Accreditation Council for Continuing Medical Education
Suite 1801 515 North State Street Chicago, IL 60654 (312) 527-9200 www.accme.org

July 31, 2013

Dr. Shantanu Agrawal
Medical Director
Center for Program Integrity
c/o Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Agrawal,

Re: **Section 904(g)(1)(i-iii)** of 42 CFR Parts 402 and 403 ; Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule

By virtue of agreements, policy and ACCME oversight, there are several layers of organizations that meet the accreditation requirements and standards for continuing education of the Accreditation Council for Continuing Medical Education (ACCME) which are not explicitly cited in Section 904(g)(1)(i) of the above referenced final rule.

The following organizations are required to meet the ACCME® Standards for Commercial Support for continuing education of the Accreditation Council for Continuing Medical Education,

1. The organizations directly accredited by the ACCME. They are listed on the ACCME website.
2. The organizations directly accredited by the state medical societies recognized by the ACCME as accreditors of CME within the ACCME system. They are listed on the ACCME website.
3. The organizations accredited by the Accreditation Council for Pharmacy Education (ACPE). They are listed on the ACPE website.
4. The organizations accredited by the American Nursing Credentialing Center (ANCC) under the terms and conditions of the Joint Accreditation offered jointly by the ACPE, the ACCME and ANCC. They are listed on the ANCC website.

The ACCME Recognized state medical societies and the Accreditation Council for Pharmacy Education have both entered into agreements with the Accreditation Council for Continuing Medical Education in which the ACCME Recognized state medical societies and the Accreditation Council for Pharmacy Education have agreed to adopt the ACCME® Standards for Commercial Support as their own **and** to ensure that their accredited organizations adhere to these Standards for Commercial Support in the same way as the accredited providers of the Accreditation Council for Continuing Medical Education.

By virtue of their adherence to the ACCME® Standards for Commercial Support, all of these accredited providers ensure that in the continuing education emanating from their programs, ***"The applicable manufacturer does not pay the covered recipient speaker directly;" and "The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program."*** As a result, and in order to provide clarification to the continuing education community, we respectfully request that you explicitly state that payments or other transfers of value provided as compensation for speaking at a continuing education program emanating from these organizations are not required to be reported under this final rule.

Sincerely,

Murray Kopelow, MD, MS(Comm), FRCPC
President and Chief Executive Officer

Association of Health Care Journalists
Center for Excellence in Health Care Journalism
Better coverage. Better health.

10 Neff Hall
Missouri School of Journalism
Columbia, MO 65211
573-884-5606

Sept. 12, 2013

To Whom It May Concern:

Thank you for the opportunity to comment on the continuing implementation of the Physician Payment Sunshine Act.

The Association of Health Care Journalists represents nearly 1,500 journalists across the United State. Our members and their news organizations cover issues relating to conflicts of interest in medicine, and they are looking forward to the agency's first data release next year.

Our main purpose in writing is to ask the agency to release the data with unique identifiers that will allow the public and journalists to more easily aggregate payments to individual doctors. This suggestion was a key aspect of our comments submitted in February 2012.

We realize that CMS is not permitted to release the National Provider Identification numbers along with the payment information. Instead, we urge CMS to assign a random unique identifier to each individual payee.

Unique identifiers would prevent inaccuracies or misunderstandings caused by common names or the inevitable typographical errors. They would also avoid confusion when family members with the same first and last name practice together, not an unusual situation. We would also request that, once assigned, identifiers remain consistent from year to year to allow for tracking payments to specific physicians over time.

We believe CMS shares our concern for accuracy both in reporting by companies and in subsequent reporting by journalists. Adding a mechanism for unique identifiers would go a long way toward preventing mistakes.

Additionally, as in February 2012, we again encourage the agency to note on the public website whenever a company updates its report, including the date of the update. Journalists need this information to follow the progress of this rule. It will also be important to correct errors companies may have made in early reports.

Thank you for your attention to this matter.

Sincerely,

Len Bruzzese
Executive Director

THE PEW CHARITABLE TRUSTS

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September 20, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via: http://www.regulations.gov

RE: CMS-10495: Paperwork Reduction Act Notice of Agency Collection Information Activities for Open Payments

Dear Administrator Tavenner:

The Pew Charitable Trusts thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments on the Paperwork Reduction Act (PRA) notice of agency collection information activities surrounding the registration, attestation, dispute and resolution, assumptions document and data retention requirements for Open Payments. 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. The Prescription Project has worked to promote transparency of financial relationships between pharmaceutical and medical device makers and health care providers.

