

# The Sunshine Act: What Manufacturers, Clinical Professionals, and Researchers Need to Know

NAMSA®

Mark Gardner, MBA, JD, Associate, DuVal & Associates, PA  
Suzanne Sullivan, RN, CCRA, Manager, Clinical Research Services, NAMSA

Clinical

*NAMSA Whitepaper #12 10/2014*



# The Sunshine Act: What Manufacturers, Clinical Professionals, and Researchers Need to Know



Mark Gardner, MBA, JD (gardner@duvalfdalaw.com, 612-382-7584) is an Associate Attorney at DuVal & Associates, PA, a law firm dedicated to counseling FDA-regulated companies. Mark's areas of expertise include FDA regulation; enforcement actions; design and implementation of regulatory compliance programs addressing sunshine, anti-kickback, false claims, and privacy laws and regulations; promotional and marketing strategy review; and regulatory submissions. Prior to practicing law Mark worked in product commercialization at three medical device companies over a 10-year span. Mark teaches FDA law at Hamline University School of Law, co-chairs the Regulatory Special Interest Group at LifeScience Alley, and is the former chairman and a current council member for the Minnesota State Bar Association Food, Drug and Device Law Section.

## Introduction

This white paper focuses on research reporting requirements set forth under the Physician Payments Sunshine Act (Sunshine Act).<sup>1,2</sup> The Sunshine Act was passed in 2010 as part of the Patient Protection and Affordable Care Act and became effective as of April 9, 2013. The new law requires that device, pharmaceutical, biologics, and medical supply manufacturers collect and report to the Centers for Medicare and Medicaid Services (CMS) information concerning payments to physicians and teaching hospitals, in addition to physician ownership or investment interests<sup>2</sup> (Final Rule, p 9458). A "payment" includes cash or in-kind transfers of value, eg, compensation, food, entertainment, gifts, travel, consulting fees, honoraria, research funding, grants, charity, education, conference funding, stock, stock options, royalties, and licensing fees, among other things. If payments are \$10 or greater, or \$100 or more in aggregate per year, they must be reported (p 9485). The reporting cycle for 2013 data is complete. On September 30, 2014, CMS published the 2013 sunshine data on its Open Payments<sup>3</sup> website. Anyone with an access to the internet may view the data. The next reporting deadline is March 31, 2015 for payments made during calendar year 2014.

The Sunshine Act does not bar gifts, it merely requires manufacturers to report them. Remuneration/payments that constitute an "inducement" are prohibited by the federal Anti-Kickback Statute and state law corollaries, and are not in compliance with voluntary industry codes such as those those developed by AdvaMed or PhRMA. Discerning when remuneration rises to the level of an inducement is subject to interpretation and is not the focus of this white paper. The Sunshine Act also requires that manufacturers disclose physician ownership or investment interests. Fines for non-compliance range from \$1000-10,000 per occurrence for unintentional conduct and \$10,000-\$100,000 per occurrence for intentional conduct, with a cap of \$1,150,000 per year per applicable manufacturer (p 9506, 9507). What follows are various Sunshine nuances related to research.

## Reporting Research Payments

In Title 42,<sup>4</sup> CMS defines research as "[A] systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-science research" (Section 50.603). Research payments made to physicians and teaching hospitals are reported under a special "research" specification and not under the "general" payments specification. Previously, "research" was included under the "general" payments specification as a "nature of payment" option. *Research was removed from the general payments specification because CMS requires research payments be presented separately and distinctly to the viewing public on the Open Payments<sup>3</sup> website.* If payments do not meet the definition of research they must be reported as general payments using various "nature of payment" categories delineated by CMS, eg, consulting, gift, food and beverage, education, etc<sup>2</sup> (pp 9475, 9481). In sum, if payments are related to research, applicable manufactures must use the research specification from CMS (p 9483). Such payments can be reported in aggregate as a single research payment if the activity in question meets the definition of research and the payments are subject to a written agreement and/

# Patient Protection and Affordable Care Act



or a research protocol where such payments are contemplated (p 9484). Reporting in aggregate can be an advantage to manufacturers since less reporting detail is required and thus time is saved.

