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Even Sunshine Causes Shadows: A Look at How the New "Transparency Act" May Affect Clinical Researchers

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As part of the current administration's healthcare reform vision, the Patient Protection and Affordable Care Act (PPACA) was passed in March 2010. This Act, along with its subsequent pieces of legislation to reform healthcare, are complex and contain many components that directly or indirectly affect the clinical research enterprise. One part in particular, "Section 6002: TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS," will significantly impact clinical research operations, as well as public trust in our activities and motives. The intent of this section is similar to the proposed Physician Payment Sunshine Act, which failed three times to get passed by Congress (Senate Bill in 2007 and House Bills in both 2008 and 2009). In 2010, it finally passed as a section of PPACA. When added to the PPACA bill, the original title of "Physician Payment Sunshine Act" was replaced by the title referenced above, but it is still often referred to in the vernacular as the "Sunshine Act."

Summary of the Law

Section 6002 of the PPACA legislation states that, "beginning March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary" of DHHS a "transparency report" of this payment. Table 1 presents the information to be included in this report. Additionally, physician (or physician family) ownership in any applicable manufacturer or group purchasing organization must also be reported, but that is beyond the scope of this article.

Definitions are always important, particularly in new legislation. The PPACA law defines an "applicable manufacturer" as one that is "operating in the United States, or in a territory, possession or commonwealth of the United States" and "is engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply)." It further defines a "covered drug, device, biological or medical supply" as meaning "any drug, biological product, device or medical supply for which payment is available under Title XVIII or a State plan under Title XIX or XXI (or a waiver of such a plan)." The law defines a "covered recipient" as meaning either a physician (except those employed by the manufacturer, unless they or their family have ownership in that manufacturer) or a teaching hospital." These definitions will be of critical importance in the implementation of this new law, as we will see in the discussion below.

Table 1: Required Items to Report

Required Item	Additional Required Descriptors
The name of the covered recipient	Also includes the business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
The amount of the payment or other transfer of value	
The date(s) on which the payment or other transfer of value was provided to the covered recipient	
A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as:	Specifically, (a) cash or a cash equivalent; (b) in-kind items or services; (c) stock, a stock option, or any other ownership interest, dividend, profit or other return on investment; or (d) any other form of payment or other transfer of value (as defined by the DHHS Secretary).
A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as:	Specifically: (I) consulting fees; (II) compensation for services other than consulting; (III) honoraria; (IV) gift; (V) entertainment; (VI) food; (VII) travel (including the specified destinations); (VIII) education; (IX) research; (X) charitable contribution; (XI) royalty or license; (XII) current or prospective ownership or investment interest; (XIII) direct compensation for serving as faculty or as a speaker for a medical education program; (XIV) grant; or (XV) any other nature of the payment or other transfer of value (as defined by the Secretary).
If the payment or other transfer of value is related to marketing, education or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply.	
Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.	

DHHS will publish the reporting procedures that applicable manufacturers must follow by October 1, 2011. The penalties for noncompliance will be between $1,000 and $10,000 for each payment or other transfer of value or ownership or investment interest not reported as required, up to an annual maximum fine of $150,000. If the manufacturer knowingly does not report, then the fines will increase to between $10,000 and $100,000 for each payment

or other transfer of value or ownership or investment interest not reported as required, up to an annual maximum fine of $1,000,000. The law states that the fines are to be used to help offset the cost of implementing the law. There are some exclusions, such as for insignificant items (e.g., payments under $10 not exceeding $100 per year) and patient-care items (e.g., a self-insured applicable manufacturer that pays a physician for providing patient care to its employees). Other exclusions are available for items like product samples not intended for resale and "90-day try before you buy" type scenarios.

Once the information is reported, DHHS will use it for its internal purposes, as well as annual reports to Congress, to the states, and to the general public. Beginning on April 1, 2013, DHHS must annually submit to Congress a report aggregating the amounts for each applicable manufacturer or group purchasing organization from the previous calendar year. Additionally, beginning on September 30, 2013, and by June 30 of each subsequent year, each state will receive a report summarizing the amounts received in the previous calendar year by each covered recipient located in their state. These reports are intended to help the states enforce their own laws.

