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Reality of costs and impact rain on Sunshine Act

Concerns mount over compliance burden on CROs, sponsors, unanticipated consequences for research

By Karyn Korieth

As pharmaceutical companies have just finished submitting first-period reports detailing their financial relationships with physicians and teaching hospitals as required under the Open Payments national disclosure program, also referred to as the Physician Payments Sunshine Act, most have found the time and resources needed to comply with the law are significantly higher than originally anticipated.

The Centers of Medicare & Medicaid Services (CMS), the agency responsible for enforcing Open Payments, estimated compliance would likely cost the industry a total of $269 million in the first year and about $180 million each subsequent year. Yet most industry insiders believe CMS grossly underestimated the costs. Large sponsors reported spending tens of millions of dollars over the past three years hiring outside consultants and internal resources, upgrading systems and bringing in new technology to create processes to collect and report the granular data needed to comply with Open Payment requirements.

While the full financial impact of the law has yet to be understood, already there are concerns about the unanticipated consequences Open Payments will have to the clinical research enterprise. A Tufts Center for the Study of Drug Development (CSDD) analysis found 22% of study budgets already are spent on costs related to regulatory compliance; the additional financial burden of Open Payments is expected to add to that bottom line drag and, as a result, drive up drug development costs—or divert resources away from clinical research and other areas of innovation.

"It's a complex industry in and of itself. When there are layers on top of it for such

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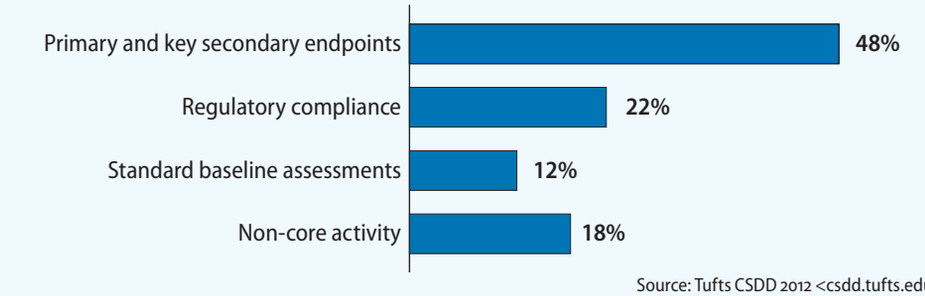
Distribution of study budget direct costs by procedure type

Procedures associated with:



Source: Tufts CSDD 2012 <csdd.tufts.edu>

Cloud computing expanding into all areas of clinical trial conduct

Benefits outweigh the complexities, challenges of finding right vendors

By Ronald Rosenberg
CenterWatch Staff Writer

Mention cloud computing for clinical trials and you're likely to hear how it has begun to lower skyrocketing R&D costs while providing ease of use, rapid scalability, flexibility and availability when compared to other storage and processing options.

Having the latest and most reliable information readily available coupled with the ability to share it in real time and run the same program across multiple disparate computers in different parts of the world is just the beginning. The ability to analyze results more quickly and communicate with clinical research teams across the globe—plus store it all virtually—are among its major benefits for large sponsors and CROs. Customers can draw as much or as little computing power they need.

The "cloud" or "cloud systems" are terms used to describe a virtual program that stores information and allows a network of computers—either publicly or with limited access—to connect and share files via the internet. All data is kept in a virtual space or "in the cloud" rather than a single storage system. This enables virtually unlimited computing resources on tap, which allows pharmaceu-

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things as the Sunshine Act, it just makes the work that much harder because of the level of administrative processes that have to be implemented across the company," said Shawn Pelletier, group director, global quality operations at Bristol-Myers Squibb (BMS). "Every change has a cost associated with it, which has a direct correlation to the overall increase of drug development costs."

Significantly, as CMS prepares to post the first reports on a searchable, public web site in September, many fear another unintended effect of the law could be to discourage physicians and teaching hospitals from participating in clinical trials. Research grants will be reported separately from other payments to physicians, such as those for consulting or travel. Yet some have voiced concerns that clinical trial payments, which could total tens of thousands of dollars or more, will be misinterpreted by the general public and could unfairly tarnish the reputation of physicians who conduct industry-sponsored studies.

