



The Sunshine Act and Clinical Research

Views from Principal Investigators and
Primary Care Physicians



Finally!

After months and months of speculation, delays, and mounting uncertainty, the industry finally received word from the Centers for Medicare and Medicaid Services regarding the final rule to the Sunshine Act. Officially called the "National Physician Payment Transparency Program: Open Payments." The rule will require drug and device manufacturers that receive government reimbursements to collect data on gifts and payments to teaching hospitals and physicians, starting on August 1st, 2013. The manufacturers will report the August to December 2013 data to CMS by March 31, 2014, which will then become public on Sept. 30, 2014. Providers will have 45 days to review the data before it goes live on the public website.

This whitepaper focuses on an important sub-set of reporting categories, namely those that center on payments for medical research activities.

During the open review period, CMS received a significant amount of feedback on the methodology and requirements proposed in the draft regulations regarding research payments. In the end, CMS made some substantial changes in the final rule. Companies will report these payments separately from the other "payments and transfers of value," and will have additional data elements to disclose, including the study name and principal investigator's name. CMS also explained when these payments are protected from publication on the public website, and when they must be published along with other payments.

CMS defines the following:

Clinical investigation

means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Research

includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Sunshine Act Timeline

August – December 2013

Manufacturers must collect data on gifts and payments to teaching hospitals and physicians.

August 1, 2013

National Physician Payment Transparency Program: Open Payments Act goes into effect, requiring drug and device manufacturers that receive government reimbursements to collect data on gifts and payments to teaching hospitals and physicians.

March 31, 2014

Manufacturers must report the data collected from August - December 2013 to CMS.

August 16 – September 30, 2014

Providers will have 45 days to review the data before it goes live on the public website.

September 30, 2014

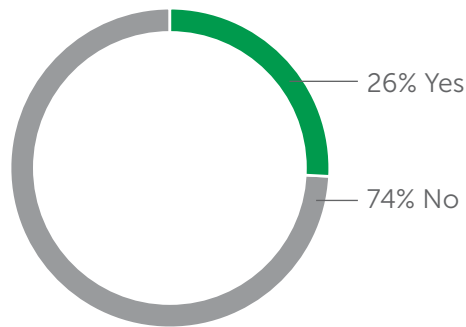
Data reported to CMS becomes public.

Not the warmest reception

The 286 pages of the final rule, of which 35 pages are regulations, preceded by 251 pages of commentary and explanations, are filled with defining which payments are considered fair-game for reporting and which are excluded from reporting.

Before we dive into the specifics of the rule, suffice it to say that, according to an ISR survey of 103 U.S. Primary Care Physicians, physicians are not in favor of the Sunshine Act and many believe it will negatively impact their practice.

"Are you in favor of a public, searchable database of all financial physician-industry relationships that would be made available to the public?" (N = 103)

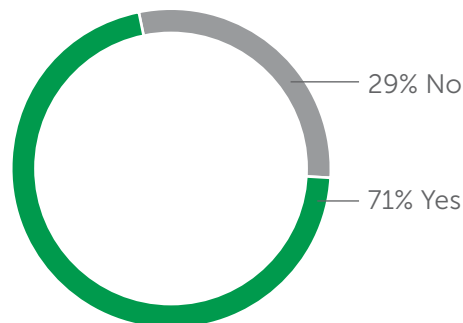


Surprise?

ISR has a long history measuring the performance of service industries. This experience has taught us that measuring how well a company meets or misses expectations is, in our opinion, the best way to benchmark performance. Something that inevitably causes strife in any relationship is a failure to communicate expectations. Very rarely do people value surprises. When it comes to reporting research payments to principal investigators, we believe pharma is at some risk of surprising physicians.

The vast majority of U.S. PCPs expect to be notified by the pharmaceutical company as to what the value of a particular service or benefit is prior to being offered it. This is relevant for clinical research because the rule is quite broad in its definition of what services are included under clinical research. CMS states "We envision that this (research payment) would include the costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items."

"Will you expect to be notified by the pharmaceutical company of the value of a particular service or benefit prior to it being offered to you?" (N = 103)

