system.[27]

CMS should allow entities under common ownership to choose whether to submit a consolidated report, but should take steps to avoid double reporting.

In the regulatory language of the proposed rule, CMS would allow but not require an applicable manufacturer and an entity under common ownership with the applicable manufacturer to file a consolidated report of payments or other transfers of value to covered recipients and physician ownership or investment interests.[28]

Pew supports this approach, with the proviso that under no circumstances should entities report in a way that would lead to double reporting. We are concerned that some companies out of an abundance of caution could report both as individual applicable manufacturers and as a single entity under common ownership. CMS should proactively clarify that this would not be acceptable.

CMS should require certification by the CEO, CFO, or CCO of an applicable manufacturer or applicable GPO on every report made in compliance with the Physician Payments Sunshine Act.

Under §403.908(f) of the proposed rule, CMS requires each report, including any subsequent corrections to a filed report, to include a certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of the applicable manufacturer or applicable

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[26] 76 Fed. Reg. 78753.
[27] See http://www.mass.gov/eohhs/docs/dph/quality/healthcare/pharm-medical-device-conduct-faq.pdf
[28] §403.908(d).

group purchasing organization that the information submitted is true, correct, and complete to the best of his or her knowledge and belief.

Pew applauds CMS for requiring certification by the Chief Executive Officer, Chief Financial Officer, or Chief Compliance Officer of an applicable manufacturer or applicable GPO that the information submitted is true, correct, and complete. Such an attestation will ensure accountability on the part of the applicable manufacturers and applicable GPOs.

CMS provided a reliable mechanism for data review and made a wise decision in refusing to mediate data disputes.

In §403.908(g)(3) and §403.908(g)(4) of the proposed rule, CMS assured covered recipients secure access to review data submitted by applicable manufacturers and applicable GPOs prior to data publication, and explicitly refused to mediate data disputes.

Pew applauds CMS for providing a reliable mechanism for review of reported data by covered recipients prior to publication. Furthermore, we believe CMS made a wise choice in refusing to mediate data disputes among covered recipients and reporting entities.

CMS should publish updates to the data published on the public website as errors or omissions are reported.

CMS proposed that applicable manufacturers, applicable GPOs, covered recipients, or physician owners or investors alert CMS as soon as possible regarding any errors or omissions after the 45-day review period, but these changes may not be made until the data is refreshed for the following reporting year.[29]

CMS has proposed that reported errors or omissions not be reflected in the data on the public website after the 45-day review period until the website is refreshed for the following year. Changes should be made sooner if feasible. If the publication of corrections is delayed it may result in unnecessary confusion among patients, physicians and manufacturers. Making timely updates to the data is preferable and important to ensure full transparency as intended by the Physician Payments Sunshine Act.

II. Provisions of Proposed Regulations; C. Public Availability

CMS should provide more details regarding the accessibility of the public website.

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[29] 76 Fed. Reg. 78755.

Generally speaking, Pew urges greater detail in the final regulations on the required public website. To accomplish the requirements of the Physician Payments Sunshine Act, the public disclosure website should be easily usable by consumers and other end-users. We recommend that the website use a platform that is user-friendly and accessible to consumers, as well as downloadable for researchers. The website should be structured so that the data can be easily searched, sorted, and aggregated without duplication, as required by the statute. Consumers should be able to search, sort, and aggregate data by covered recipient, value of the payment or transfer of value, form and nature of the payment or transfer of value, specialty of the covered recipient, and the covered recipient's business address. We also stress that certain data, namely the NPI or State license number of the covered recipient, may not be made publicly available on the website, as required under the law, but shall be made available to qualified researchers under a data use agreement.

CMS has proposed, as required by statute, to include on the public website 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.[30] We support the inclusion of this information. Although details of certain payments may be granted delayed publication, it is important that the public website include basic information about the aggregate value of payments receiving delayed publication by individual company. This information will allow the public to gain a more complete picture of the current scope of payments and transfers of value while protecting the proprietary interests of applicable manufacturers.