The law states that not later than September 30, 2013, and on June 30 of each calendar year thereafter, the information submitted for the preceding calendar year will be made available to the public through an Internet website. The website will contain, at minimum, the following information, as well as provide an opportunity to review and submit corrections to the information for a period of not less than 45 days prior to such information being made available to the public:

- With minor exceptions (i.e., excluding any National Provider Identifiers numbers), all information in the transparency report (i.e., Table 1), including names, addresses and amounts
- A description of any enforcement actions, including any penalties imposed during the preceding year
- Background information on industry-physician relationships
- Separately listed information for funding of clinical research (including amounts and the product researched)
- Any other information the Secretary determines would be helpful to the average consumer

One special consideration for research is the delayed publication rule, which gives some protection to sponsor confidential information for items like a new medical technology, a new application of an existing medical technology, or the development of a new drug, device, biological or medical supply. In these scenarios, the posting on the website (as well as the disclosure in the reports to Congress and the states) can be delayed until the sooner of (a) the date of the approval or clearance of the covered drug, device, biological or medical supply by the Food and Drug Administration or (b) four calendar years after the date such payment or other transfer of value was made. This delay applies to DHHS' disclosure obligations to Congress, states and the public, but not to the reporting obligations of companies. Nor does it prevent states from enacting their own laws to obtain this information sooner.

Discussion

The following discussion is not meant to render an opinion on the merits of disclosure, only to consider the implications of the legislation, its implementation, and the expected impact. Advocates of the new law believe that it will provide information essential to determining potential conflicts of interest. The consolidation of the disclosure information on a single

website may help eliminate duplication of effort, as well as provide a means to verify previously unverifiable self-reports by clinical investigators and others.

While giving everyone access to the same knowledge is a worthy ideal, there is always debate on the methods involved. While there is conflicting evidence from multiple studies on whether or not industry payments make physicians act contrary to their patient's best interests, "Big Pharma" payments to physicians are almost universally portrayed to the general public in a negative light.

The debate starts with the absolute beginning of the legislation — the title. Using the word "Sunshine" in the original title of the legislation was an intentional allegory. In a statement at the U.S. Senate Special Committee on Aging on September 7, 2007, the original authors of the bill (Senators Grassley and Kohl) stated that it was about "letting the sun shine in" and "bringing [pharmaceutical company] influence-peddling out from the shadows." The term "Sunshine Act" implies "an aura of corruption," according to Harvard professor Tom Stossell, MD, who founded an organization to defend interactions between physicians and industry from unbalanced criticism from the press or government. Having it labeled as "sunshine" implies that the recipient is guilty of something that needs to be brought to light, even when a situation is entirely innocent. This perpetuation of the "guilty until proven innocent" culture reinforces the public's belief that accepting funding for research from private companies is never a legitimate collaboration but always a sin to be confessed.

The PPACA replaced the term "sunshine" with the perhaps more neutral term "transparency." However, this term is potentially even more misleading to the public. "Transparency" implies that all information is available, when this clearly will not be the case by design, as the so-called "transparency reports" contain only payment (revenue) but not cost or profit figures. The Act thus does not achieve "transparency"; instead it achieves a selective translucency ("permitting light to pass through but diffusing it so that persons, objects, etc., on the opposite side are not clearly visible").

For example, if Sponsor A pays Physician B $100,000 to conduct a clinical trial, and Physician B earns a profit (or loss) of $10,000 on his or her investment of time and capital, the only information on the website is the $100,000 payment. Neither will there be anything on the website about any medical malpractice liability risk Physician B incurs in the trial or any loss of income from his or her clinical practice.

While the law requires that the website must contain background information on industry-physician relationships, there is no guarantee of adequate balance. Also, it is unlikely that the public or media will be very interested in the "fine print" or the nuances of clinical research cost accounting when the headline says "Company A pays $100,000 to Physician B."

