

# ICO Newsletter

## Let the Sunshine In

The Physician Payments Sunshine Act (variously called the Sunshine or Open Payments Act), a component of the Affordable Care Act (ACA), is now in force. The Sunshine Act requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. The Act requires research sponsors to report such payments in a timely manner, although certain exceptions and delays related to research are allowed.

Companies subject to the Act were required to begin reporting payments by March 31, 2014. The Centers for Medicare and Medicaid Services (CMS), the federal agency charged with implementing the Act, calls the program Open Payments and has rolled out an associated website. The CMS website, the entry point for reporting and reviewing reported information, is at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>

Industry sponsors of medical research at Stanford (and elsewhere) have been busy interpreting Sunshine Act requirements and addressing them in research agreements. In ICO's experience, most sponsors propose terms that serve as notice of their reporting obligations. In certain instances, however, Stanford is asked to review or confirm information in payment reports. ICO generally refuses such proposals since Stanford University is not a manufacturer, health care provider or teaching hospital, and therefore doesn't have legal obligations under the Act.

Stanford investigators who are physicians should be aware that, whether or not they are acting as a physician on a sponsored project, sponsors are likely to report related payments. Generally, reporting sponsors will link project payments only with the principal investigator, and reported amounts may include all amounts paid (including salaries, benefits, tuition, materials and indirects). Stanford encourages investigators to review reported payments for accuracy; the Open Payments site provides a process to dispute reporting errors.

Researchers should also be aware that, to protect confidentiality of their expenditures, sponsors may elect to delay reporting of certain research-related payments or other transfers of value made under what they determine to be a product research or development agreement. The rules defining such agreements and allowing for reporting delays are somewhat complex, and CMS is currently in the process of revising reporting guidelines in this area.

### Hurry up and invoice, please...

For various reasons, research sponsors occasionally ask to be invoiced immediately after contract signing. Although timely payment is always welcome, Stanford Sponsored Receivables Management (formerly Accounts Receivable or A/R) generally doesn't issue an invoice until all of the following occur: 1) ICO issues the Advance Award Notice (AAN), 2) a spending account is created, and 3) the Notice of Award (NOA) issues. If the sponsor requires an invoice for business management purposes, assuming that the contract is fully executed and the invoicing process is properly documented, ICO will ask Sponsored Receivables Management to send an expedited invoice.

Previous issues: <http://www.stanford.edu/group/ICO/newsletters.html>

Unsubscribe: [ico@stanford.edu](mailto:ico@stanford.edu)



1705 El Camino Real  
Palo Alto, CA 94306  
Mail Code: 1850

T (650) 723 0651  
F (650) 725 7295  
[ico@stanford.edu](mailto:ico@stanford.edu)

### MEET OUR TEAM

Sally O'Neil  
Director  
[sally.oneil@stanford.edu](mailto:sally.oneil@stanford.edu)

Stefani Shek  
Associate Director  
[stefani.shek@stanford.edu](mailto:stefani.shek@stanford.edu)

Neil Morimoto  
Senior Contracts Officer  
[neil.morimoto@stanford.edu](mailto:neil.morimoto@stanford.edu)

Jim Gasiewski  
Senior Contracts Officer  
[jim.gasiewski@stanford.edu](mailto:jim.gasiewski@stanford.edu)

Jaysen Rajkomar  
Industrial Contracts Officer  
[jaysen.rajkomar@stanford.edu](mailto:jaysen.rajkomar@stanford.edu)

Janina Maniaol  
Material Transfer Associate  
[janina.maniaol@stanford.edu](mailto:janina.maniaol@stanford.edu)

Van Dinh  
Administrative Associate  
[van.dinh@stanford.edu](mailto:van.dinh@stanford.edu)