CMS should provide more detail about how it will continue to engage the public on the design of the website to ensure the maximum utility of the information disclosed under the law.

II. Provisions of Proposed Regulations; D. Delayed Publication for Payments made Pursuant to Product Research or Development Agreements and Clinical Investigations

CMS should not allow delayed publication of payments made for services in connection with research on new applications of previously approved or cleared drugs, biologics, or medical supplies.

In its proposed rule, CMS proposed that delayed publication should apply to payments to covered recipients for services in connection with research on, or development of new drugs, devices, biologics, or medical supplies, as well as new applications of existing drugs, devices, biologics, or medicals supplies. Conversely, CMS proposed limiting delayed publication for payments in connection with clinical investigations for new drugs, devices, biologics, or medical

[30] 76 Fed Reg. 78756.

supplies, and not new applications of existing drugs, devices, biologics or medical supplies.[31] We strongly support the definition of "research" in the proposed rule for the purposes of delayed publication as well as CMS' suggestion that applicable manufacturers be required to confirm each year that a previous payment remains eligible for delayed publication.

The statute allows for delayed publication of payments for services furnished in connection with research on "medical technology" with regard to research on potential new medical technologies and new applications of existing medical technologies. Pew firmly believes that "medical technology" should be defined to include medical devices, but to explicitly exclude drugs, biologics and medical supplies. Medical devices and drugs have distinct innovation pathways. Devices frequently have an iterative development process and research often builds upon existing technologies, whereas drugs are unique molecular entities that do not evolve in the same way devices do. This limited definition of "medical technology" maximizes the transparency of financial relationship associated with drugs that are already on the market and used by large numbers of patients. The definition is also consistent with the legislative history of terms like "new potential medical technology" and "new use of an existing medical technology."

Department of Justice enforcement actions on the illegal promotion of off-label uses of prescription drugs have resulted in at least $3.3 billion in fines, accounting for 53% of financial penalties on the drug industry from 2006 to 2010. Too frequently, payments to physicians to serve on scientific or clinical advisory boards related to off-label uses of prescription drugs have been implicated in this fraud. For example, the extensive litigation by the Department of Justice concerning the drug Neurontin® revealed that the manufacturer:

> paid doctors to attend so-called 'consultants meetings' in which physicians received a fee for attending expensive dinners or conferences during which presentations about off-label uses of Neurontin were made. These events included lavish weekends and trips to Florida, the 1996 Atlanta Olympics and Hawaii. There was little or no significant consulting provided by the physicians.[32]

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[31] 76 Fed. Reg. 78757. See also §403.910(a)(1).

[32] US Department of Justice. Press release: Warner-Lambert to pay $430 million to resolve criminal & civil health care liability relating to off-label promotion. May 13, 2004. http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm. Accessed Feb. 15, 2012. See also Melvin, Cathy L. et al, Marketing Off-Label Uses: Shady Practices Within a Gray Market, Psychiatric Times, Aug. 2009 (citing Chen H, Reeves JH, Fincham JE, et al. Off-label use of antidepressant, anticonvulsant, and antipsychotic medications among Georgia Medicaid enrollees in 2001. J Clin Psychiatry. 2006; 67:972-982. and Teinman MA, Bero LA, Chren MM, Landefeld CS. Narrative review: the promotion of gabapentin: an analysis of internal industry documents. Ann Intern Med. 2006; 145:284-293).

This and other examples[33,34] illustrate why payments for research associated with new uses of existing drugs should be excluded by rule from any delayed public disclosure.

In sum, we recommend excluding from delayed publication any payments to covered recipients for services in connection with research regarding new applications of existing drugs, biologics, and medical supplies. Limiting delayed publication to payments made for services in connection with research regarding new applications of "medical technology," that is, medical devices, is appropriate.

CMS should require manufacturers to indicate the status of each payment eligible for delayed publication in subsequent reports until the payment may be posted publicly.

We support CMS' proposal that payments or other transfers of value subject to delayed reporting must 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. We also support the proposed requirement that manufacturers confirm in a subsequent annual report if a payment is no longer eligible for delayed publication.