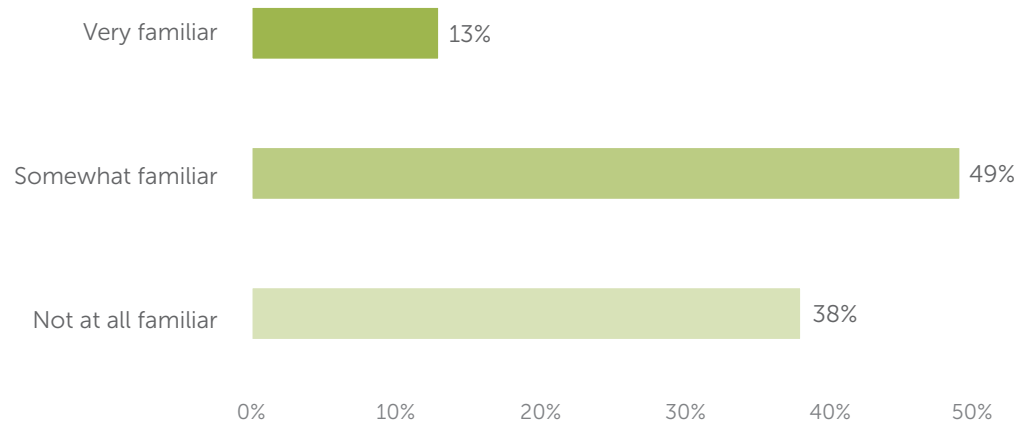


Pharma must make it very clear to principal investigators as to the amount of payment that is going to make its way to the searchable, public database or risk potential negative repercussions. The possibility of a negative fallout stems from a desire for prior notification combined with a general lack of awareness of the Sunshine Act and its implications.

Overall, there is a general lack of awareness among both U.S. Primary Care Physicians (PCPs) and U.S.-based principal investigators regarding the Physician Sunshine Act (Sunshine Act). Over one-third of PCPs are “not at all familiar” with the Sunshine Act and only 10% of principal investigators have a “complete understanding of the act.”

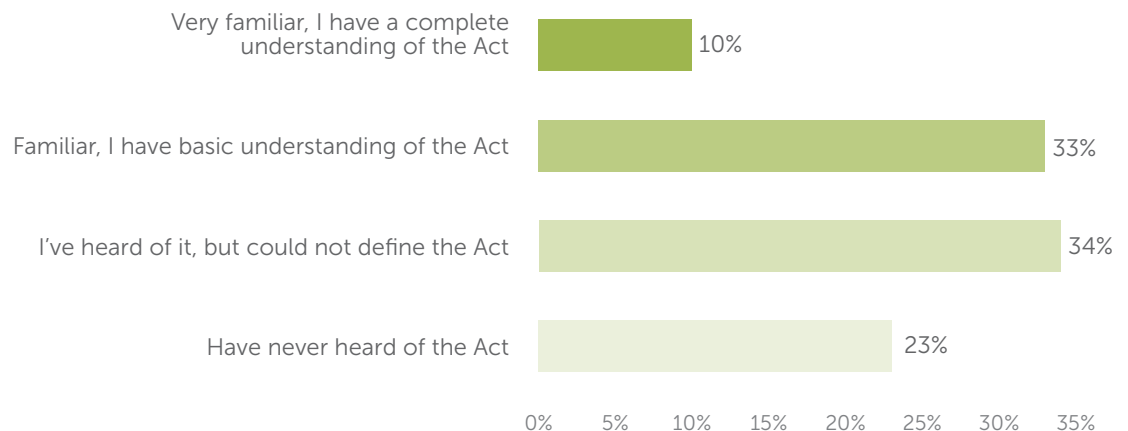
PCP Awareness of Sunshine Act

“Please indicate your familiarity with the Physician Payment Sunshine Act (PPSA).” (N = 186)



Principal Investigator Awareness of Sunshine Act

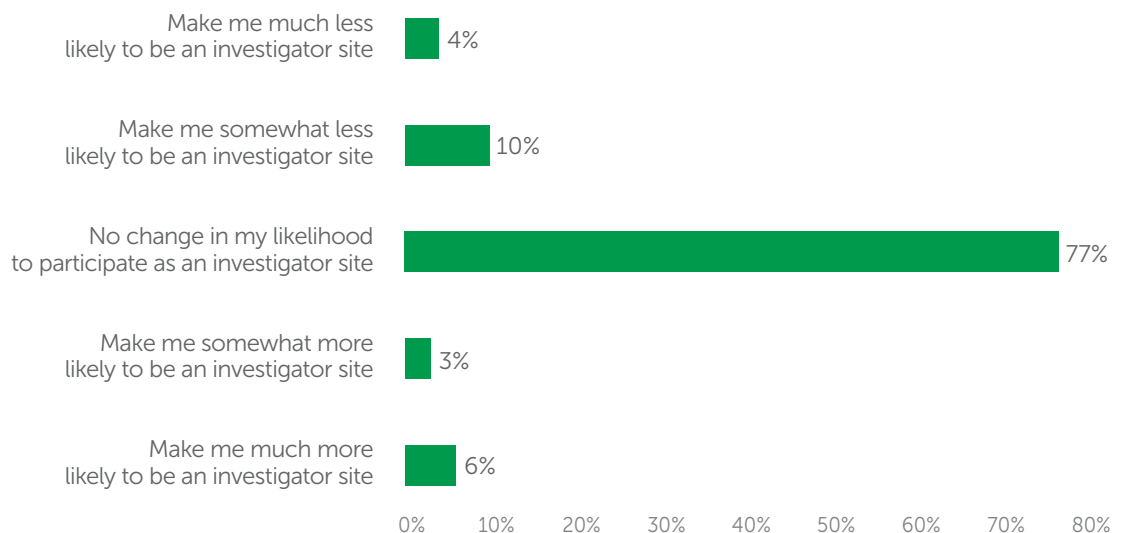
“How familiar are you with the Sunshine Act?” (N = 100)



