



American Optometric Association

Sunshine Act

Impact on Optometry

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AOA Ethics & Values Committee Report: April 1, 2013

On Febr. 1, 2013, the Centers for Medicare & Medicaid Services (CMS) released final regulations titled "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests." These regulations carry out a provision of the Affordable Care Act (ACA) commonly referred to as the "Physician Sunshine Act." This provision was included in the ACA as an attempt to increase transparency with regard to financial relationships that exist between health care product manufacturers and physicians.

The Sunshine Act and corresponding regulations require certain manufacturers that produce drugs, medical supplies and devices covered under Medicare or state plans under Medicaid or Children's Health Insurance Program (CHIP) to report annually to the Secretary of the Department of Health & Human Services payments or "other transfers of value" made by the manufacturer to physicians and teaching hospitals.

The Sunshine Act does not prohibit or restrict any such payments or transfers in value. The law only requires public reporting. Meanwhile, state laws that require additional reporting remain valid, but state laws that collect the same information would be pre-empted by the federal law. In addition, state laws that govern or restrict such transactions are unaffected.

This concept of publicly disclosing payments made to physicians by manufacturers is attributed to Sens. Charles Grassley (R-Iowa) and Herb Kohl (D-Wisc.). It is believed that public disclosure

of these types of manufacturer payments could limit actual and perceived conflicts of interest that may have been prevalent in the past. While each health profession, including optometry, provides ethical standards of conduct for practitioners, the influence of industry on doctors' decision-making has more recently come under much closer scrutiny. An article in the Journal of the American Medical Association (JAMA) proposed a policy for academic health centers resulting from studies clearly indicating these marketing "incentives" often pose significant challenges in medical decision-making.¹ While physicians have a primary commitment to patient care, a segment of practitioners are often influenced by financial incentives offered by industry as a means of more effectively marketing their products.

Although physician groups and medical-related industries have enacted self-regulations in recent years, evidence continues to mount that conflict of interest guidelines do not satisfactorily protect patients when physician integrity is clouded by personal financial incentives.² In a recent article, the American Medical Association (AMA) urged more clarity in gift-giving guidelines.³

The Sunshine Act will affect physicians, including medical doctors, osteopathic physicians, dentists, optometrists, podiatrists and chiropractors. The burden for tracking and reporting payments and transfers of value will fall to the manufacturers. The impacted manufacturers must begin to collect the required data regarding payments or "other transfers of value" on Aug. 1, 2013, and report the data to the CMS by March 31, 2014. There will be no retroactive reporting.

Optometrists and other doctors will not be required to submit reports to the HHS; only manufacturers will be required to submit this information. It is important to note that prior to

SUNSHINE ACT

Impact on Optometry

public reporting, optometrists will be provided the opportunity to review the manufacturer-provided report regarding gifts provided to the physician. Although it may be an additional documentation burden, optometrists may want to keep a log of gifts received from manufacturers to ensure the manufacturer report is accurate.

Not all gifts provided to physicians by manufacturers will be required to be reported. Only payments or other transfers of value of more than \$10 need to be reported, or, if the total annual value of payments or other transfers of value provided by a manufacturer to a physician exceeds \$100, those payments would also need to be reported. By regulation, several exemptions exist. Most notably, there are some exemptions for large-scale conferences sponsored by manufacturers. Small incidental items under \$10 (such as pens and note pads) provided at large-scale conferences and similar large-scale events are exempt from reporting. These items are also exempt from the need to track them for aggregation purposes. Additionally, if a manufacturer provides a large buffet meal, snacks or coffee that are made available to all conference attendees and where it would be difficult to establish the identities of the physicians who partook in the meal or snack, no information would need to be reported.

The broad definition of “payment” or “transfer of value” includes:

- Cash or cash equivalent
- In-kind items or services
- Provision of stock, or stock options, or any other ownership interest, dividend, profit, or other return on investment.

More specifically the “payment” or “transfer of value” refers to any of the following:

- Honoraria (speaker fees) sponsored in

whole or part by industry

- Consulting fees for services rendered to industry
- Compensation for other services, aside from the aforementioned consulting fees, such as speaking at an event not related to continuing education
- Gifts (cash or product) other than samples intended for patient care
- Entertainment
- Travel and housing
- Food and beverage
- Education, sponsored in whole or part by industry where the costs are partially or fully absorbed by industry or the education is related to product manufactured or distributed by industry
- Research sponsored by an industry grant
- Charitable contributions from industry
- Royalty or license fees
- Grants.

There is a concern in the provider community that required public reporting could result in misleading perceptions regarding relationships between industry and physicians. Likewise, these disclosures alone do not ensure the establishment of ethical standards or physician integrity. The CMS has acknowledged these concerns in its final regulations and noted: “disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts.”⁴

SUNSHINE ACT

Impact on Optometry

In the ever-changing and evolving world of health care, it is an imperative for physicians to continuously expand their knowledge of new treatment strategies, technologies, and products to enhance patient care. This information is available in a myriad of ways, including the scientific literature, educational programs, marketing materials, exhibits at professional meetings, and direct contact with industry representatives whose performance is based on sales. However, it is important to understand interactions between physicians and industry representatives can be of high value and lead to improved patient care without necessarily compromising the ethics and integrity of the physician.

The [AOA Code of Ethics and Standards of Professional Conduct](#) both subscribe to the tenets of transparency, truthfulness and avoidance of conflicts of interest that are contained within the Sunshine Act reporting guidelines. The code includes the resolve that optometrists recognize their obligation to protect the health and welfare of society and to conduct themselves as exemplary citizens and professionals with honesty, fairness, kindness and compassion.

The Standards of Professional Conduct directly address these tenets under Non-Patient Professional Relationships. To quote, "Optometrists have an obligation to conduct themselves with integrity and without conflicts of interest in all of their professional relationships. In their interactions with industry, optometrists are expected to maintain the highest level of ethical conduct in order to retain their professional autonomy and clinical integrity. Optometrists have a responsibility to provide the best care possible for their patients and to continuously advance their clinical and scientific knowledge. Industry can be a valuable resource in these endeavors. However, optometrists should

avoid situations and activities that would not be in the best interests of their patients. Any financial and/or material incentive offered by industry that creates an inappropriate influence on an optometrist's clinical judgment should be avoided."

The Sunshine Act's intent to increase transparency and truthfulness while avoiding conflicts of interest could enhance the doctor-patient relationship in harmony with our fiduciary responsibilities detailed in the AOA Code of Ethics and Standards of Professional Conduct. However, the precise impact to optometry of this new federal regulation is not clear, and concerns regarding the expense, efficacy, and potential overreach are prudent.

References:

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2. Bieri D. "PhRMA's Code on Interactions with Healthcare Professionals." *Am J Bioeth*. 2010 Oct; 10 (10):18.
3. Fiegl, Charles. "AMA urges more clarity in gift-reporting rules." *amednews.com*. American Medical Association. 22 October 2012.
4. Department of Health & Human Services. Rules & Regulations. Federal Register. <http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf> ; 2013 Feb 8.