"I don't know what the impact is going to be. I don't think it will shut down clinical research. But for a significant portion of investigators, this is going to be a disincentive to do clinical research. And that is really sad," said Richard Litov, Ph.D., director of Pedia Research, which has sites in Kentucky and Indiana . "What benefit does the law have? None. How does it help clinical research? Not at all. It only prevents quality physicians, who otherwise would be interested, from conducting clinical research."

The Open Payments program was meant to address concerns that industry payments to doctors could directly or indirectly affect their scientific independence and clinical judgment; the information is intended to allow consumers to make better healthcare decisions. Yet critics fear the data posted on the national web site, particularly concerning clinical research payments, will be unhelpful and confusing to the consumers who are supposed to benefit from the transparency.

"I think it's likely to have an inflammatory impact on a fairly unsophisticated public that doesn't, for the most part, understand the real ins and outs of what goes on, particularly in research," said Gary Shangold, M.D., immediate past chair of the Association of Clinical Research Professionals (ACRP) board of trustees, CEO of startup InteguRx Therapeutic and president and managing member of Conviotech. "It's going to just enhance their pre-established biases that any activity by profit-seeking pharmaceutical companies involving physicians is inherently evil, deceptive and wrong. And I think that does the entire enterprise a tremendous disservice."

"For a significant portion of investigators, this is going to be a disincentive to do clinical research. And that is really sad… The bottom line is that it absolutely has nothing to do with patient safety or the quality of the data. That is what additional legislation should be about."

—Richard Litov, Ph.D., director, Pedia Research

Compliance more complicated

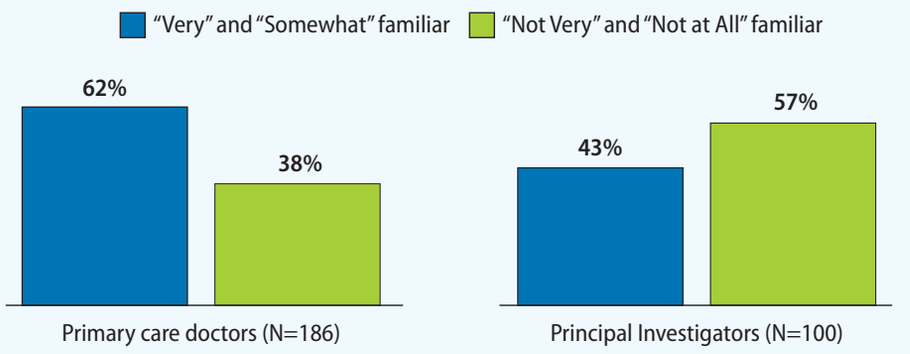
When Congress passed Open Payments as part of the Patient Protection and Affordable Care Act in 2010, pharmaceutical companies initially focused on the difficulties of implementing new systems to comply with the law and didn't anticipate the significant investment that eventually would be required.

At BMS, which has been an industry leader in clinical trial transparency efforts, teams initially reviewed internal processes and workflows to identify spend within core areas, such as R&D, and then determined whether systems captured the required level of detail for physician payments. The goal was to use current processes and systems whenever possible to collect the data for physician payment reports.

Yet, since no single application collected the level of detail required, BMS needed to enhance its existing systems by linking multiple systems or expanding data fields, including those that track clinical trial activities through a Clinical Trial Management System (CTMS) and other trial and consultant payments that include travel, dinner or reimbursement expenses associated with the activities. Legacy systems needed updating to fill gaps identified, and some information required for CMS reports, such as physician taxonomy codes, was manually retrieved from government web sites and entered into BMS systems.

"I don't think that anyone really anticipated the level of complexity that we were going to have to undergo in order to identify covered-recipients expenditures that would be reported under the act," said Toni Brock, director of business projects and planning, enterprise services, at BMS. "When we started this process, we had a number of legacy systems that didn't contain the level of detail that we needed for reporting. We did a lot of work to ensure

Familiarity with the Sunshine Act



Source: Industry Standards Research (ISR), 2013

not only did we integrate master data that initially wasn't contained in our source systems, but we also made modifications to those systems to ensure we were collecting the data in real time as the transactions were happening with individuals. Whether it was R&D or commercial, that same level of detail had to go into each of those source systems in order to comply with the act."

