Physician Payment Sunshine Act FAQ  
Revised May 17, 2012

Q. On what has ISMPP based the responses in this FAQ document?

A. The responses in this FAQ have been developed from the information contained in section 1128G of the Patient Protection and Affordable Care Act (commonly referred to as the Physician Payment Sunshine Act or simply the Sunshine Act) and the proposed rules for implementation.¹,²

Disclaimer: ISMPP is providing this information to assist our members in understanding some of the details of the Sunshine Act. It is not intended to provide legal guidance, and we recommend that readers consult the full guidance (see References) for more details before acting on information provided in this document.

Q. What types of companies are covered by the Sunshine Act?

A. The Sunshine Act requires “any applicable manufacturer that provides a payment or other transfer of value [to covered recipients] to report certain information to the Center for Medicare and Medicaid Services (CMS), part of the US Department of Health and Human Services (DHHS) regarding those payments and other transfers of value.” Applicable manufacturers include all companies operating in the US that manufacture drugs, devices, biologics, or medical products that are reimbursable by the US Federal Government or are under common ownership of such companies.

Q. Who are the “covered recipients”?

A. According to the proposed rules for implementation, covered recipients are defined as (1) US physicians (doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and licensed chiropractors); however employees of applicable manufacturers are exempt; 2) US teaching hospitals.
Q. **What are the minimum reporting requirements?**

A. The proposed regulations require that the following minimum information be reported:
   1. Covered recipient’s name, address, specialty and national provider identifiers
   2. Amount of payment or transfer of value
   3. Date of payment
   4. Associated covered drug, device, biologic or medical supply (where applicable)
   5. Form of payment (selected from a pre-defined list)
   6. Nature of payment (selected from a pre-defined list)
   7. Third-party recipient, if applicable (eg, charitable contribution on behalf of a physician)
   8. Ownership or investments associated with the applicable manufacturer (direct recipient and immediate family member[s])

Q. **Does reporting apply only to payments and activities associated with products that are available in the US?**

A. No. The proposed rules suggest that reporting requirements will apply to all products, including those in development, if a company has one or more products available in the US.

Q. **Does it matter where the support was given from, eg, US or Europe?**

A. No. The proposed rules suggest that the Sunshine Act will apply to all companies that manufacture products that are reimbursed by the US federal government, irrespective of geographic location, if they meet the definition of an ‘applicable manufacturer’, as outlined above.

Q. **When does reporting begin?**

A. According to the most currently available information (as of March 9, 2012), due to a delay in finalization of the rules for implementation data collection is now required to begin in January 1, 2013.³
Q. What happened during the open comment period, which allowed for a response to the proposed rules in the December 18, 2011, Federal Register?

A. The CMS received 350 comments during the open comment period, which were posted by a wide range of stakeholders. The CMS has committed to reviewing the comments, and to including input from stakeholders as they write the final rules for implementation. As noted below, ISMPP was among the stakeholders who submitted a comment during the open comment period. As of May 14, 2012, the CMS has not committed to when the final rules for implementing the new law will be published.

Q. What steps should I be taking now to prepare for and be able to respond to the Sunshine Act?

A. The proposed CMS database will include extensive information. It is critical to set up a system now that allows for the tracking of this information.

Q. Is publication support covered by the Sunshine Act?

A. As of now, there are no specific requirements stated in the Sunshine Act with respect to support for publications. However, it is anticipated that publication assistance will be included in the final regulations for implementation.

Q. How should I respond to authors who are asking questions now about how this will impact them?

A. It is suggested that you let the author know that there still is no clear guidance on this particular issue, and that you will update the author as soon as details become available. In the meantime, you hope that he/she will continue to work with you to ensure that data are available in an end-user-friendly format that will support clinicians in their clinical healthcare decision-making.

Q. What is ISMPP doing to help its membership with respect to the Sunshine Act and publications?

A. ISMPP has established a Sunshine Act Task Force, details of which can be found at http://ismpp.org/initiatives/sunshineact.html. The remit of the Task Force is to follow the issues, understand the details and implications, and, most
importantly, provide information and tools to our membership with respect to the Sunshine Act and medical publications. Activities to date include research, media and activities monitoring, response to the proposed rules in the December 18, 2011, Federal Register, publication of an article in the AMWA journal (March 2012 issue), and attendance at key industry and other associated meetings. Outputs from our various activities will be available on the ISMPP website.

On May 14, 2012, ISMPP participated in a meeting at HHS CMS to elaborate on our concerns and to provide suggestions on how we think the law can be implemented without causing unintended consequences to the dissemination of clinical trial data through publications or unnecessary burden to ISMPP members. Details about the meeting can be found at http://www.ismpp.org/initiatives/Files/ISMPP%20meeting%20with%20HHS%20CMS%20May%2014%202012%20FINAL.pdf

References