Impact on Clinical Research

When ISR asked principal investigators how the Sunshine Act might impact their willingness to participate as an investigative site for a clinical trial, thankfully, only a handful indicated they would be less likely to participate.

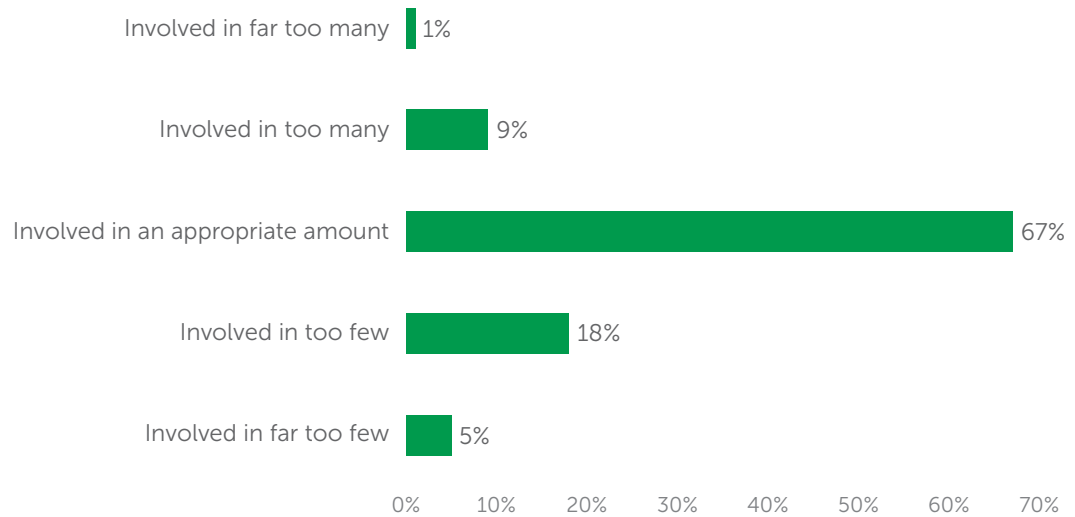
"Assuming the legislation continues as-is and any payments, including grants/ fees for recruiting patients into clinical trials, are made publically available via a national database, how would this change the likelihood your site would be an investigative site for clinical trials?" (N=100)



Setting expectations is going to be important if pharma wants to ensure their principal investigators are not taken by surprise when it comes time to make research payments publically available. Looking at the clinical development industry from a macro level, one thing is clear; the pharmaceutical industry cannot afford to lose any principal investigators.

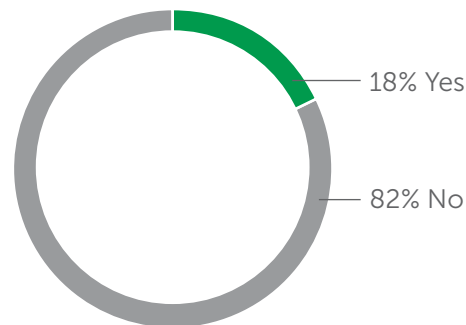
ISR data show that the vast majority of principal investigators are involved in the “right” amount of trials for them. This means that if the industry loses principal investigators, the gap created is not likely to be picked up by existing investigators. For more information on the industry’s patient recruitment challenges, see ISR’s infographic on Patient Recruitment: http://www.isrreports.com/files/ISR_Reports_-_Patient_Recruitment_Bottleneck_-_Infographic.pdf

“Overall, what is your opinion of the number of clinical trials you are involved in?” (N = 100)



However, when ISR pushed a little further about the possible ramifications the Sunshine Act might have on investigators' willingness to participate in clinical trials, we found that there is a pocket of investigators that could be at risk. Nearly one-in-five investigators ISR surveyed (18%) indicated they would stop participating in some trials if they started to do "too many" trials for one sponsor.