Holly V. Malin, director, study support services, global clinical services/global development operations, Takeda Pharmaceuticals International, said the Takeda Boston site implemented a web-based system that allows tracking payments to each investigator it works with, both on the clinical and commercial side. Some parts of the system are manual. Additional data is pulled from internal departments and systems in order to populate all of the fields required by CMS.

"An internal team spent several months visiting different departments trying to educate and promote awareness about what payments we are obligated to track per the Sunshine Act," she said.

Outsourcing strategies further compounded data collection challenges for sponsors. Since CROs typically make investigator payments on behalf of sponsors when they manage a study, companies needed to define a process to receive payment information from CROs in a timely manner. Many sponsors have amended their contracts with CROs to include a transparency section that requires the CROs to have data assurance mechanisms for tracking physician payments. Even though CROs already have their own payment systems in place, sponsors are requesting data in a specific CMS format, which can then be validated and incorporated into the company's reporting process.

As a result, CROs also have spent significant time and money to overhaul their own IT and reporting systems in order to report detailed physician payment data requested by sponsors. One top company reportedly spent more than $500,000 to develop and license its tool and another $500,000 a year on resources, including an aggregate spend team and IT and support systems staff.

At Quintiles, the world's largest CRO, one of the additional challenges has been that different clients request different physician payment data for their CMS reports. Although Quintiles has a standard template, about 100 customers have asked for different templates, meaning the CRO must use nearly 100 templates to report physician payments.

"It's been really costly for us and it's been very interesting, because that cost doesn't seem to be considered by CMS. We've had to hire people. We've had to totally revamp our IT systems and our reporting systems. It's been a pretty big investment. And it's not just us. All CROs are having to do the same thing," said Judy Beach, Ph.D., senior vice president, senior associate and general counsel regulatory & government affairs, global chief privacy officer, Quintiles.

Some sponsors and CROs have turned to service providers that offer centralized systems that both manage clinical trial payments to investigators and provide data needed for CMS reporting obligations. Many smaller companies, in particular, that lack the resources to develop their own internal reporting processes and are less able to scale infrastructure costs, have turned to outside companies for data collection help.

"There still are sponsors that do not have a good solution in place," said Kyle Cunningham, vice president of product management at Greenphire. "It's changed even over the last year in terms of how many have put processes and/or internal systems in place to adhere to the CMS requirements for Open Payments. But there still are organizations that don't have strong solutions in place and they are looking for help from us to, basically, give them not just the data, but in the appropriate format so they can simply turn around and provide those reports to CMS."

One cost driver was that CMS was late in publishing its final guidance on reporting requirements. CMS issued its first proposed rules for reporting payments in 2011, about a year after the act became law, but delayed release of the final rule until February 2013, only a few months before companies needed to begin collecting data to comply with the law. In the end, CMS made substantial changes in the final rule, including a requirement that companies report payments for pre-clinical research, phase I-IV clinical trials and investigator-initiated trials in separate templates.

Yet, the delays meant sponsors had to develop their systems over the past three years based on predictions of what might be required, rather than definitive rules.

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"The government did not quickly provide us with final regulations," said BMS' Brock. "We were constantly having to respond to uncertainty and build systems to support internal business processes at the lowest level of detail possible so that, regardless of what the final regulation looked like, we were going to be able to respond. That is what drove cost, and it also drove the number of resources we needed to comply with the law."

As sponsors submitted physician payment data for the first reporting period (August through December 2013), they have been frustrated with the lack of useful feedback from CMS about errors and how to correct them, which contributes to the number of resources needed for the work, as well as the amount of time spent trying to interpret the feedback.

"When we submitted our data to CMS, we received feedback that we had a few errors. There wasn't enough specific detail in that communication about the error to clearly identify the problem. With other government databases like the EMA or the NIH, if there is an error the communication is very specific about which data field or special character, so it's easy to identify and correct the error; maybe it's a dash or a country code causing the error. When we submitted our data to CMS, BMS received a list of errors on the R&D side, but the communication didn't provide specific information to easily identify and correct the error. We spent a lot of time investigating the data, including trial and error, to correct it," said BMS' Pelletier.

