

Client Alert December 2011

Physician Payment Sunshine Act— Proposed Rule Finally Published

Dear Clients and Friends of the Firm,

CMS finally published a Proposed Rule for the Physician Payment Sunshine Act (the “Act”), which was passed last year. The Proposed Rule was initially due by October 1, a deadline CMS missed. All 121 pages of the Proposed Rule are located here: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2011-32244.pdf>. We have attempted to break the Proposed Rule down to save you some time! Please call us if you need help preparing for the new law. Companies that fail to report are subject to fines ranging from \$1000-10,000 per occurrence for unintentional conduct and \$10,000-\$100,000 for intentional conduct.

Delayed Implementation

The regulation was supposed to go into effect on January 1, 2012. However, CMS has proposed that the law be delayed and that manufacturers and GPOs only submit information for a partial 2012 next year even though the full-year reporting is due by March 31, 2013. CMS did not propose a new date for reporting. We suspect that CMS will require reporting only for the second half of 2012; much like Massachusetts did when its sunshine law was enacted. One thing is for sure, CMS will not require manufacturers and GPOs to begin collecting the required information until the final rule is published. We will keep you posted.

Political Background

The intent of the law championed by Senators Kohl (D-WI) and Grassley (R-IA) is to increase transparency. For example, the law will allow a patient to determine whether their doctor accepts money from a manufacturer for things like consulting. The Senators were quite pleased that the Proposed Rule was finally published. Sen. Kohl said, “As we move forward, it’s vital that stakeholders have a voice in this process to ensure transparency and accountability in our health care system.” CMS stated in its publication of the Proposed Rule in the Federal Register that, “[f]inancial ties alone do not signify an inappropriate relationship. However, transparency can shed light on the nature and extent of relationships, and may dissuade inappropriate conflicts of interest from developing.”

CMS estimates that the Act will cost companies \$224 million in the first year. We can understand the thought process the government employed here, but given the great burden this new law creates for companies, we are not so sure that this law will do anything to better patient care or reduce costs. Physicians play a vital role in the development of new medical technology. We see little value in regulations that diminish or impede that role, while driving up costs for manufacturers and ultimately patients. This law also comes at an inopportune time when companies are straddled with new taxes resulting from health care reform and endlessly growing regulatory hurdles.

Overview of the Act

The Act requires any “payments or other transfer of value” made by companies to physicians or teaching hospitals that are greater than \$10, or \$100 in aggregate per year, be reported to the government. The law also requires manufacturers and GPOs to disclose to CMS physician ownership or investment in their respective companies. The law applies to all companies regardless of size, i.e., there is no exemption for small companies. Certain transfers of value can be delayed for products not yet approved. This is discussed below. CMS defines a “covered drug, device, biological, or medical supply” as any drug, biological product, device, or medical supply for which payment is “available” under federal payor programs, e.g., Medicaid, Medicare, and Children's Health Insurance Programs (CHIP).

For additional information on the Act, please see our previous Client Alert on it here: <http://duvalfdalaw.com/docs/DuVal%20Client%20Alert-Apr%202010.pdf>

Information Required for Reporting

The information required for reporting is (i) the **name** of the recipient, (ii) recipient business **address**, (iii) **specialty and National Provider Identification**, (iv) **date** of payment, (v) the associated **product name**, (vi) **nature** of payment, and (vii) **form** of payment. CMS did not add new categories established by the Act for “forms of payment” or “nature of payment.”

A few types of payments that CMS listed under ***nature of the payment*** in the Proposed Rule include: consulting fees; compensation for services other than consulting; honoraria; gift; entertainment; food; and many others.

CMS listed the following under ***form of payment***: cash or a cash equivalent; in-kind items or services; stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; and any other form of payment determined by the Secretary.

Other Notable Items Discussed in the Proposed Rule

- **Exclusions**—There are other items discussed in the Proposed Rule that are given special attention such as accounting for meals, investment interests, and **exclusions** such as: transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds \$100 in a calendar year; product samples that are not intended to be sold and are intended for patient use; educational materials that directly benefit patients or are intended for patient use; the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient; items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device; and many others.
- **Consulting Contracts**—Reporting “transfers of value,” i.e., payments, from companies to physicians for R&D or clinical investigations is required, but the government will delay publication for purposes of confidentiality if the product is not approved or cleared yet and the company requests such a delay each year. Such payments must be communicated when (i) products are approved or cleared, or (ii) 4-years after the payment (or transfer of value) is made. There are other more complicated provisions to help determine what is or is not reportable.
- **Reviewing Submitted Data**—Manufacturers, physicians and teaching hospitals, will be allowed 45 days to review and correct information prior to its publication.
- **Misc.**—The Proposed Rule also covers discounts, charitable donations, identification of covered recipients (e.g., types of companies, discussion on teaching hospitals) and covered products (e.g. types that are covered), applicable manufacturers, physician ownership and investment interests, among other things.

We assist many drug and device companies each year with all their state (MA, VT, NV, CT, CA, MN, WV, DC, ME) sunshine and compliance law needs including **submissions** and **registrations**. We are in the process of helping many clients prepare for the Physician Payment Sunshine Act.

Please contact us if you have questions.

Best regards,
DuVal & Associates, P.A.



CALL US FOR HELP WITH YOUR REGULATORY & COMPLIANCE NEEDS

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DuVal & Associates understands the corporate interaction between departments like regulatory affairs, sales, marketing, legal, quality, clinical, compliance, R&D, manufacturing, finance, etc. Because of our industry experience in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We actually work with FDA every day on pre-market submissions, clinical trials inspections, warning letters, administrative appeals, and the like. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results, while practical, timely advice can help companies succeed. For more information, visit our website at www.duvalfdalaw.com or call us today for a consult at (612) 338-7170.

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