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## **ISMPP Suggested Approaches for Sunshine Act Interpretation and Implementation for Publication Support Requirements**

### **Introduction and Background**

The International Society for Medical Publication Professionals (ISMPP) Sunshine Act Task Force (Task Force) has developed suggestions for its membership on the interpretation and implementation of the Sunshine Act requirements. These suggestions are specifically related to defining and reporting the value for publication support provided by applicable manufacturers (AM) to covered recipients (CR) who are authors on medical publications.

The Task Force offers these suggestions for consideration. They are not based on specific guidance received from the government; rather, they are based on our internal discussions and review of the Centers for Medicare and Medicaid Services (CMS) final rule and Q&A, which we have interpreted and translated to our profession. Members are advised to seek individual legal guidance on how their company interprets the Sunshine Act. Further, it is important to remember that the Sunshine Act does not replace any other reporting that may be required pursuant to Corporate Integrity Agreements or other agreements that an AM may have. Also, the Sunshine Act only preempts State or local laws to the extent that those laws require AMs to report the same type of information concerning payments or other transfers of value to CRs for the same purposes (ie, transparency). Finally, please note that the opinions expressed herein do not necessarily reflect those of the Task Force members' employers.

The Sunshine Act, Section 6002, Transparency Reports and Reporting of Physician Ownership or Investment Interests of the Patient Protection and Affordable Care Act, is referred to as the National Physician Payment Transparency Program: Open Payments. CMS provides details of the Sunshine Act and Open Payments program, definitions of AM and CR, reporting templates, exclusions, and other information at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>. Please note: CMS frequently updates the information on this site.

In order to create this suggestions document, ISMPP took several important steps. First, the Task Force, which was established approximately two years ago, spent significant time reviewing the final rule that was issued on February 8, 2013. Second, we met with representatives from the CMS, and conducted both formal and informal meetings with various stakeholders in the medical publications space. Based on these evaluations, we believe that

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publications support could be considered as a reportable transfer of value (TOV). Our third step was to draft a preliminary suggestions document, which was then reviewed and commented on by 12 representatives of AMs and the ISMPP Board of Trustees. The AM sectors included large and small pharmaceutical, biotech, and device companies. Finally, the Task Force members reviewed and integrated the reviewers' feedback, and the final document was approved by the ISMPP Board of Trustees.

During our meetings, we heard from many industry stakeholders, and many believe that the provision of publications support is a TOV to CRs who are authors on medical publications. However, there remain the questions of **how to determine the value that is transferred** and **how to apportion that value among CRs**. This document shares ISMPP's suggestions on how to approach this question, and is divided into the following sections:

- I. Scope of Reportable Activities
  - a. Suggested Activities Comprising Publication Support
  - b. Research versus Stand-Alone Activities
- II. Allocation of Value
  - a. Include the Work That an Author Most Likely Would Do
  - b. Do Not Include Work an Author Most Likely Would Not Do
- III. Assigning Value
  - a. Project-by-Project Determination
  - b. Average Fair Market Value
- IV. Reporting Date
  - a. As of August 1, 2013
  - b. Prior to August 1, 2013
- V. Communication with Covered Recipients
- VI. Acknowledgements

## **I. Scope of Reportable Activities**

The Task Force's understanding of the intent of the law is to promote transparency by reporting the value of all direct and indirect payments and TOVs made by AMs to CRs. Reporting obligations apply whether the actual payment or provision of support is provided directly by the AM or indirectly by a third party (eg, medical publications agency) at the instruction or direction of the AM.

For the purpose of medical publications, we consider the TOV as any support provided to CR authors for any publication that will be submitted, or is intended to be submitted, to a scientific or

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medical journal, or provided to authors/speakers for submission to or presentation at a professional congress (hereafter referred to as publication). A TOV is not reportable for authors of publications who are employees of the AM that provided the support; by extension, this also includes authors who are employees of the agencies that are paid by AMs.

Publication support may be provided to CRs either by an agency hired by the AM or by the AM directly (internal writers who are not authors). AMs should consider how to handle each of these scenarios if they occur in their organizations.