## What Information Needs to Be Collected and Reported Under the Research Specification?

Certain information needs to be collected and reported to CMS<sup>2</sup> (pp 9483-9484), such as covered recipient name; National Provider Identifier (NPI); primary type (MD, DO, DDS, DPM, OD, DCP); state license number (at least one state where license maintained and held); specialty; address; tax ID for teaching hospitals; payment amount; name of the research study; name of product(s) (include NDC if drug); and principal investigator. Manufacturers may at their discretion (but are not required to) report contextual information, eg, ClinicalTrials.gov identifier; research expenditure category (salary, writing/publication, patient care, non-patient care, overhead, other); recipient email; and trial website (Title 42,<sup>4</sup> Section 403.904 for more information).

## Medical Research Writing

Payments for medical research writing and/or publication may be included in reporting for research payments if the work performed meets the definition of research and the payments are subject to a written agreement and/or a research protocol where such payments are contemplated. In other words, research writing would need to be contemplated and included in the clinical trial agreement and/or protocol and paid as a part of the research payment in order to be reported under the research specification<sup>2</sup> (p 9484).

## Delayed Publication

Manufacturers may qualify to have payment information delayed up to 4 years<sup>2</sup> (p 9505). To qualify, payments must be related to, 1) bona fide research or development of a new product or a new application of an existing product; or clinical investigations regarding a new product; and 2) have a written agreement in place and/or a research protocol (p 9504). It should be noted that “new” does not include new uses for old “approved” (eg, PMA and NDA) products, but that “new” does apply to new generic drugs and 510(k) products. *If a manufacturer is eligible*



Suzanne Sullivan, RN, CCRA (ssullivan@namsa.com) is currently Manager of Clinical Research Services with NAMSA. Suzanne has been with NAMSA (previously Alquest) for 17 years, where she provided clinical and management support for multiple medical device clients and products. Prior to NAMSA, Suzanne was a Project Manager with Empi and Seismed Instruments as well as a cardiac nurse at Hennepin County Medical Center. Suzanne was clinical co-chair for Medical Alley (now LifeScience Alley), has attended multiple Sunshine Act forums, and worked with Mark Gardner on Sunshine Act training documents for NAMSA.

# The Sunshine Act: What Manufacturers, Clinical Professionals, and Researchers Need to Know

*“After a product is deemed “covered,” eg, once a medical device is approved and reimbursement is available for it under Medicare, Medicaid, or CHIPs, the manufacturer has a 180-day grace period to comply with the law.”*

*then the delay takes place until the earlier of 1) product approval or clearance, or 2) up to 4 years after the payment is made* (p 9505). The manufacturer must indicate to CMS whether the payment is related to “research and development” or “clinical investigation” of a new product. CMS must be notified each year the manufacturer elects to delay reporting. Once a product is approved (or cleared) by FDA the manufacturer must notify CMS so that the payment data can be published in the following reporting cycle. Failure to do so is considered a failure to report. CMS reports data after 4 years regardless of FDA approval status.

## Reporting and Principal Investigators/Sub-Researchers

CMS does not require reporting of all research payments made to physician covered recipient sub-researchers who perform research for a teaching hospital if such sub-researchers “would not normally be considered ‘principal investigators’ in the normal industry understanding of the word”<sup>5</sup> (CMS Open Payments, FAQ 8266). CMS has noted that such sub-researchers are “not directing or in charge of the research overall.” Manufacturers are only required to report the names of principal investigators and may report up to five covered recipient principal investigators for each research payment.

## Companies Without FDA-Approved or FDA-Cleared Products

Companies currently in the research and development phase for devices and pharmaceuticals which are not approved or cleared by the FDA may not be subject to the Sunshine Act. If a company is not an “applicable manufacturer” as defined by Title 42, Section 403.902,<sup>4</sup> then the law does not apply. In other words, if the company is not “engaged in the production, preparation, propagation, compounding, or conversion of a *covered drug, device, biological, or medical supply*, or is under common ownership with an applicable manufacturer and provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a *covered product*” then the law does not apply because the company is not an applicable manufacturer [emphasis added].