The state of Massachusetts has provided a case study of what can happen. It launched a website on November 22, 2010, highlighting payments made between July 1 and December 31, 2009, resulting from reporting requirements in a similar state law. Almost immediately, the Boston Globe published the name of the physician who received the most money during that period of time ($194,275) and stated that its check of state records showed that she was not listed as a registered physician in Massachusetts. In a follow-up article the next day, it was revealed that this physician had not practiced medicine (i.e., seen patients in clinical practice) since the year 2000, as she had retired from clinical practice and was acting as a safety consultant to the manufacturer. Despite the clarification, six months after the posting, the effects still linger. In a Google search for her name today, four of the top five hits (including the top two) are links to information specifically about her being the pharmaceutical industry's "top paid" physician in the state and not about the research she may have contributed, the education she may have provided, or the safety her consulting may have provided to patients. This effect did not apply to other physicians mentioned in

the article, but many physicians prefer to avoid the risk of unfair public denigration, adding yet another possible challenge to finding and retaining clinical investigators in the U.S.

Other questions raised by the Act await resolution by the implementing regulations. For example, the so-called "Stark Laws" originally allowed a possible loophole for payments to businesses that employ physicians, rather than payments directly to the physicians. It remains to be seen whether the Transparency regulations will apply the Stark Law standard of "stands in the shoes of the practice" to physicians. The Transparency law partially addresses this issue by stating that, "in the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient." This aspect of the law would apply in a situation where the physician states, "I am personally owed the money but instead of paying me, pay my hospital/foundation/practice/etc.," but it is unclear how the regulations will treat separate companies, site management organizations, and the like. If a pharmaceutical company pays a hospital $100,000 for conducting a clinical trial, will the law allocate all the departmental fees, institutional overhead charges, etc., to the investigator? Will it matter whether the investigator is an employee or just on the staff of the hospital? Will it matter how much, if any, of the payment goes into the investigator's pocket? Will it matter whether the payment flows through the hospital to the investigator, through the investigator to the hospital, or directly to each? Will it matter how payments to subcontractors flow (such as multiple sub-investigators that are paid by the lead investigator or their practice)? Will it apply to non-U.S. physicians/hospitals? These are all questions that need to be answered by regulations.

In another example, the law does not define the term "teaching hospital." Many community hospitals are thus curious about whether they will be covered by the law. Will it matter how the teaching activities and clinical research activities of the hospital are structured for business purposes?

Similarly, the law applies to "applicable manufacturers." A strict interpretation of the definition suggests that payments would not need to be reported by (a) a company located outside the U.S.; (b) a sponsor that is not a manufacturer; (c) a company that does not have at least one drug/device/biologic for which payment is available under Title XIX or XXI (e.g., a small biotech company with no approved products, or a company that develops cosmetics not reimbursable under Title XIX or XXI); (d) a CRO or other intermediary; or (e) a co-developer if it is not the one writing the checks. It remains to be seen how the forthcoming regulations and guidance implement the spirit of the law.

The PPACA law talks about "research" without differentiating between clinical trials, observational research, registries, investigator-initiated protocols, or the like. Reporting is required for all of them.

The phrase, "other transfer of value," means that reporting requirements are not limited to payments of cash or cash equivalents, and will include equipment and other forms of remuneration, regardless of whether they are detailed in the clinical trial agreement. The breadth of covered payment forms remains to be seen.

The industry is already adapting its practices to meet the new requirements. For example, sponsors are adding language to clinical trial agreements to explicitly permit disclosures. However, clinical sites are reluctant to sign agreements with uncertain ramifications and definitions that are yet to be defined in regulation.

It is yet to be seen how other federal, state or private agencies will react to the law. It will be especially interesting to see whether other programs to collect similar information within the research industry (i.e., 21 CFR 54 "Financial Disclosures," ICMJE disclosures, etc.) and

outside the research industry but in general healthcare (i.e., formulary committees, health technology assessors etc.) will migrate to this single system to avoid costly duplications of effort.

In closing, all stakeholders having the same knowledge is indeed a worthy goal; as they say, "Who could be against that?" When sunshine creates shadows, however, we do not see the entire picture. We need to be aware what those shadows are and how we can eliminate them to achieve true transparency.

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