We urge CMS to revisit several of the assumptions regarding the estimated burden on physicians who may choose to register and review the data submitted on Open Payments. Based on the data and analysis we provide below, these assumptions may overstate the actual burden to those doctors in participating in this program.

The current estimate of three hours of total support staff time for physician registration should be reduced to 30 minutes.

According to the supporting statement accompanying the PRA notice, CMS estimates that physician registration on Open Payments will take a total of three hours of support staff time. This estimate is far higher than a previous PRA estimate for a document requiring similar amounts of information. Specifically, the PRA notice concerning CMS-855O, released in April 2012, estimated a burden of 30 minutes of support staff time to complete.[1] CMS-855O is a Medicare registration form for eligible ordering and referring physicians and non-physician practitioners. In our side-by-side analysis of the data required for both CMS-855O and for physician registration on Open Payments, we found that the differences between the two are negligible. In fact, CMS-855O requires several pieces of information, including physician gender, Medicare ID number (PTAN), medical or professional school and year of graduation, and information about any adverse legal actions, that are not required for Open Payments registration. Obtaining a CMS User ID, as required for Open Payments, does not require any additional data beyond that required for CMS-855O.

[1] CMS. Details for CMS Form Number: CMS-855O. April 27, 2012. Available online: http://cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1246134.html?

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Accordingly, we recommend that CMS reduce the time estimate for Open Payments registration to 30 minutes, which more accurately reflects registration times on comparable websites.

The number of physicians who will register is likely closer to 224,425 than to the current estimate of 448,850.

CMS estimates that 50 percent of all U.S. physicians—448,850—will be reported as having received transfers of value, and that 100 percent of them will register with Open Payments. CMS has not articulated a basis for this assumption.

We note that data from state disclosure programs indicate that many physicians receive only modest payments. For example, analysis of the Massachusetts physician payment database indicates that fully half of reported payments were between $50 (the disclosure threshold) and $100. The majority of such payments were for meals.[2] Because the federal disclosure threshold is even lower ($10), the median payment on the Open Payments website will also be lower. We believe physicians receiving small payments will be less likely to register, and suggest that 50 percent, or 224,425 physicians, is a more realistic estimate.

The number of physicians who, after review, will dispute the reported information will be a fraction of the currently estimated 224,425.

CMS estimates that 50 percent of all doctors who register and review their payments on the Open Payments site will dispute the accuracy of the payments. In order to assess the reasonableness of this estimate, we obtained information from states with disclosure laws and from manufacturers with voluntary payment registries in order to ascertain how commonly physicians have disputed the accuracy of their reported payments.

Since 2002, Vermont has required disclosures of all payments to health care practitioners of $25 or more. A representative at the Office of the Attorney General of Vermont,[3] which operates the state's disclosure program, said that her office receives one to two inquiries from health care practitioners (HCPs) per year. These are generally not complaints about the accuracy of payments but rather other questions, such as whether practitioners have a reporting obligation under the law or why an HCP's name and license number appears on the website.

Minnesota has collected information on industry payments valued at $100 or more to HCPs since 1997. A representative of the Minnesota Board of Pharmacy[4] reported that there has been one physician question regarding the accuracy of payment information and one amended manufacturer report due to an inaccurately reported payment over the 15 years that the program has been operational.

Since July of 2009, Massachusetts has required disclosures of payments of $50 or greater to physicians. According to a representative from the Massachusetts Department of Public Health[5], few doctors call the

[2] Kesselheim, AS, et. al. Distributions of Industry Payments to Massachusetts Physicians. *N Engl J Med* 368(22): 2049-52. doi: 10.1056/NEJMp1302723. 2013.
[3] Kate Whelley McCabe, Assistant Attorney General at the Vermont Office of the Attorney General. Personal communication. September 12, 2013.
[4] Cody Wideberg, Executive Director, Minnesota Board of Pharmacy. Personal communication. September 16, 2013.
[5] Andrew Sinatra, Bureau of Health Care Safety and Quality, Massachusetts Department of Public Health. Personal communication. September 20, 2013.