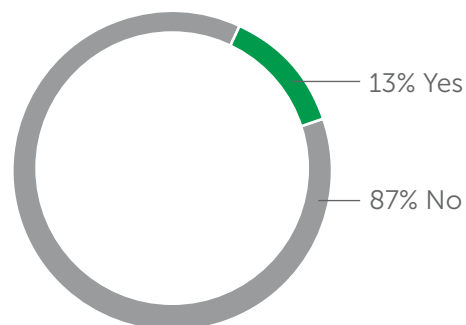
"In thinking about how this might affect your trial selection based on who the pharmaceutical sponsor of the research is, would you stop participating in some trials if you started to do "too many" trials for one sponsor?" (Base = 100)



When ISR probed a little further, we discovered that, on average, investigators start to get uncomfortable when the percent of trials they run with one pharmaceutical company reaches approximately 40%. In other words, if a site runs approximately 40% of their trials with one sponsor, then they might start to get uncomfortable and possibly throttle back the number of trials they conduct with that sponsor.

Similarly, we found that roughly one-in-eight investigators (13%) would stop participating in some trials if their site started to make "too much" money from clinical trials.

"In thinking about how this might affect your trial selection based on the amount of the investigator grants, would you stop participating in some trials if your site started to make "too much" money from clinical trials?" (N = 100)





Transparent red tape

Ultimately, only time will tell what implications the Sunshine Act will have on pre-clinical and clinical research. Over the years the pharmaceutical industry has whispered about the “investigator-prescriber effect.” The effect has been hypothesized, but to our knowledge never proven, to imply that physicians who work on clinical development studies are more likely to prescribe that drug once it becomes commercially available. Whether the “investigator-prescriber effect” is fact or fiction and whether the sections of the Sunshine Act that relate to research were meant to account for this is unknown. What is clear in the world of clinical development is that patient recruitment is one of the largest bottlenecks to faster drug approvals and patient recruitment starts with principal investigators, physicians wanting to do clinical research. Transparency is usually a positive attribute, as long as the potential unintended consequences have been fully vetted.

It is hard to argue against a law/rule/act designed to ensure transfers of value do not unduly impact healthcare decisions. Our hope is that since the world of clinical development operates under a constant struggle to find productive principal investigators, the Sunshine Act will not materially delay the development of innovative treatments.

Further definition of "research"

CMS went on to define and give examples of research payments. CMS concluded that *"We believe this definition includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations.* We have finalized that payments reported as research should be made in connection with an activity that meets the definition. In addition, we agree that requiring both a written agreement or contract and a research protocol is limiting for some types of research, so we are finalizing that if a payment falls within the nature of payment category for research, it only needs to be subject to a written agreement or contract or a research protocol. This may include an unbroken chain of agreements (instead of a single agreement between the applicable manufacturer and the covered recipient) which link the applicable manufacturer with the covered recipient because we understand that many applicable manufacturers use other entities such as contract research organizations (CROs), or site management organizations (SMOs) to manage their clinical research activities. For example, agreements between an applicable manufacturer and a CRO, between a CRO and an SMO, and then between an SMO and a teaching hospital would be considered a continuous chain of agreements from the applicable manufacturer to a covered recipient and would be considered a research agreement."

Research payment components and reporting

The rule explains what should be included in research payments. "We are also finalizing guidelines for what should be included in the total research payment amount. The amount should include the aggregated amount of any payments for services included in the written agreement/research protocol. *We envision that this would include the costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items.* The payment amount should not include any payments for activities which are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research. For example, payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately. Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment. In addition to research payments, we also believe that meals and travel should be reported separately (under the food and travel nature of payment categories) unless included in written agreement or research protocol and paid for through the large research contract."

CMS also instituted several additional reporting structures for research payment. The actual language used in the rule is outlined below:

"All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

- 1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by §403.904(c)
 - a. Name of the research institution, individual or entity receiving the payment or other transfer of value.
- 2) If paid to a physician covered recipient, all of the following must be provided:
 - a. The physician's name as listed in the NPPES (if applicable).
 - b. National Provider Identifier.
 - c. State professional license number(s) (for at least one State where the physician maintains a license) and State(s) in which the license is held.
 - d. Specialty.
 - e. Primary business address of the physician(s).
- 3) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.
- 4) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.
 - a. Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.
 - b. Name of the research study.
 - c. Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section) and for drugs and biologicals, the relevant National Drug Code(s), if any.
 - d. Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.
 - e. Contextual information for research (optional).
 - f. ClinicalTrials.gov identifier (optional).
- 5) For pre-clinical studies (before any human studies have begun), only report the following information:
 - a. Research entity name (as required in this section).
 - b. Total amount of payment (as required in this section).
 - c. Principal investigator(s) (as required in this section)."

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