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Medical Ethics

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Shadows Amid Sunshine

Regulating Financial Conflicts in Medical Research

Richard S. Saver, JD

Under brand new rules implementing the Physician Payments Sunshine Act (Sunshine Act), a wide range of financial relationships, including many research-related payments, between industry, physicians, and teaching hospitals will be publicly disclosed through comprehensive, standardized payment reporting. The Sunshine Act represents the latest in a series of regulatory attempts to address financial conflicts of interest that may bias research conduct and threaten subject safety. This article summarizes the major aspects of the Sunshine Act affecting medical research, how it interacts with existing laws and policies, and identifies important unresolved issues and implementation challenges that still lie ahead with the rollout of the legislation underway. The Sunshine Act primarily depends on disclosure as a regulatory tool. As such, its long-term impact remains open to question. Disclosure in this context may have limited utility given, among other reasons, uncertainty about who the intended recipients are and their ability to use the information effectively. Apart from the insufficiency of transparency, this article further explores how proportionality, fairness, and accountability considerations make optimal regulation of financial conflicts in medical research quite challenging. ***CHEST 2014; 145(2):379–385***

Abbreviations: CMS = Centers for Medicare and Medicaid Services; FDA = US Food and Drug Administration; GPO = group purchasing organization; IOM = Institute of Medicine; NIH = National Institutes of Health

Financial conflicts in medical research attract increasing concern. The Institute of Medicine's (IOM) influential 2009 Conflict of Interest Report identified serious risks posed by financial conflicts, including withholding of negative results, erosion of trust, and harm to patients.[1] Even following the IOM report, questionable research conduct continues to be linked to financial ties. For example, a 2011 systematic review of earlier trials of bone morphogenetic protein as an adjunct to spine surgery found that study authors underestimated adverse events while failing to disclose financial relationships with the commercial sponsor, including lucrative consulting arrangements.[2]

Such financial relationships will come under increased scrutiny as a result of the new Physician Payments Sunshine Act (Sunshine Act).[3,4] Under this significant change in federal law, many research-related payments between industry and academic medicine will be publicly disclosed through comprehensive, standardized payment reporting.

As Justice Brandeis long ago famously observed, "Sunlight is said to be the best of disinfectants."[5] Indeed, in theory, the Sunshine Act's disclosure approach offers many advantages. Transparency has long been

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Affiliations: From the University of North Carolina School of Law and University of North Carolina School of Medicine, Chapel Hill, NC.

Correspondence to: Richard S. Saver, JD, University of North Carolina School of Law, Van Hecke-Wettach Hall, CB #3380, Chapel Hill, NC 27599-3380; e-mail: saver@email.unc.edu

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a preferred strategy for advancing important health law and policy objectives and for optimal regulation more generally.[6] It can facilitate market discipline and incentivize participants to self-regulate problematic behavior.

Nonetheless, there are reasons to question whether sunshine has its limits. Disclosure in this context may have limited utility given, among other reasons, uncertainty about who the intended recipients are and their ability to use the disclosed information effectively. Apart from the insufficiency of transparency, this article explores how proportionality, fairness, and accountability considerations make optimal management of financial conflicts in medical research quite challenging. In addition, this article summarizes the major aspects of the Sunshine Act affecting medical research, how it interacts with existing laws and policies, and identifies unresolved issues and implementation challenges that still lie ahead with the rollout of the legislation underway.

Basic Requirements

What Gets Reported

A distinct part of the federal health-care reform law (the Patient Protection and Affordable Care Act of 2010), the Sunshine Act attempts to shine light on a broad range of financial relationships among industry, physicians, and teaching hospitals, not just research-related payments. After extensive public comments, the Centers for Medicare and Medicaid Services (CMS) issued final implementing regulations in February.[4] The Sunshine Act requires that manufacturers of products covered by the Medicare, Medicaid, or Children's Health Insurance Programs, and group purchasing organizations (GPOs) report annually to CMS ownership or investment interests held by physicians and their immediate family members. In addition, manufacturers must report annually to CMS all "transfers of value" to physicians and teaching hospitals. CMS will release most of the data on a publicly available website.

The dollar threshold to trigger reporting of a transfer of value is quite low: Payments of $>$ \$10 per instance or \$100 per year must be disclosed. In addition, manufacturers must name the recipient's identity and provide a reason for the payment by placing it within a broad range of reportable categories, including consulting fees, entertainment expenses, gifts, and speaker fees.[4] Limited exceptions to the reporting requirements apply, such as for providing physicians with product samples.

Reporting of Research Payments

A distinct reportable category covers "research" payments that are subject to a research protocol or pursuant to a written agreement, such as the typical clinical trial sponsorship contracts between pharmaceutical companies and academic medical centers. It is expected that many payments related to clinical trial work will be reported under this category. Manufacturers making research payments must generally report the entity paid (either directly or through a contract research organization), as well as the name of the principal investigator(s), the total amount paid, the study name, and the associated investigational technology.

Manufacturers may worry that public disclosure of research-related payments will let competitors know about proprietary information and business strategies. To address this concern, the Sunshine Act allows delayed public disclosure. If the research payment relates to a new product still being tested and developed for regulatory approval, CMS will grant a delay before the information is made available to the public until the earlier of (1) the approval by the US Food and Drug Administration (FDA) of the study product or (2) 4 years after the date of payment.[3] There was some initial confusion as to whether the delay process would apply to research payments concerning off-label uses for already approved drugs, a rapidly expanding area of research. CMS clarified in the final rule, however, that research-related payments for such off-label studies will be disclosed to the public without delay and under the ordinary time frame.[4]

Timing, Challenging Report Accuracy, Sanctions

Under the final rules, manufacturers had to begin collecting data on August 1, 2013, and must submit the information to CMS no later than March 31, 2014. CMS will release most of the data on a public website by September 30, 2014.[4]

While the initial burden of reporting falls on manufacturers and GPOs, erroneous reports could damage a physician's reputation, subject the physician to unwarranted regulatory scrutiny, or at least give a misleading view of how funds flow in the research system. CMS is to provide each physician at least 45 days to review and dispute reported information before posting it on the publicly available website.[4] Physicians will want to carefully scrutinize the information and access the dispute resolution process promptly to address any errors.

The Sunshine Act provides civil fines up to \$10,000 for each violation of the reporting requirements, capped annually at \$150,000. Knowing violations are subject to civil fines up to \$100,000 for each incident, subject to annual caps of \$1 million.[3] The fines apply not to physicians but to the entities that actually must report under the law: manufacturers and GPOs.

Interaction With Existing Laws and Policies

The Sunshine Act breaks new ground by imposing a uniform reporting requirement, at least at the federal