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department with concerns about the accuracy of reported payments—approximately ten such calls have been received annually out of 15,000 to 20,000 reported payments per year.

Although state disclosure programs do not include the kind of formal dispute process contained in the federal program, the very low number of disputes from physicians suggests that relatively few physicians will dispute payments at the federal level.

In addition, our discussions with individual companies that are already disclosing data indicate that physicians have rarely disputed the accuracy of the payments and transfers of value attributed to them. This may be because some companies have proactively informed physicians that payments will be disclosed, and have maintained communication with such physicians in order to identify potential disagreements before they arise. While it is possible that there is less attention paid to individual companies' websites than there will be to the federal website, the experience of companies indicates that relatively few disputes will occur after payment data are transmitted to CMS.

Taken together, the existing information on payment disputes from both states and manufacturers indicates that CMS has significantly overestimated the number of physicians who will dispute payments. CMS should reduce the number of physicians expected to dispute information to 10,000 or fewer to reflect the historically low levels of such disputes.

We thank the agency for its efforts to fully and efficiently implement the Open Payments program. We appreciate the opportunity to provide comment on this PRA request, and urge CMS to revisit the current draft estimates to better reflect the patterns of use in comparable state and manufacturer disclosure programs. More accurate estimates will facilitate future evaluations of the program and support physician participation.

Sincerely,

Daniel Carlat MD

Daniel J. Carlat, M.D.
Director, Prescription Project
The Pew Charitable Trusts

PhRMA
RESEARCH • PROGRESS • HOPE

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September 20, 2013

VIA ELECTRONIC SUBMSSION

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number CMS–10495
Room C4-26-05, 7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: DOCUMENT IDENTIFIER/OMB CONTROL NUMBER CMS–10495: REGISTRATION, ATTESTATION, DISPUTE & RESOLUTION, ASSUMPTIONS DOCUMENT AND DATA RETENTION REQUIREMENTS FOR OPEN PAYMENTS

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments to the Centers for Medicare & Medicaid Services (CMS) in response to the agency's request for information regarding compliance with the final rule implementing section 6002 of the Patient Protection and Affordable Care Act (ACA), Transparency Reports and Reporting of Physician Ownership or Investment Interests (the "Sunshine Act)."[1] In particular, PhRMA's comments address the accuracy of CMS's estimated burden for applicable manufacturers. PhRMA is a voluntary, nonprofit association that represents the country's leading biopharmaceutical research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

The purpose of the Sunshine Act is to ensure that patients have meaningful and relevant information about the relationships between biopharmaceutical and medical device companies and health care providers. PhRMA member companies are available to provide any assistance to CMS that would be useful as the agency reviews the burden imposed on various stakeholders by the Sunshine Act reporting requirements.

I. Introduction

PhRMA remains committed to and supportive of the goals of transparency and appreciates the opportunity to comment on the burden of complying with the Sunshine Act data collection requirements. In addition to commenting on the burden of complying with the data collection requirements, PhRMA would like to provide additional information on several other important issues concerning reporting requirements under the Sunshine Act.

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[1] Pub. L. No. 111-148, 124 Stat. 119, 689 (2010) (codified at Social Security Act § 1128G).

II. Burden of Complying with Sunshine Act Reporting Requirements

A. Overall Burden of Compliance

The reporting requirements of the Sunshine Act final rule impose a tremendous burden on applicable manufacturers. PhRMA believes that CMS's estimates regarding this burden greatly underestimate the actual burden imposed by the Sunshine Act reporting requirements.

Specifically, CMS estimates that the average applicable manufacturer will spend approximately $159,234 to implement the Sunshine Act final rule in year 1, taking into account the cost of both the compliance officer and supporting staffs (based on a total of 5,200 hours per company). CMS further estimates the average infrastructure costs for applicable manufacturers as $10,000 in the first year (the costs for large companies would be $50,000) and approximately $1,000 per year in subsequent years.

The actual burden imposed on applicable manufacturers is significantly higher than the estimates provided by CMS. PhRMA members report that both the initial cost of implementing the Sunshine Act requirements and their ongoing expenses will be significantly higher than the estimates in the final rule. Company efforts to prepare to submit reports in 2014 span a range of functional groups including, but not limited to, information technology, data stewardship, training and communications, legal, medical, compliance, sales operations, and transparency reporting. One PhRMA member reports that its costs in the first year will exceed $9 million, and compliance with the requirements will require 23 full-time equivalents (FTEs). The company expects to spend similar amounts in the second year and anticipates that its ongoing burden thereafter will be approximately $5.4 million and 14 FTEs per year.