Unfortunately, CMS did not set FDA approval or clearance as a bright line test for classifying a product as “covered” for reporting purposes. An important question to answer in order to determine whether a company falls under the definition of an “applicable manufacturer” is whether the product is “reimbursable.” In order for medical devices to be covered, the product in question must be subject to FDA clearance or approval and be “reimbursable” by CMS under Medicare, Medicaid, or CHIPs. In order for pharmaceuticals or biologics to be covered, the product must require a prescription to be dispensed (ie, over-the-counter drugs and biologics are excluded) and be “reimbursable” by Medicare, Medicaid, or CHIPs. If the product under investigation is not reimbursable, eg, under the Medicare Clinical Trial Policy, and the company has no covered products, then the law most likely does not apply. Companies should seek legal counsel in making a final determination. After a product is deemed “covered,” eg, once a medical device is approved and reimbursement is available for it under Medicare, Medicaid, or CHIPs, the manufacturer has a 180-day grace period to comply with the law<sup>2</sup> (p 9463).



*“An applicable manufacturer with both covered and non-covered (eg, investigational) products generally is required to report payments associated with non-covered investigational unapproved/uncleared products even for payments associated with preclinical research. This is because the company has covered products and non-covered products.”*

### Companies with Covered Products and Non-Covered Products

An applicable manufacturer with both covered and non-covered (eg, investigational) products generally is required to report payments associated with non-covered investigational unapproved/uncleared products even for payments associated with preclinical research. This is because the company has covered products and non-covered products. If the applicable manufacturer meets a reporting limitation<sup>4</sup> (Title 42, Section 403.902) it is only required to report payments related to the covered products<sup>5</sup> (CMS Open Payments FAQ 9132).

### Devices and Equipment Used in Trials

Study devices, equipment, diagnostics, supplies, etc, provided to a covered recipient, eg, for a clinical trial, are considered a transfer of value<sup>2</sup> (p 9484). These must be reported. Such transfers of value can be reported in aggregate as research, assuming the definition of research is met and the payments are subject to written agreement and/or a research protocol. Non-research payments not contemplated by the agreement and/or protocol must be reported separately as general payments.

### Reporting Investigational Products

Manufacturers are not required to assign a specific value to clinical study products that are provided to principal investigators. Instead, manufacturers should report the total amount of the research payment, including all research-related costs outlined in the clinical trial agreement, research protocol or both<sup>4</sup> (Title 42, Section 403.904).

### Research Overseas

Physicians located outside of the United States are not considered physician covered recipients for reporting purposes unless they are actively licensed (not actively practicing, rather just actively licensed) in the US. Under the Sunshine Act, “physicians” include doctors of medicine, osteopathy, dentists, podiatrists, optometrists and chiropractors who are legally authorized to practice by a state (Title 18, Section 1861(r) of the Social Security Act<sup>6</sup>). The Sunshine Act

# The Sunshine Act: What Manufacturers, Clinical Professionals, and Researchers Need to Know

*“For example, payments made by applicable manufacturers to US-licensed physicians conducting a clinical trial in Germany must be reported even though the work is done outside of the US.”*

includes fellows but excludes residents. In essence, the law follows the US-licensed physician regardless of geography. For example, payments made by applicable manufacturers to US-licensed physicians conducting a clinical trial in Germany must be reported even though the work is done outside of the US.

## CROs

Contract research organizations (CROs) that are not applicable manufacturers are not required to report information under the Sunshine Act. But when an applicable manufacturer is making payments indirectly through a CRO to covered recipients such payments are reportable by the manufacturer. If the payments meet the definition of research and are subject to written agreement and/or a research protocol they may be reported under the research specification. Applicable manufacturers are not required to report the name of the CRO that indirectly provides the “research” payment.

