Frequently Asked Questions

Sunshine Act
1. What is the Sunshine Act and where did it come from?

The Sunshine Act and corresponding regulations require certain manufacturers that produce drugs, medical supplies and devices to publically report payments or “other transfers of value” they make to physicians (including optometrists) and teaching hospitals. The Sunshine Act does NOT prohibit activities or interactions. Rather, the Sunshine Act requires that certain gifts and payments are publically disclosed.

Senator Charles Grassley, M.A., Ph.D. (R-IA) and former senator Herb Kohl (D-WI) championed the law because they wanted to draw attention to possible conflicts of interest that could influence patient care and potentially harm patients.

2. Why is AOA educating members on the Sunshine Act?

The Sunshine Act will affect members of the American Optometric Association (AOA) and state affiliates because manufacturers will be required to track and report payments and transfers of value made to optometrists. Manufacturer reports will be submitted to the Centers for Medicare & Medicaid Services (CMS) and CMS will ultimately make these reports publically available. Patients who are treated by optometrists will be able to review this data.

3. What are PhRMA / PhRMA Guidelines? Do they relate to the Sunshine Act?

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code is voluntary for research-based pharmaceutical and biotechnology companies to guide their interactions with health care professionals primarily with respect to marketed products and related pre-launch activities. Companies that choose to abide by the PhRMA Code agree not to engage in certain activities.

The Sunshine Act is a federal law that requires some manufacturers to report on payments or other “transfers of value” that the companies provide to physicians, including optometrists. The Sunshine Act does not prohibit activities or interactions between manufacturers and optometrists.

4. What is AdvaMed? Does it relate to the Sunshine Act?

The Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals is voluntary for companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies to facilitate their ethical interactions with health care professionals. Companies that are certified to abide by the AdvaMed code agree not to engage in certain activities.

The Sunshine Act is a federal law that requires some manufacturers to report on payments or other “transfers of value” that the companies provide to physicians, including optometrists. The Sunshine Act does not prohibit activities or interactions between manufacturers and optometrists.
5. Are contact lenses 'covered products' subjecting their manufacturer to reporting requirements?

Contact lenses are considered “medical devices” by the Food and Drug Administration (FDA). The FDA does not classify contact lenses as drugs or pharmaceuticals. It is important to note that pharmaceuticals are not the only products that are impacted under the Sunshine Act. Specifically, the law affects manufacturers “operating in the United States to produce, prepare, propagate, compound, or convert a drug, device, biological, or medical supply covered by Medicare, Medicaid, or CHIP.” Additionally, the regulations indicate that generally, if a manufacturer has at least one covered product for sale or distribution in the United States, it must report all payments to doctors, including payments to doctors that are not associated with a covered product.

6. What Is Health Care compliance?

In this context, “compliance” generally refers to manufacturers’ efforts to abide by various federal and state healthcare fraud and abuse laws. The two core activities that these laws are intended to prevent are:

- Kickbacks – payments or other transfers of value given in a manner that unduly influences the prescription or sale of a drug or medical device,
- Off label promotion – manufacturers promoting their products in a manner that’s inconsistent with the package insert or direction for use.

A strong healthcare compliance program should be founded upon the seven elements of effective compliance as established by the Office of Inspector General (OIG), Department of Health and Human Services (HHS), in the document entitled, “Compliance Program Guidance for Pharmaceutical Manufacturers.”

7. What can a company support? What are the differences between sponsorship and education grant funding?

Optometry is a unique medical profession as corporate support comes from a broad spectrum - from pharmaceutical companies to medical device companies. Based on their line of products, each supporter may have their own rules and guidelines for funding. Those that are directly impacted by the Sunshine Act are required to report value of support that the companies provide to physicians, including optometrists.

The state affiliate should first determine if the intended sponsor(s) is following any specific guidelines or is impacted by the Sunshine Act.

Pharmaceutical and contact lens manufacturers typically have two avenues of support:

1) “independent medical education” grants, where the manufacturer typically provides unrestricted funding and does not influence the content or receive value in return, and
2) marketing/promotional funds where a manufacturer purchases an exhibit or similar promotional opportunity.

Most pharmaceutical and device companies typically have stringent policies directing what activities and benefits may be received for funding support.
8. Examples of compliant collaborations/scenarios

- Promotional exhibits in an exhibit hall and payments for promotional podium time (when the time is clearly separate from any continuing education (CE) content). These are evaluated to ensure they’re consistent with Fair Market Value (FMV). This sometimes involves comparing multiple, similar events that occur in separate parts of the country, as well as comparing optometry events to events involving medical doctors. The best collaboration occurs when the organizer is flexible and understanding if asked to alter the benefits to meet our FMV assessment.

- Exhibits and/or corporate or product branding opportunities at programs or events for industry-relevant organizations such as patient advocacy groups, charitable organizations, healthcare professional groups and associations, not-for-profit colleges and universities, civic and cultural organizations, professional groups and other similar groups.

- Exhibits or displays located completely apart from any independent educational activities or continuing medical education (CME) events.

9. Can you provide an example of a sponsorship request that was declined?

An affiliate association submitted one “promotional” request to a pharmaceutical company for support of its annual meeting. The single request included benefits such as receive recognition on a golf hole, recognition on a CE course, an exhibit booth and promotional/branding on signage at the meeting.