Another PhRMA member, a large pharmaceutical manufacturer, calculates that its total infrastructure costs associated with implementing the Sunshine Act will be more than $14 million. The same PhRMA member estimates that its ongoing annual expenses will be in excess of $5 million. At least one other additional large pharmaceutical manufacturer reports similar estimates. A mid-sized pharmaceutical company estimates that its total annual implementation burden will be at least $2 million.

As an additional example, a PhRMA member company currently operating under a corporate integrity agreement (CIA) reports that it spent several years and tens of millions of dollars to build a robust system for collecting and aggregating data. Although the company's CIA reporting obligations are less extensive than those under the Sunshine Act, this system includes data feeds from almost two dozen sources. Additional sources are being added to meet the expanded requirements of the Sunshine Act. In its current capacity, the company's system tracks approximately 80,000 line items on a monthly basis. That number is expected to rise markedly to reflect the additional data that must be reported under the Sunshine Act. The total costs to implement this system are expected to approach $8 million annually.

Although company estimates vary some, they are vastly higher than CMS's estimates of the cost and burden of implementing the Sunshine Act and continuing to comply with the reporting requirements. The large amount of information that must be reported and the complexity of the pharmaceutical organizations require massive investments in reporting and extensive manpower. PhRMA urges CMS to fully consider these complexities, and their associated costs, when making decisions regarding the implementation of Sunshine Act reporting requirements.

B. Burden Associated with Dispute Resolution

Addressing and resolving disputed transactions is likely to be a complicated process, in part because each disputed transaction must be individually researched. This research could include reviewing the original transaction and supporting documentation and contacting employees. The latter process could be extraordinarily complicated due to employee turnover rates, which tend to be higher for pharmaceutical sales positions than non-sales positions.

PhRMA member companies estimate that resolving most individual disputes will take several weeks. As a result, the current CMS dispute resolution period would be adequate only if a small number of disputes are logged. For a large applicable manufacturer that could submit more than a million line items, addressing all disputes may not be possible in such a short window. One member company has estimated the cost of reviewing disputes and making corrections to existing data in a controlled manner to be approximately $100 per dispute, though there may be additional costs for more complex investigations.

III. General Concerns Regarding Sunshine Act Reporting Requirements

A. Limitation of CME Organizations to Five Enumerated Organizations

PhRMA respectfully urges CMS to reconsider its answer to FAQ 8398, which limits the exclusion for payments to speakers at CME events to those events that are accredited or certified by one of the five organizations listed in the final rule. CMS's answer provides that to qualify for the exclusion, the payment must be provided to a speaker at a CME event that is accredited or certified by an organization enumerated in §403.904(g)(1)(i). Specifically, CMS states that "the list of accrediting or certifying bodies in the final rule at 42 CFR § 403.904(g)(1)(i) is exhaustive; in order to qualify for the exclusion in § 403.904(g)(1), CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities in § 403.904(g)(1)(i) and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities."

CMS's answer to the FAQ is contrary to language in the final rule and in the preamble to the final rule. The final rule provides that payments and transfers of value related to continuing education programs are exempt from reporting if the event, among other requirements, "meets the accreditation or certification requirements and standards for continuing

education of one of the following. . . ."[2] The final rule then lists five organizations. The final rule does not require that the event be run by one of the five organizations; it requires only that the event "meet the accreditation or certification requirements and standards" of one of the enumerated organizations.

The preamble to the final rule also provides that to qualify for the exclusion, the event must meet the accreditation or certification requirements or standards of one of the five listed organizations, not that the CME event must be certified or accredited by one of the listed organizations. The preamble states that the program must "meet[] the accreditation or certification requirements and standards of the ACCME, AOA, AMA, AAFP or ADA CERP."[3]

The FAQ's requirement that the CME be "run by" one of the listed entities contradicts the language of the final rule and inappropriately narrows the scope of entities that can accredit or certify CME programs. Numerous other CME providers have standards that are the same as--or higher than--the five listed organizations. One example of an accreditation or certification body that should not have been excluded from CMS's list is the Council on Optometric Practitioner Education, which is an accreditation body for optometrists. From a policy perspective, there is no reason to limit accredited CME to programs organized by the five entities listed in the final rule, provided other entities follow the same standards. Doing so may discourage companies from providing funding to CME programs accredited by these other organizations, which could have negative consequences for physician education and patient care.