Increased burden on sites

Investigators are bracing themselves for an increase in administrative and accounting burdens as a result of the law. Although sponsors are responsible for submitting physician payment data to CMS, many now add language to study contracts requiring investigators to give them access to all site financial information and to provide payment information required by CMS, if needed. In addition, since there is no universally accepted template for the information, every sponsor and CRO wants the data in a different format.

"This is going to be a bigger burden on us because everyone wants different types of numbers or to put it together in a different way. Nobody knows how much it's going to cost us until we know how frequently they ask for the information," said Pedia Research's Litov. "To me, the bottom line is that it absolutely has nothing to do with patient safety or the quality of the data. That is what additional legislation should be about. There is absolutely no benefit and it's going to be a huge accounting burden."

Sponsors report one of their biggest challenges is the need to educate the physicians they work with about the new reporting requirements and what information will be posted on the public CMS web site. Research payments posted on the site will include the entire research grant amount and attribute it to the principal investigator (PI). Sometimes the amounts reported are for an institution and the investigator named would receive only a portion of the payment, but that aspect may not be evident to the general public.

An Industry Standard Research (ISR) report found only 10% of PIs have a "complete understanding" of the act, and almost 75% said they expect sponsors to notify them about payment amounts that will be reported to CMS. The report said sponsors risk "potential negative repercussions" if they fail to notify investigators before payments are posted on the public database.

"Some of the physicians who work with us internally were taken aback by the fact that so much personal information would be shared," said Malin. "I'm concerned about whether public scrutiny of this information will change our relationships with HCPs (healthcare professionals). Will HCPs walk away from engaging in legitimate and important research and other work with us to avoid the public exposure of payment information? That is my concern. Without collaborating with HCPs, it's very hard to do our research."

ISR found nearly one in five PIs said they might stop participating in clinical trials if they began to conduct "too many" trials for one sponsor; in particular, if a site runs about 40% of its trials with one sponsor, it might get uncomfortable and pull back on the amount of work for that company. Similarly, ISR found 13% would stop participating in some trials if their site started to make "too much" money from clinical trials.

Many worry payments to investigators posted on the national web site could be

Anticipated impact of the Sunshine Act on investigator willingness to participate in clinical trials

Once the Sunshine Act has gone into effect:	"Much less" and "Somewhat less" likely	"No change," "Somewhat more" and "Much more" likely
Likelihood you will continue to conduct clinical trials	14%	86%
Likelihood you will continue to participate in one sponsor's clinical trials if you are conducting too many for them	18%	82%

N=100 Principal Investigators

Source: Industry Standards Research (ISR), 2013

misinterpreted by the public, since CMS expects the amounts to include costs associated with patient care, laboratory expenses, salaries for clinical research coordinators and other staff, study drugs and other in-kind items. Most principal investigators barely profit from conducting research—many actually lose money on clinical trials—but the payments reported on the CMS website could report research grants to investigators or teaching hospitals worth millions of dollars.

"Only a very small percent of the money spent in a typical, large phase II or phase III trial ever ends up in the pocket of the PI," said Shangold. "And yet, the way it is being reported on this national web site, the investigator may have received millions of dollars for the study. So he looks like he is in the pocket of the drug company, when he is spending tremendous amounts of time and effort to do legitimate scientific medical research and he is barely profiting at all from this research."

Christine Pierre, president of the Society for Clinical Research Sites (SCRS), a trade organization representing 14,000 investigators at sites in 37 countries, said the Sunshine Act was created to ensure the transparency of physician payments for activities such as honorariums and travel that could be perceived to influence a physician's decision-making. Yet, she said, when clinical research was included in reportable activities under the act it was largely interpreted as "a stipulation that fundamentally deviated" from the law's original intent.

"This 'misrepresentation' of payments being made to sites is rendering a negative impact on the medical community's willingness to remain engaged in clinical research. Receiving subsidies to conduct a clinical study is absolutely different than other payments," said Pierre. "Some investigators confronted with this complex problem have simply decided, 'I'm out,' in terms of conducting research. They don't want their patients, or the communities in which they practice, to be imparted with the misguided, unsavory idea that funds are being awarded for something ethically questionable. This loss of participation of qualified and experienced investigators is extremely disheartening."

