Mixed experience with the Sunshine Act

Open Payments process smoother but adding burden for sites

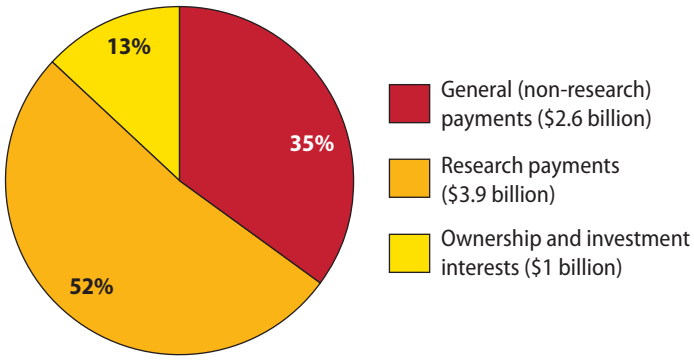
Pharmaceutical companies have finished submitting the third batch of data detailing their financial relationships with physicians and teaching hospitals under the Open Payments program, also referred to as the Physician Payment Sunshine Act. Investigators now face the prospect of implementing sophisticated new processes and systems that can track and verify clinical research grant payment information.

The increasing burden associated with Open Payments regulatory requirements already has resulted in some investigators, particularly private practice physicians who conduct clinical research part-time, leaving the clinical research enterprise or cutting back on their participation.

"Research has become much harder than it was 10 or 15 years ago. It's gotten more complex. We are struggling just to stay above water. It's hard, when you are struggling, to add more layers," said Ana T. Marquez, founder and CEO of Marquez Clinical Site Partners and a site owner and chief financial officer for a number of research sites in Florida.

For pharmaceutical companies, the recent reporting cycle has been fairly straightforward and lacking in controversy, compared to previous years, and many of the initial problems related to data submission have been resolved. Companies applied lessons learned from prior reporting periods to their processes, and communications have improved between sponsors and the Centers for Medicare & Medicaid Services (CMS), which manages the program, concerning reporting and technical requirements. Both sponsor companies and investigative sites also have become more familiar with the CMS Open Payments reporting template.

Distribution of 2015 Sunshine Act payments to physicians
(Total: $7.5 billion)



Source: Centers for Medicare & Medicaid Services Open Payment Report

"Companies experienced far fewer challenges submitting their data to the system than they had in prior years," said Lauren Roth, assistant general counsel for the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group that represents research-based pharmaceutical companies in the U.S. "Interacting with the Open Payments system has, in general, improved."

Yet the impact of Open Payments on investigative site operations is less understood, and the full effect of its implementation will not be clear for several years. Sponsors and CROs have added contractual requirements for sites to track and report third-party payments, which have the potential to add cost and time burdens, yet many investigative sites don't fully understand the obligations or fail to comply. Some sponsors have begun asking investigators to validate payment information prior to publication. An overly complex registration process and inadequate review period, however, has prevented many investigators from participating in the CMS data validation process and has raised questions about the accuracy of the information posted.

Investigators have criticized the method used to report research payments, arguing that it misrepresents the amount of money principal investigators (PIs) receive in support of clinical trials, and expressed concerns about the implications of reporting