For the reasons discussed above, PhRMA respectfully recommends that CMS revise FAQ 8398 to more faithfully adhere to the provisions of CMS's final rule.

B. CMS Should Exclude All Meals at Accredited CME Events from Reporting

PhRMA recommends that CMS reconsider its position and exclude all meals at accredited CME events from reporting. Meals provided at accredited CME events should be excluded from reporting because the meals are not indirect payments to the physicians who attend the event. The final rule defines an indirect payment as a payment or transfer of value made by an applicable manufacturer to a covered recipient in which the applicable manufacturer "requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient."[4] When an applicable manufacturer sponsors a CME event, the CME provider has the discretion to use funds to provide meals to attendees or to direct it to other aspects of the event. The provision of meals at CME events does not meet the definition of indirect payment because the applicable manufacturer does not require, instruct, direct, or otherwise cause the CME provider to provide the meals at the event. Even if

[2] 42 C.F.R. § 403.904(g)(1)(1).

[3] 78 Fed. Reg. 9458, 9492 (Feb. 8, 2013).

[4] 42 C.F.R. § 403.902.

the applicable manufacturer is aware that a meal will be provided, the decision to provide the meal is solely that of the program organizer.

In addition, the reporting requirement discourages applicable manufacturers from providing funds for educational events. CME events are important means by which physicians receive additional education regarding medical advances and information about emerging technologies. The provision of meals at an educational event is a common practice in many professions. However, applicable manufacturers may be less inclined to sponsor CME events if part of the funds they provide will be reportable as meals provided to physicians.

Finally, PhRMA believes that requiring applicable manufacturers to report meals provided at CME events imposes an unnecessary burden on CME providers, who are not within the scope of the Sunshine Act. Applicable manufacturers must obtain information regarding attendees who receive meals at CME events from CME providers. CME providers are often small organizations that are not in the position to provide such information. Moreover, requiring CME providers to make information about attendees available to sponsoring applicable manufacturers is inconsistent with the notion of strict separation between the CME provider and commercial supporters, which is one of the hallmarks of the accrediting standards cited in the final rule.

For these reasons, PhRMA believes that CMS should exclude from reporting all meals provided at CME events.

C. Provision of Reprints to Covered Recipients Should Be Excluded from Reporting

Although CMS has indicated that the costs associated with reprints must be reported, PhRMA again recommends that CMS exclude reprints from the Sunshine Act reporting requirements. Reprints are an important means of providing prescribers with independent information regarding products and treatment options. Specifically, reprints provide prescribers with information, written by scientists and physicians, about diseases, products, treatment options, and other educational subjects.

FDA recognized the importance of reprints in providing scientific information about products in its guidance: *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*.[5] In this document, FDA established guidelines governing reprint practices, and companies have adopted standards to comply with FDA's guidelines. In particular, the guidance emphasizes the importance of providing the actual article or publication, rather than a summary prepared by the company.

Courts have also recognized that there is a First Amendment interest in providing truthful and nonmisleading scientific information to prescribers, most notably in the *Washington*

[5] *Available at* http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm.

Legal Foundation case.[6] The reporting requirements restrict this interest because covered recipients may refuse to accept reprints if doing so will lead to a report of a payment or transfer of value, suggesting that the recipient physician derived some economic benefit from the reprint. Requiring reprints to be reported therefore has the potential to harm the flow of information between physicians and the companies marketing the products.

PhRMA member companies report that they have already observed this decreased flow of scientific information to prescribers. For instance, some physicians have refused to accept reprints because they do not want the distribution of the reprints to be reported as a payment or transfer of value. Additionally, some physicians may be prohibited from receiving reprints because their institutions have adopted policies prohibiting transfers of value from pharmaceutical companies.

