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TECHNOLOGY

# Technology: Changes ahead for clinical trials

## Anticipating the Sunshine Act

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The Center for Medicare & Medicaid Services (CMS) recently announced that it will delay implementing the Physician Payment Sunshine Act and will not begin collecting data until 2013. Despite this delay, many U.S. drug and medical device manufacturers have focused sharply on tracking and analyzing their payments to physicians and teaching hospitals—and on tackling the unique challenges of doing so in the clinical research context.

Under the Sunshine Act, which is part of the health care reform law, "applicable manufacturers" of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program must report annually to the Secretary of Health and Human Services certain payments or transfers of value to physicians and teaching hospitals as well as certain information regarding ownership or investment interests held by physicians in such manufacturers. CMS must then publish the reported data on a public website.

The goal of the Sunshine Act is to enhance the transparency of financial arrangements between physicians and teaching hospitals on the one hand and manufacturers of federally reimbursable drugs, biologicals and covered medical devices and supplies on the other in order to reduce the risk that inappropriate financial incentives could interfere with medical judgment and patient care.

CMS released a proposed rule to implement the Sunshine Act in December 2011 and accepted comments until mid-February. A final rule was expected shortly thereafter, but on May 3, CMS reported that applicable manufacturers would not be required to start data collection prior to Jan. 1, 2013, so as to allow time for the agency to address the comments—over 300—submitted during the 60-day comment period, and for affected organizations to establish their data capture processes. A final rule is now expected by the end of the year.

Issues that those involved in clinical research should consider while awaiting the Final Rule include the following:

**Will payments by drug, device and biologic startups to physician researchers for early-stage development work be reportable?** Under the proposed rule, reporting requirements are limited to applicable manufacturers of a "covered drug, device, biological or medical supply." Covered drugs and biologicals are limited to those that require a prescription to be dispensed, and covered devices are limited to those that require premarket approval by or notification to the Food and Drug Administration (FDA).

These limitations appear to exempt companies that have no FDA-approved products. Relieving startups from the burden and expense of the reporting obligations unless and until they have an FDA-approved product would support early research that is critical to product development.

**How will contractual obligations change?** The possibility of significant monetary penalties for violations of the Sunshine Act ($1,000 to $10,000 or $10,000 to $100,000 if the violation is "knowing") will put significant pressure on clinical research sponsors to submit timely, accurate and complete payment information. To the extent that sponsors use contract research organizations (CRO) to make payments to teaching hospitals and physicians, the sponsors will probably strengthen provisions in their contracts with CROs relating to records and reports of payments made.

**How will disputes between clinical trial sponsors and teaching hospitals and physicians over reported payments be resolved?** Under the Sunshine Act, covered recipient teaching hospitals and physicians have 45 days to review the data submitted by manufacturers before it becomes available to the public. Commentary to the proposed rule notes that CMS will not be actively involved in arbitrating disputes between applicable manufacturers and covered recipients about payment reports.

Instead, CMS plans to allow either the applicable manufacturer or the covered entity to report that a payment is disputed, and if the parties cannot resolve the dispute, the modified information provided by the covered recipient will be posted on the website. Those involved in research should stay abreast of what the reporting and dispute process will look like in the final rule, e.g., whether the rule will require manufacturers to share with covered recipients the data they plan to report prior to reporting it to CMS, as some have recommended.

**How will Sunshine Act reports be reconciled with other requirements governing the collection and reporting of similar information?** In recent years, reporting requirements from multiple sources have been imposed on those involved in research, including the National Institutes of Health conflicts of interest final rule, International Committee of Medical Journal Editors disclosure requirements and state aggregate spend laws, none of which will necessarily be preempted by the Sunshine Act. Satisfying these requirements and assuring the consistency of reported information will challenge all involved.