II. Provisions of Proposed Regulations; F. Annual Reports

CMS should ensure the Secretary submits a report to Congress in 2013 regarding the data collected in 2012.

In its proposed rule, CMS noted the difficulty associated with submitting a report to Congress one day after data submissions from applicable manufacturers and applicable GPOs are due. CMS therefore proposed that the Secretary report to Congress information submitted by applicable manufacturers and applicable GPOs during the preceding year rather than information submitted in the current year regarding the previous year.

In order to comply with the statute, the Secretary is required to provide a report to Congress on April 1, 2013 regarding data collected in 2012. However, covered entities are not required to

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[33] Department of Justice, Press Release, Pharmaceutical Companies to Pay $214.5 Million to Resolve Allegations of Off-label Promotion of Zonegran, Dec. 15, 2010, available at http://www.justice.gov/opa/pr/2010/December/10-civ-1444.html. Accessed Feb. 15, 2012. The settlement arose from a whistle-blower lawsuit by psychiatrist who reports being invited to attend a Florida seminar at the manufacturer's expense if he became eligible by beginning to write prescriptions for the drug Zonegran. Upon doing so, he reports that though the meeting was described in the promotional materials as an "Advisory Meeting" for which attendees would be paid between $750 and $1,250 for their time, no opinion or advice was solicited during the meeting, and that, in any event, the psychiatrist would have been unable to provide any significant insight into the clinical effectiveness of the drug due to his relative inexperience with [the drug.]" See United States ex rel. Chartock, et al. v. Elan Corporation, PLC, et al., Civil Action No. 04-11594-RWZ, Complaint, at para. 31, 34, 35.

[34] U.S. Department of Justice, Press Release, Novartis Pharmaceuticals Corp. to Pay $422.5 Million for Off-Label Drug Marketing. http://www.justice.gov/usao/pae/News/Pr/2010/Sept/novartis_release.pdf, Accessed Feb. 15, 2012.

make their annual reports regarding data collected in 2012 to CMS until March 31, 2013. While we understand that producing the report to Congress in a single day would not be feasible, we cannot support the proposal that the Secretary postpone the report until the next calendar year, on April 1, 2014. We suggest that instead, the Secretary submit a report on the previous year's data on the day the information is made available on the public website, September 30, 2013 and then on June 30 of each subsequent year.

CMS should include information on the Secretary's annual reports to Congress in the regulatory text.

Pew is concerned that the Secretary's annual reports to Congress were not discussed in the regulatory language. The annual reports to Congress are required by the statute and should be discussed with some level of detail as to the content of the report in the actual regulation. In particular, we recommend that for payments granted delayed publication, the aggregate data by company and payment type be included in reports to Congress. This information will allow Congress to gain a more complete picture of the current scope of payments and transfers of value while protecting the proprietary interests of applicable manufacturers.

Enforcement Mechanism

CMS should provide details on the enforcement mechanism in place for ensuring applicable manufacturers and applicable GPOs report the correct data on time.

There is very little information regarding the mechanism that will be in place in order to enforce the reporting requirements under the proposed rule. Pew requests additional information, including which agencies will be responsible for investigating failure to report and what measures will be used in order to discover potential failures to report.

Background Information on Industry-Physician Relationships.

In accordance with the statute, CMS should provide background information on industry-physician relationships.

We are concerned that the proposed rule did not address in detail how CMS will meet the statutory requirement that the public reports must "contain background information on industry-physician relationships." We recommend citing the Institute of Medicine (IOM) as a basic resource to meet the requirement of this provision, as the IOM has reviewed much of the literature in this area.

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The goal of the Physician Payments Sunshine Act is to protect consumers by ensuring transparency in industry-physician relationships. Swift implementation is crucial to begin to work toward achieving the goal of complete transparency. Effective transparency is possible only if the rules clearly define what information must be reported, when the reports are due, and how the reported data will be published in the public website, as required by the statute.

Thank you for your consideration of our comments. Should you have any questions, please contact me at 202.540.6466 or ACoukell@pewtrusts.org.

Sincerely,

Allan Coukell
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