PhRMA also notes that requiring applicable manufacturers to report each instance in which a physician covered recipient is provided a reprint will drastically increase the amount of information submitted to CMS, which could prove onerous for the agency and decrease the utility of the information ultimately made available to the public. One PhRMA member, which is a mid-sized pharmaceutical company, estimates that it will provide between 8,000-10,000 reprints per year. The vast increase in reportable information will make it more difficult for the public to understand the actual nature of the relationship between pharmaceutical companies and physicians, and it could potentially stigmatize the exchange of scientific information regarding products and treatments.

D. Recruitment Expenses Should Be Excluded from Reporting

PhRMA respectfully urges CMS to reconsider its decision to require applicable manufacturers to report recruitment expenses for physicians. Specifically, PhRMA believes that CMS should exercise its enforcement discretion with respect to requiring applicable manufacturers to report the meals, travel, lodging, and other similar expenses associated with recruitment activities. PhRMA believes that requiring applicable manufacturers to report such expenses will harm the ability of physicians to investigate employment options at applicable manufacturers, and it would violate the confidential nature of employment searches.

Requiring applicable manufacturers to report recruitment expenses is contrary to the confidential nature of job searches. The confidential nature of recruitment is broadly accepted across professions in the United States, and the ability of physicians to explore changing employers is dependent on this information not being shared with their current employer. Confidentiality is essential to the recruitment process because it allows physicians to consider alternative employment options without worrying about how the search will affect their current positions. Disclosing information about physician recruitment activities will almost

[6] *See, e.g., Washington Legal Foundation v. Friedman*, 36 F. Supp. 2d 418 (D.D.C. 1999); *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).

certainly discourage some physicians from seeking employment with drug and device manufacturers.

E. Payments to Physician Board of Directors at Applicable Manufacturers Should Be Excluded from Reporting

PhRMA also encourages CMS to exclude payments or transfers of value made to physicians that serve on the board of directors of applicable manufacturers from reporting. PhRMA believes that such payments or transfers of value should be excluded from reporting because those payments and transfers of value are not made to the covered recipients in their capacities as treating physicians.

The statute recognizes that applicable manufacturers may make payments or transfers of value to physician covered recipients outside of their treatment of patients. In particular, the statute provides exemptions for certain payments and transfers of value when the physician is not acting in his or her role as a treating physician. Additionally, the final rule expands upon the statute's exclusion from reporting of payments or transfer of value when the physician provides services in connection with a civil or criminal action or an administrative proceeding.[7] For example, under the final rule, payments made to a physician serving as an expert witness for a legal defense would be excluded from reporting under the Sunshine Act. PhRMA also notes that while the statute does not include an exemption for payments or transfers of value provided in connection with existing personal relationships, CMS excluded these payments and transfers of value from reporting in the final rule.

Payments and transfers of value provided in the context of physicians serving on corporate boards at applicable manufacturers are similarly distinguishable. These payments and transfers of value are not related to the physician's role as a treating physician but are made to the physicians acting only in their capacity as corporate officers and directors.

Finally, requiring applicable manufacturers to report payments or transfers of value made to physicians serving on corporate boards could create misperceptions regarding compensation provided to non-physician members of corporate boards. If applicable manufacturers are required to report payments or transfers of value made to physicians serving in their capacity as corporate board members, such payments or transfers of value could be imputed to non-physician board members, who expect that this information will be kept confidential.

IV. Conclusion

PhRMA appreciates CMS's efforts to solicit the input of stakeholders on the burden on applicable manufacturers of implementing the Sunshine Act reporting requirements. PhRMA further appreciates the opportunity to comment on other key issues. We hope to

[7] 42 C.F.R. § 403.904(i)(13).

continue to serve as a constructive partner, together with other stakeholders, as the agency continues to implement this important legislation.

We plan to follow-up personally in the near future by seeking an in-person meeting to discuss these issues in greater detail. In the meantime, if you have any questions please do not hesitate to contact us.

Respectfully submitted,

Kendra A. Martello
Deputy Vice President, Strategic Operations
State Advocacy

John A. Murphy, III
Assistant General Counsel

PUBLIC SUBMISSION

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Docket: CMS-2013-0191
Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments (CMS-10495)
Comment On: CMS-2013-0191-0001
Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments (CMS-10495)
Document: CMS-2013-0191-DRAFT-0004
TX

Submitter Information

Name: Fred Trotter
Address:
Houston, TX, 77004
Email: fred.trotter@gmail.com

General Comment

Obviously you should use a unique identifier for each record. This should be a simple hash from the NPI.