**a. Suggested Activities Comprising Publication Support**

ISMPP suggests that AMs consider the following activities when determining what comprises publication support provided by AMs to CRs:

- Medical writing and editing under the direction of the author(s)
- Statistical support performed specifically for the publication
- Literature searches and provision of references
- Graphic support
- Securing permissions/permission fees
- Journal submission
- Submission and publication fees (includes fees associated with open-access journals)
- Direct costs for travel, meals, and other expenses associated with performance of work associated with publications (eg, congress attendance; publication steering committee meeting)

This list is intended to be representative of typical activities and is not all inclusive.

**b. Research Versus Stand-Alone Activities**

The Task Force suggests that publication support activities are reportable regardless of whether they are included in or are outside of a research contract. The difference is the category in which the support is reported (ie, 'research' versus another reporting category). That is, a publication that is part of a larger research initiative pursuant to a research protocol or agreement would be reported on the Research Payments template, while support for a stand-alone publication would likely be reported in the 'compensation for services other than consulting' category on the General Payment (non-research) template. The templates (General Payments, Physician Ownership, and Research Payments) that have been provided by CMS are helpful in determining where to report

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research versus non-research-associated publication support (<http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10419.html>). According to the current Research Template (released on August 1, 2013), costs and TOV associated with research activities are reported as the total amount of the research payment for activities outlined in the research protocol or agreement. However, the Task Force suggests that AMs track all individual costs and TOV, including those associated with publication support, to ensure they are available should they be requested by CMS or requested by a CR in the dispute resolution process.

## II. Allocation of Value

The Task Force suggests that, in many instances, only a portion of the costs associated with the development of a publication should be regarded as a TOV to authors; some AM-mandated internal/operational activities may not be of value to authors. After considerable discussion among the Task Force and with the stakeholders who reviewed our draft suggestions, and in light of lack of specific guidance from CMS, we suggest that AMs individually determine the method for allocating specific TOV to each CR who was provided with publication support. The defining question is: What is the value of the specific tasks that the authors would have had to perform or secure for themselves if the AM had not provided publication support? Section III of this document proposes examples of how to calculate the answer to this question.

The Task Force suggests that AMs consider the following types of activities when determining the value of the publication support provided to CRs:

### a. Include the Work That an Author Would Most Likely Do

- Time to develop a submission-ready abstract and time associated with the submission process
- Time to develop an oral or poster presentation following abstract acceptance
- Time to develop content, incorporate co-author comments, and create graphics for submission-ready manuscript for publication
- Statistical analyses and support specifically for the publication
- Time associated with journal submission
- Time to revise manuscript based on peer-reviewers' feedback

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- Direct costs associated with any of the above activities; eg, copyright permissions, reference purchasing

**b. Do Not Include the Work That an Author Most Likely Would Not Do**

Do not include tasks that would most likely have no bearing on the value of the support provided to the author (tasks performed internally, ie, by AM employees, or externally, ie, by an agency), such as:

- Time spent to develop contracts or author agreements and time spent for review (direct client, legal, etc) and revisions
- Schedule development, time tracking, proposal development, general project management
- Information management (eg, publication planning database input, financial tracking, status reports)
- Status meetings
- Providing authors with information on GPP

These lists are intended to be representative of typical activities, not all inclusive.

**III. Assigning Value**

Once the TOV (value of the support) is calculated, each AM will have to determine how to assign value to individual authors. The Task Force suggests 2 approaches for consideration. Please bear in mind that companies may have other interpretations on how to assign value. The Task Force encourages individuals to seek internal legal and policy guidance on interpretation and application of the law to their company.

**a. Project-by-Project Determination**

The first approach is calculation of the TOV on a **project-by-project** basis, whereby the total cost of the publication support is divided by the number of authors associated with that publication. In this method, actual costs are determined and allocated to each external CR as completely as possible. Internal/company and ex-US authors are included in the calculation, but the TOV for these authors is not reportable.