## Reporting Research Involving Non-Teaching Hospitals

Applicable manufacturers should be cautious not to under-report research payments made to non-teaching hospitals. Payments made to non-teaching hospitals can still be reportable if part of the payment goes to a physician. The application of the law turns on the role of the physician. CMS has stated, “[T]he applicable manufacturer shall be required to report the ... research-related payment that ultimately is paid, *in whole or in part*, to a covered recipient”<sup>2</sup> (p 9483) [emphasis added]. In other words, if a physician covered recipient is serving as a principal investigator for research supported by an applicable manufacturer and part of the research payment inures to the physician, then the payment is reportable.

## Reporting NIH Grants

National Institute of Health (NIH) grants are not exempted from reporting. Applicable manufacturers that receive research grants from NIH are required to report a sub-award from the NIH grant as a research payment, eg, when the manufacturer contracts with teaching hospitals to conduct research, so long as the activity meets the definition of research.

## Fellows and Military Physicians

The exemption from reporting payments made to medical residents does not apply to “fellows.” The Final Rule exempts payments to medical residents but not fellows. In addition, payments and transfers of value made to physician principal investigators who work for the military must also be reported<sup>2</sup> (p 9467).

*“Reporting errors can lead to reputational harm, damage to customer relationships, and legal exposure. Nine states and the federal government have laws that limit or ban gifts, regulate behavior, and require registration and reporting, among other things.”*

### Conclusion

Do not underestimate the business impact the Sunshine Act can have on your company. Reporting errors can lead to reputational harm, damage to customer relationships, and legal exposure. Nine states and the federal government have laws that limit or ban gifts, regulate behavior, and require registration and reporting, among other things. These states include California, Connecticut, Louisiana, Massachusetts, Minnesota, Nevada, Vermont, Washington DC, and West Virginia, in addition to the federal 20/50 Rule.<sup>7</sup> Companies that fail to follow these laws may legally expose themselves with the data they report under the Sunshine Act. In addition, CMS’s interpretation of the new law is subject to change. Changes were recently proposed by CMS for 2015. Stay current by following the CMS Open Payments website.<sup>3</sup> CMS will begin auditing companies for compliance starting in the fall of 2014. Manufacturers should develop sunshine policies and procedures, audit compliance, and provide annual training to employees in order to avoid exposure and fines. Questions regarding the legal application of the Sunshine Act should be discussed with legal counsel.

*This white paper is not legal advice. Questions regarding application of the Sunshine Act should be discussed with legal counsel.*

## REFERENCES

1. Social Security Administration. Patient Protection and Affordable Care Act, Section 6002, which added section 1128G to the Social Security Act. [http://www.ssa.gov/OP\\_Home/ssact/title11/1128G.htm](http://www.ssa.gov/OP_Home/ssact/title11/1128G.htm)
2. Centers for Medicare & Medicaid Services. Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule. *Federal Register*. 2013;78(27):9458-9528. <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf>
3. Centers for Medicare & Medicaid Services. Open Payments. The Official Website for Open Payments (the Sunshine Act). <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>
4. US Government Printing Office. Electronic Code of Federal Regulations (e-CFR). Title 42. [http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42tab_02.tpl)
5. Centers for Medicare & Medicaid Services. CMS.gov—Frequently Asked Questions. <https://questions.cms.gov/faq.php?id=5005>
6. Social Security Administration. Social Security Act. [http://www.ssa.gov/OP\\_Home/ssact/](http://www.ssa.gov/OP_Home/ssact/)
7. **California:** California Health & Safety Code §§119400-119402; **Connecticut:** Substitute Senate Bill No. 270, File No. 468, Cal. No. 333; **Louisiana:** R.S. §§42:1115-1115(A); **Massachusetts:** Massachusetts Chapter 111N of the Massachusetts General Acts; **Minnesota:** Minnesota Statute §151.47 (general), §151.461 (gifts); **Nevada:** Nevada Revised Statute §639.570; **Vermont:** 18 V.S.A. Section 4631a, 4632; **Washington DC:** DC Code Ann. §§48-833.01-48-833.09; **West Virginia:** West Virginia Code §5A-3C-13, §16-29H-8; **US Office of Government Ethics:** 20/50 Rule, [http://education.oge.gov/training/module\\_files/ogegovctr\\_wbt\\_07/31.html](http://education.oge.gov/training/module_files/ogegovctr_wbt_07/31.html)