It is deeply confusing why the NPI is not used by default here. It is a though you want to make it difficult to deal with this information as data. Its the bad old days of government obfuscation.

Is there no one who we could appeal to for reasonableness here? Its just silly.

-FT

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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September 20, 2013

Martique Jones
Deputy Director
Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

RE: Public Comment on Proposed Information Collection: *Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments*
Document Identifier: CMS-10493 and CMS-10495

Dear Ms. Jones:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Proposed Information Collection: *Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments* [also referred to as the Physician Payments Sunshine Act]. The proposed data collection exceeds the necessity and utility of the proposed data elements needed to implement the Open Payments Program (hereinafter referred to as the Sunshine Act Program). We strongly urge the Centers for Medicare & Medicaid Services (CMS) to adopt the recommendations outlined below in order to comply with the Paperwork Reduction Act (PRA).

CMS Enterprise Portal and User Identity Management Systems

CMS specifies that, in addition to registering for the Sunshine Act Program physician portal, physicians must first register with the CMS Enterprise Portal and User Identity Management Systems (EPIM). The discussion document does not contain a justification under the PRA for this requirement. As a result, we cannot evaluate whether or not there is a rational basis for this requirement. CMS is urged to provide a discussion and justification for this requirement and solicit comments before imposing this administrative burden.

Physician Emails and Phone Numbers

Physicians are not required by the Sunshine Act to provide CMS with their emails or phone numbers. The data templates appear to mandate the submission of information in order for physicians to utilize the Sunshine Act Program physician portal to review, dispute, and seek correction of reports, including

emails (business and personal) and phone numbers (business and personal). Requiring physicians to submit a broad scope of information not mandated by law, or creating the impression that such information is required as opposed to voluntary, violates the Sunshine Act statutory provisions. It also runs afoul of the congressional intent to limit the scope of personally identifiable physician information that would be disclosed to the public through the public Sunshine Act Program website or pursuant to Freedom of Information Act (FOIA) requests. To the extent that CMS concludes such information is essential for the implementation of elements of the program, such as electronic notification, we urge CMS to unambiguously communicate that the information solicited is not required and is protected by the Privacy Act and exempt from disclosure to third parties under FOIA.

Specifically, we urge CMS to clarify that the submission of phone numbers (business or personal) or emails (business or personal), is voluntary, and is not required to review Sunshine Act consolidated reports, dispute the contents of such reports, or secure corrections. Furthermore, to the extent that physicians (or their representatives) elect to receive notifications, they should not be compelled to provide more than one email or phone number for such notifications. Further, CMS must notify physicians in advance if the agency takes the position that voluntarily submitted information, such as emails and phone numbers, will be disclosed to the public based on a FOIA request or used for other agency or government activities. The agency is also required to notify physicians if it intends to use such contact information for any purpose other than the Sunshine Act Program.

The Sunshine Act limits the information that CMS may compel parties subject to the Sunshine Act to submit and further restricts what information may be provided to the public. For example, manufacturers are required to submit a physician's national provider identifier number (NPI), but the agency is prohibited from publishing this information in the Sunshine Act Program public database. The Sunshine Act Program provision of the Affordable Care Act modified the Social Security Act by adding a new section. This new section requires reporting entities to provide CMS with: (1) the name of the covered recipient; and (2) the business address of the covered recipient, and in the case of a covered recipient who is a physician, the specialty and NPI of the covered recipient. In a subsequent section, CMS is prohibited from including the NPIs in the public website. The data elements for identifying physicians were limited by Congress to ensure that the minimum amount of information was collected to protect the privacy interests of physicians and, equally important, to minimize the risk of identity theft.

To the extent physicians want to have CMS notify or communicate with the physician or the physician's representative, CMS should specify that physicians (and/or their representatives) have the option of: (1) logging into the online portal to obtain information without notification (via email, phone, or mail); or (2) selecting a method or method(s) of notification. Further, CMS should urge physicians to carefully select the method of communication or contact with the agency.

Estimated Impact and Burden of Review and Dispute Resolution

A number of erroneous assumptions were made when estimating the number of physicians who will be impacted by the reporting requirement and the burden of this program on physician practices. CMS' projections of anticipated burden on physicians and their designated representatives of reviewing Sunshine Act reports and achieving dispute resolution is based on an inadequate assessment of the number of physicians subject to reporting and extrapolated from state-based Sunshine reporting requirements that are not as broad in scope or nearly as complicated. Further, it does not appear that

physician organizations were systematically asked to provide comments on these projections though it appears other stakeholders were.