**Examples**

A primary manuscript costs \$30,000. There are a total of 6 authors; 3 authors are US CRs, 2 authors reside and practice outside of the US and do not hold current US licenses, and 1 is an AM employee. For the purpose of this example, it is determined

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that 30% (\$9,000) of the total cost is for non-content-development activities. The total value of the content-development activities is \$21,000; the reportable TOV per author for the development of the manuscript is \$3,500 (\$21,000/6). TOVs are reported for the 3 US authors (3 x \$3,500). The 3 non-reportable authors do not affect the TOV to the CRs.

A secondary manuscript costs \$24,000; the authorship scenario and the non-content-related costs are the same. In this example, the total value of publication-support activities to authors is \$16,800, and the reportable per-author TOV is \$2,800 (\$16,800/6).

#### **b. Average Fair Market Value**

The second approach is to determine an average fair market value (FMV) for each publication type (eg, one for abstracts, one for manuscripts) such that regardless of the number of authors on a particular publication, the same FMV amount would always be reported per author. The FMV would be a sum of average costs associated with the type of publication (eg, average internal or vendor costs for medical writing, average cost for statistical support, average congress/submission fees, and other costs deemed reportable by the AM) divided by the average number of authors on that publication type (each AM to determine a representative sample size).

#### ***Example***

The average cost per manuscript for Company X is determined to be \$28,000 with an average of 6 authors per manuscript, based on a historical assessment of costs of manuscripts and number of authors over an extended period of time. For the purpose of this example, the average non-content-related costs are 27%. Thus, the content-related work costs \$20,440, and the reportable per-author FMV is \$3,406 per manuscript (\$20,440/6). This value will be reported for each author for all manuscripts, regardless of the number of authors.

Regardless of the approach used to determine the value reported, the Task Force suggests preparing and submitting an assumptions document to CMS that provides transparency into the method used to calculate the attributed value of publication support provided to a CR.

The Task Force recognizes the complexity of this assessment, given the variety of situations and varying levels of support and involvement that multiple authors may have in any publication.

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Since CMS has given no specific guidance on how to apportion individual TOV to specific situations, the Task Force is not in a position at this time to suggest a prescriptive algorithm to apportion specific TOV.

#### **IV. Reporting Date**

##### **a. As of August 1, 2013**

Applicable manufacturers must track the date that a payment or TOV was provided to the CR, as well as the amount of payment or TOV and appropriate payment or TOV category. In certain circumstances, AMs have flexibility to determine the methodology for reporting the date of the TOV. For example, in the instance of travel benefits, the purchase date (of airline tickets, for example) may be different than the date the value is actually “transferred” to the CR (ie, when the physician takes the flight). Applicable manufacturers have some flexibility to choose which payment date they will use for travel payments; however, the methodology used must be consistent within a single nature of payment category.

With respect to publications, the Task Force suggests that, generally, the date of initial submission to the journal or congress be used as the date of provision of the TOV. There may be situations, however, where this approach is not feasible (ie, the journal/abstract is not ultimately submitted) and, in such cases, the AM must determine if and when a CR has received a TOV.

##### **b. Prior to August 1, 2013**

If a physician provides consulting or other services prior to August 1, 2013, but an AM does not pay the physician for the service until or after August 1, 2013, such payment is reportable because the payment was provided to the physician after the start of the tracking and reporting requirements. AMs do not have flexibility to designate the date of the physician’s service as the “date of payment.” Rather, the date of payment would be the date the AM post-marked the check or funds transfer to the physician to compensate him/her for the services rendered. A TOV provided or paid for prior to August 1, 2013 is not required to be reported to CMS.

#### **V. Communication with Covered Recipients**

The Task Force suggests that consideration be given to informing CRs that data collection began on August 1, 2013, and that any TOV they receive after this date will be reported as

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required by the law. AMs may wish to do this as part of the author communication process that is already in place.

## **VI. Acknowledgements**

*The following members of the Task Force authored this document. Please note: the opinions expressed by the authors may not necessarily reflect those of their employers.*

- Kim Pepitone, BA, CMPP (Task Force Vice Chair); Scientific Director, Cactus Communications
- Bob Norris; Founder, CHC Group; ISMPP Past President (2005-2006), and Founding Member, ISMPP
- Angela Cairns, BSc, CMPP; SVP, Medical & Scientific Services and Global Compliance Team Leader, KnowledgePoint360 Group

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