



520 White Plains Road, Suite 500, Tarrytown, NY 10591 USA / Tel & Fax: +1 914 618 4453 / email: ismpp@ismpp.org

ISMPP Sunshine Act Information Update

The ISMPP Sunshine Act Task Force (Task Force) has prepared this document in keeping with our commitment to share information that we learn about the interpretation of the Sunshine Act (Open Payments). It contains information based on recent discussions with industry company representatives who are involved with medical publications, and is provided as information supplementary to that contained in the ISMPP Suggestions Document issued August 13, 2013.¹

Based on our most recent research and discussions, we have learned that there are a number of categories of interpretation regarding the question: “Is support for the development of medical publications provided by applicable manufacturers (AM) to covered recipients (CR) a reportable transfer of value (TOV)?” The Centers for Medicare and Medicaid Services (CMS) definitions of AM and CR can be found on page 2 of this document. The table below presents three broad categories of interpretation and the associated proposed rationale. Please bear in mind that based on the differing interpretations by industry companies, there may be other categories of interpretation that are not captured below.

Table. Three general interpretations of reportability of publication support provided by AMs to CRs

Interpretation	Proposed Rationale
Yes , support for medical publications is a reportable TOV	There is a TOV associated with support provided by an AM to authors who are CRs for work that authors would have had to perform or secure for themselves if the AM had not provided the support
No , support for medical publications is not a reportable TOV	The value of the support provided by AMs to CR authors is to the AMs, as it helps the AMs meet their ethical obligations to publish their data in a timely manner; there is no value to be transferred to authors
Support for publications may be a reportable TOV, depending on the circumstance	<p>Examples</p> <p>Original research: The value of the support provided by AMs to CR authors is to the AMs, as it helps the AMs meet their ethical obligations to publish their data in a timely manner; there is no value to be transferred to authors</p> <p>Reviews; author-initiated request for help: The value of the support provided by AMs to CR authors is to the CRs; the reportable TOV is for the work that authors would have had to perform or secure for themselves if the AM had not provided the support</p>

Prior to taking any action regarding the Sunshine Act, or responding to queries, we advise you to seek individual legal guidance on how your company interprets the law.

¹ [http://www.ismpp.org/assets/docs/Inititives/Sunshine_Act/ismpp%20task%20force%](http://www.ismpp.org/assets/docs/Inititives/Sunshine_Act/ismpp%20task%20force%20update.pdf)

The information presented here regarding interpretation and implementation of the Sunshine Act offered to ISMPP members is based on the research of the Task Force and should not be construed as legal advice. Members are advised to seek individual legal guidance on how their company interprets the law.



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About the Sunshine Act

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. The Act requires that AMs in the pharmaceutical, biotechnology, and device industries, among others, report certain payments and TOVs made to CRs, broadly defined as physicians licensed to practice in the US. Details about the act, reporting templates, exclusions, and other information can be found 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.

CMS Definitions

Applicable manufacturers (AM) are entities that operate in the United States and (1) are engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biologic, or medical supply, but not if such covered drug, device, biologic or medical supply is solely for use by or within the entity itself or by the entity's own patients (this definition does not include distributors or wholesalers [including, but not limited to, repackagers, relabelers, and kit assemblers] that do not hold title to any covered drug, device, biologic or medical supply); or (2) are entities under common ownership with an entity described in part (1) of this definition, which provide assistance or support to such entities with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biologic, or medical supply.

Covered recipients (CR) are any physicians who are not employees of the applicable manufacturer that is reporting the payment (they include doctors of medicine and osteopathy, dentists, doctors of dental surgery, podiatrists, optometrists, and chiropractors, who are legally authorized to practice); or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient hospital prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available.

Disclaimer

When making decisions with respect to implementation of the Sunshine Act, ISMPP members are advised to seek individual legal guidance on their company's interpretation of the 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.

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