In addition, due to lack of specificity from CMS about what expenses or in-kind items should be reported, items such as indirect payments, the value of equipment and pass-through costs included in the research grant will vary depending on each sponsor's interpretation of the guidelines, making it impossible for the public to fairly compare payments from different companies. Quintiles, for example, found some of its customers include pass-through expenses, such as clinical supplies or equipment needed for the study, in the aggregate payment, while others exclude those costs.

Tracking the potential for conflicts of interest

Percent of respondents

Receiving from pharmaceutical and biotechnology companies:	Physicians (N=1,662)	IRB board members (N=563)
Consulting fees	18%	14%
Speaking fees	16%	14%
Advisory board fees	9%	10%
Clinical trial patient/review fees	3%	23%

Source: Campbell et al. *NEJM* 2006 & 2007 surveys of academic and community-based physicians and Institutional Review Board professionals

"We are worried about the chilling effect on investigators participating in research," said Quintiles' Beach. "If I had been doing trials in the past, I would be okay. But if I were a new investigator and they said everything you are getting paid, even pass-through costs or money you may not be benefiting from is going to be attributed to you and put on the internet, you'd have to think twice. It's worrisome to me. It's hard to get really good investigators to participate. I'm hoping that is not going to be the case. But that is a little bit troubling."

The Open Payments program gives PIs the chance to review data before it's published on the national web site, and CMS has established a process that allows physicians to challenge the payment amounts reported by sponsors. Many companies have set up their own systems to address physician disputes about reported payments.

"We also are developing a process to help manage questions or disputes with HCPs about information reported to CMS before that information is made available to the public in September," said Malin. "We have good relationships with these HCPs. We wouldn't want disputes about a transfer of value provided to interfere with those relationships. We have people available by phone to speak with HCPs. We anticipate it could require a lot of effort to deal with those disputes and make sure there is a clear process for coordinating those communications."

Practically, however, it will be difficult for physicians to find the time or have access to an auditable paper trail that would allow them to win a dispute with a sponsor over payment amounts. Leadership in the physicians group of ACRP recently distributed an internal memo to its members recommending they consider ignoring the Open Payment dispute process, even if they disagree with the payment amount.

"Many physicians who, up until now, have been working with pharmaceutical

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companies in one way or another are very troubled by their ability, let alone their practical capacity, for evaluating and ultimately disputing, and prevailing in disputes, when they don't agree with the amounts of money being reported in their names," said Shangold. "What is bothering a lot of physicians is whether they have the means, let alone the time, to figure out all of the components of those transfers of value, disputing it in the fairly compressed time period that has been allotted for that process and having any hope of the data being corrected by the company. To the extent some doctors are sensitive about what gets said publicly about them, it's likely to discourage them from wanting to do research."

Looking forward

In many ways, the Sunshine Act codifies transparency efforts already underway across the industry. As awareness and sensitivity about the potential for industry money to corrupt various processes in healthcare and clinical research have increased over the past decade, organizations and medical journals have adopted rules requiring physicians to disclose potential conflicts of interest. Many sponsors also have adopted their own disclosure rules, sometimes as part of corporate integrity agreements, and already collect the kind of data now mandated under the Open Payments act.

Cost to implement systems to report physician payments under Open Payments, however, have been unexpectedly high. Many also argue that the way research-related payments are reported under Open Payments is misleading and does nothing to increase transparency and protect patients, since they include amounts the physician never actually receives. Sponsors are concerned that posting research grant payments on a searchable, national database could harm their relationships with investigators.

Yet, because of the strong momentum for increased transparency, these unintended consequences are unlikely to create any kind of impetus for reform of the Open Payments law anytime soon. Before CMS issued its final rule, there was significant pushback from both industry groups and physicians about specific Open Payments reporting requirements, including many comments that clinical research should not be included in a law meant to disclose the value of gifts, travel, meals and other transactions that might cause a physician to favor one product over another. In almost 400 comments, many argued the cost and compliance burden would harm clinical research.

CMS, however, showed no willingness to exclude payments or "transfers of value" related to clinical research in the final rule, saying it would be "inconsistent" with the intent of Congress. In addition, since Open Payments is part of the Affordable Care Act, changing the law requires an act of Congress and the President's signature, unlikely in the current political environment.

Going forward, sponsors will need to adjust to the high costs of reporting physician payments to CMS and strengthen relationships with their investigators to keep them engaged in clinical research.

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