Spotlight on the Sunshine Act in CTAs

By J. Andrew Lemons

The federal Physician Financial Transparency Reports Act (Sunshine Act) was adopted as part of the Affordable Care Act of 2010 (the ACA). The Centers for Medicare and Medicaid Services (CMS) proposed implementing regulations in late 2011 and finalized them on February 8, 2013.1

At its most basic, the ACA requires Applicable Manufacturers of Covered Products to publicly report payments or other transfers of value to physicians or teaching hospitals. Applicable Manufacturers include those “manufacturers of drugs, devices, biologicals or medical supplies” operating in the United States. Covered Products include drugs, devices, biologicals and medical supplies for which reimbursement is available under Medicare, Medicaid or the Children’s Health Insurance Program. In addition to the requirement that reimbursement is available for Covered Products, those Covered Products must also require a prescription (for drugs and biologicals) or premarket approval by or notification to the FDA (for devices). The intent behind the reporting requirements is to aid the government and patients in identifying potential conflicts of interest that may skew treatment decisions.

For better or worse (mostly worse), payments to investigators and institutions for services related to clinical research are captured by the broad language of the Sunshine Act and its regulations. Sponsors, already sensitized to their risks under the federal Anti-Kickback Statute, must now also report these payments. Fortunately, CMS recognizes that “research payments are unique and do not necessarily represent a personal payment to physicians.” Thus, while giving a nod to the statutory requirement that research payments be included, CMS significantly lessened the burden on Applicable Manufacturers. Nevertheless, clinical research payments, given their relatively large size, are prominent in the online database at www.cms.gov/openpayments and could be misconstrued as “profit from research.”

Research Payments

CMS adopted the Public Health Service Act definition of research: “A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health...” Included in this definition are pre-clinical research, FDA Phase I through Phase IV trials, and investigator-initiated studies. The Sunshine Act covers payments that are subject to a written contract or a protocol, including payments from an Applicable Manufacturer to a Covered Recipient directly or via an unbroken chain of agreements. A common example of an unbroken chain of agreements is research sponsor (here, the Applicable Manufacturer) contracting with a CRO, which then contracts with a Covered Recipient. Such payments must be reported.

In its final rule, CMS decided that research payments should be treated differently than other payments covered by the Sunshine Act. Accordingly, CMS adopted the approach suggested by many commenters to the proposed regulations: “where a single research payment is reported once and includes the entity paid, as well as the name of the principal investigator(s).” CMS created a separate template, which requires reporting the following information:

1. Name of research institution or other person/entity receiving payment.
   a. For payments directly to a physician Covered Recipient, the report must include the NPI, state and state license number(s).
b. For payments to a teaching hospital Covered Recipient or to a non-Covered Recipient, which then pays a Covered Recipient, the report must include the name and address of the institution.

2. Total amount of research payment, meaning "the aggregated amount of any payments for services included in the written agreement/research protocol," including patient care services, diagnostic tests, laboratory work, study administration, provision of study drug or device, etc.²

3. Name of the study.

4. Name(s) of the covered drug, device or biological, and NDC, if applicable.

5. Name, NPI, state license number(s) of the Principal Investigator.³

In other words, all the payments can be aggregated in one number, rather than broken out in detail. Thus, from a clinical research contracting perspective, the reporting is straightforward, leaving aside the complexities of the law, costs of compliance, and lingering questions about its effectiveness.

Clinical Trial Agreements

As expected, study sponsors have begun including language in their clinical trial agreements (CTAs) that specifically address the reporting obligations under the Sunshine Act. However, some of these contractual provisions go well beyond the reporting requirements of the Sunshine Act, such as the following two examples:⁴

Sunshine Act Reporting. Institution and Investigator acknowledge and agree that Sponsor and its affiliates may disclose information about Institution and Investigator, including information regarding payments to Institution and Investigator, to the public and/or government agencies as Sponsor determines in its sole discretion. Institution shall maintain adequate records of all payments, costs, expenses and reimbursements associated with this Agreement and make such records available to Sponsor and its representatives promptly upon request.

Payment Transparency. The parties understand that Sponsor is obligated by federal and/or state law to report certain payments and other transfers of value to Site or Investigator. Site and Investigator acknowledge and agree that Sponsor may use and disclose, or otherwise make public, information about Site or Investigator learned through participation in this Study.