Reasons why this request was denied from a pharmaceutical company standpoint:

- Recognition on the CE course was problematic because education grants must be independent of any marketing or brands. The education grant request should be for the overall education only and not have any marketing benefits. The association should not be directed or receive input by the company on specific speakers for the program.

- Recognition on a golf hole implies that the supporter is sponsoring the hole. This may raise red flags with the compliance at the PhRMA company as this may be perceived as “entertainment.” These types of benefits or programs are typically not activities that PhRMA companies can support.

When these benefits are packaged together, if there are benefits a PhRMA company cannot be involved with, the entire request is declined.

10. Why can't a PhRMA company sponsor a state affiliate reception or golf outing?

This type of activity may be viewed as entertainment. Companies that adhere to the PhRMA and AdvaMed Codes typically do not support these activities.
11. What are the trends in activities/events that a PhRMA or AdvaMed company cannot support?

Trends are showing that many companies who follow PhRMA typically do not support receptions, golf tournaments or entertainment activities.

Food and beverage activities that include spouses are not supported based on PhRMA guidelines.

12. Why do companies that follow PhRMA or AdvaMed, have different interpretation and guidelines?

The PhRMA and AdvaMed guidelines do not necessarily cover every situation. As guidelines, they can be open to interpretation. Some companies have their own internal risk aversion or compliance policies.

13. What does a state have to do to be compliant and eligible to receive sponsorship support?

In general to be able to receive support or sponsorship, an affiliate should first determine what guidelines the company may be following.

The company may require certain conditions for funding – including tracking state license numbers at sponsored functions.

With regard to the Sunshine Act, by statute, manufacturers, not states or optometrists, are required to comply with the Sunshine Act. The Sunshine Act does not prohibit manufacturers from sponsoring events. Rather, the Sunshine Act requires that certain gifts and payments are publically disclosed.

14. Is there a uniform "form" to fill out?

Yes. CMS will provide data collection templates for manufacturers. The 2013 reporting period data collection templates can be found on the CMS OPEN PAYMENTS website.

15. Does the Sunshine Act require awareness by the individual optometrist or must all members of the practice be informed as well?

It is important to emphasize that the burden of compliance falls to manufacturers. Manufacturers must report to CMS certain payments and gifts provided to optometrists. Optometrists may want to share AOA resources regarding the Sunshine Act with staff members so they are aware that certain gifts provided by manufacturers will be reported by the manufacturer to CMS.
16. What Impact does the Sunshine Act have on local (smaller) society and association meetings when attendance is recorded and a meal or other refreshments are provided by an industry stakeholder?

The responsibility for complying with the Sunshine Act falls to manufacturers. However, manufacturers may call on societies for assistance in complying with the Sunshine Act in the sponsorship or support agreement with the society. Again, associations and societies are not responsible for complying with the Sunshine Act, and the law does not prohibit industry support.

17. Why do I have to track the state license number(s) of attendees that participate in a sponsored branding symposium?

Under the regulations for the Sunshine Act, CMS will require manufacturers to include state license numbers for all of the physicians they report. The manufacturers have to track state license numbers. In turn, the manufacturers may turn to state affiliates to help collect this information. You may be asked to track state license numbers if you are receiving corporate funding from a company impacted by the Sunshine Act.

18. Who gets this information and what do they do with it? What can a member do if an inaccurate finding is posted by a company on Centers for Medicare and Medicaid Services (CMS) site?

The CMS will receive this information and post for public review. Manufacturers will begin data collection August 1, 2013 and report this data to CMS by March 31, 2014. CMS will post the information to the CMS Open Payments website on September 30, 2014.

CMS will announce a 45-day period next summer when optometrists will have the opportunity to review the data submitted by manufacturers and dispute information in their reports. The manufacturer will then work with the physician to correct the information. If the dispute is resolved, then the manufacturers will send CMS a revised report. Unfortunately, CMS will not help resolve discrepancies, so some reports may include incorrect information. The AOA was disappointed that CMS will not ensure that incorrect information will be removed.

CMS will provide additional information about registration later in 2013 and AOA will share that information with members.

CMS has also indicated that they will notify physicians and teaching hospitals of the review period using email list serves, online postings (including both on the CMS Web site and the Federal Register) and directly (likely by email) to any physicians or teaching hospitals that have registered with CMS ahead of time.
19. Will the AOA help publicize when and how members can view the initial reported information during the 45-day period before the data is posted for the public?

Manufacturers will be expected to report information to CMS by March 31 annually, and CMS will publish the information annually by September 30. Although the review and correction process may be available year-round, AOA expects the specific 45-day pre-publication review to occur in the summer. AOA and CMS will publicize the deadlines.

AOA will continue to educate members regarding the impact of the Sunshine Act. Members should also know that CMS plans to ask optometrists that would like to review their reported information to register with CMS using the CMS Enterprise Portal. Once registered, optometrists will be able to access a secure website that allows them to submit or review data securely.

20. What resources will the AOA make available to members regarding the Sunshine Act?

The AOA has written a white paper entitled *Sunshine Act – Impact on Optometry*.

Additional resources can be found at the AOA’s Sunshine Act webpage. This site will be monitored and updated as new information becomes available. CMS also has numerous resources available.

CMS has released two mobile apps to streamline the Open Payments program. The apps are available to help physicians and others track payments and other information they receive throughout the year, making annual reporting easier and ensuring greater data accuracy.

Members and affiliates are also welcome to contact the AOA Office of Regulatory Policy, Washington, D.C. at 800-365-2219 with any additional questions.