State-based reporting requirements are not reasonably comparable to the national Sunshine Act reporting requirement in terms of scope of items that are reportable, the number of physicians subject to reporting given the broad scope of indirect transfers included by CMS, as well as the inclusion of reprints and medical textbooks. Extrapolating the resource impact based on state transparency reporting requirements seriously underestimates the impact of the federal Sunshine Act. The Sunshine Act regulations include a broad number of indirect transfers, unrivaled in most state reporting requirements and well in excess of what is reasonably authorized by the federal statutory language. Furthermore, in recently issued sub-regulatory guidance, CMS expanded the reporting requirements to include reprints of articles from peer reviewed medical journals that are already readily available to physicians for free. Not only is this last minute decision estimated to triple the expected reporting requirement, but it is highly unlikely that the majority of physicians and patients would consider clinical resources, such as journal articles, reportable gifts. To the extent that physicians continue to accept such reprints, we anticipate widespread disputes over the correct fair market value since the reprint articles would be free in many cases to physicians and any other valuation would be contrary to the statute and congressional intent as the Sunshine Act was designed to capture the transfer of value to physicians—not convenience costs to manufacturers. At a time of austerity, these disputes are likely to consume significant physician resources and agency resources well in excess of projections based on indirect transfers and reprints alone.

Physician interest in reviewing such reports will be far more robust compared to state reporting registries given the ease of access to the national public registry and what is reasonably expected to be in-depth media coverage. CMS should anticipate that the majority of licensed physicians will seek to review and secure corrections to such reports in 2014. Currently, many physicians are unaware that they are receiving reportable indirect transfers. After the information is made public, there may be significant disputes related to valuations or characterizations of such transfers. Given the unworkable standard governing indirect transfers that undermines the limits established in the statute, we expect that there will be litigation that was not factored into the resource assessment of this document. Because false and inaccurate reporting could cause reputational harm and damages, including loss of patients, termination from employment or sanctions, increased governmental scrutiny, and deterioration in professional standing, CMS has underestimated the resources physicians will need to expend to ensure reports are accurate and fair and the costs in these other areas due to false and inaccurate reports. We expect the costs are easily double the current per physician time and cost estimate and should include most physicians.

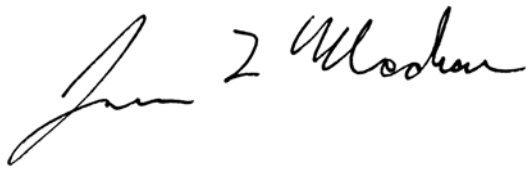
Finally, in light of the foregoing concerns, physicians are entitled as a matter of law, based on the Sunshine Act provisions and fundamental due process rights afforded to individuals who would be harmed by government action, to include public comments in the public registry on all transfers without regard to whether there is a dispute. Government actions that facilitate the publication of false, inaccurate, and/or misleading information about individuals without affording the individuals, in this case physicians, the opportunity to present their perspective is a denial of a fundamental due process. The AMA strongly urges the agency to give physicians the opportunity, through the public registry, to provide commentary about all reported transfers of value and ownership interests. CMS must provide physicians with the option to provide comments on their public reports similarly to reporting manufacturers and group purchasing organizations. Any other outcome denies physicians their fundamental due process rights and undermines the congressional intent that is at the core of the Sunshine Act that the public will

receive fair and accurate information with appropriate context. Furthermore, CMS has the authority to provide this option through sub-regulatory guidance since this was not prohibited in the final regulation.

The above is all the more pressing in light of reports that the majority of inaccurate reports will not be corrected prior to publication. Congress reasonably expected that the agency would provide an adequate amount of time for disputes to be resolved prior to publication. However, the AMA has received reports from individual manufacturers as well as major stakeholders, that there will be widespread errors and little to no likelihood that the disputes will be resolved prior to publication. Congress intended that disputes would, for the most part, be resolved prior to publication otherwise the pre-publication review period is without any meaningful value.

We appreciate the opportunity to comment and urge CMS to adopt the recommendations outlined above.

Sincerely,



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