In the first example, the Sponsor puts the burden on the Institution to maintain the information to be reported and provide it to the Sponsor. However, it is inappropriate for the sponsor to shift the burden of maintaining the reportable data (and more) to a site because responsibility for reporting under the Sunshine Act belongs to the sponsor. Sponsors already have access to the information they are required to report. Nonetheless, research sites might want to keep track of this information so it is available to field questions by sponsors and to confirm that information reported by sponsors is accurate.

The information to be provided to the Sponsor in the first example goes well beyond the aggregate research payments that must be reported under the Sunshine Act. In addition to the recordkeeping and reporting burden, such information might include information that is proprietary to the Institution and should not be disclosed.

The language in both of these provisions grants the sponsor significantly more authority and discretion than necessary to meet the disclosure requirements of the Sunshine Act or other applicable laws. Despite its title, by the plain language in the first example, the Institution is giving the Sponsor free rein to disclose any information whatsoever about Institution and Investigator that the Sponsor desires to disclose. The second example refers to various laws
that may require the Sponsor to report information. However, there is no reference or link in the second sentence that would limit the Sponsor’s disclosure of information to that required by law.

The provisions above might also appear to conflict, at least to some degree, with CTA confidentiality language that extends to site confidential information. However, most confidentiality provisions in CTAs today are one-sided, protecting only the sponsor’s information. A site that has negotiated confidentiality language that protects its confidential information may be able to rely on that section to limit a sponsor’s disclosures other than as required by law. However, that approach is likely to require significantly more effort at the time of a problematic event, as compared to addressing the issue during CTA negotiations.

Unless there is reasonable justification for such broad disclosure authority, teaching hospitals and physician investigators should resist agreeing to expansive disclosure provisions and insist on limiting the disclosures to those required by applicable law.

The following is an example of language that should be satisfactory to both sponsors and sites:

**Disclosure of Payments.** Payments made pursuant to this Agreement may be subject to disclosure by Sponsor in accordance with domestic and foreign financial transparency disclosure laws and other federal and state laws, rules and regulations. Sponsor shall make such disclosures deemed necessary in its reasonable discretion for compliance with such laws without the need to request or obtain consent from Institution or Investigator.4

Although the focus of this article is on the U.S. federal Sunshine Act, some states and foreign jurisdictions have laws and regulations that require reporting these types of financial relationships. In addition, many sponsors have entered into Corporate Integrity Agreements (CIAs), Deferred Prosecution Agreements (DPAs), or similar settlement arrangements, which require heightened reporting requirements for a period of time. Therefore, it is necessary and appropriate for sponsors to address their legal obligations in this respect.

It is also reasonable and appropriate that sponsors not require further consent or action from sites or investigators when fulfilling these requirements. CMS notifies the relevant parties when reported information is available for review, at which time corrections can be requested. CMS contacts Applicable Manufacturers through the point of contact they identify during the reporting process. It notifies Covered Recipients with an online posting on CMS listserves. Covered Recipients may also register with CMS to receive notifications. Once notified, the parties have 45 days to review and submit corrections before CMS releases the information to the public. Additional details about the review and correction process can be found in the regulations.

**Conclusion**

Despite initial concerns surrounding the Sunshine Act, disclosing relationships, even the financial terms of those relationships, between Applicable Manufacturers and Covered Recipients may turn out to have limited practical value. Although many physicians initially feared the public relations toll they might have to pay once they were identified as a significant recipient of funds from pharmaceutical and device companies, it did not take long before enterprising physicians began citing these payments as evidence of their stature and credibility in the medical profession. It remains to be proven to what extent the Sunshine Act’s enormous compliance costs can be justified through benefits to the public. As CMS has acknowledged, research payments are unique. Although the parties must comply with the Sunshine Act’s reporting requirements, disclosure authority should not exceed the
requirements of the Act or other applicable law, unless the Applicable Manufacturer can articulate a compelling reason to go further.

Notes

1. 42 C.F.R. § 403.900 et seq.
2. Expenses that can be classified in another category (e.g., consulting payments or payment for meals or travel expenses) should be reported in the appropriate category, not under the research umbrella.
3. The Applicable Manufacturer, at its option, may also include information regarding the (a) context of the research, and (b) the clinicaltrials.gov identifier for the study.
4. This language is from actual clinical trial agreements, altered to protect the identity of the parties and their attorneys.

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