



Physician Payment Sunshine Law

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act requires health care product companies to track and report certain payments made to, and transfers of value provided to, physicians and teaching hospitals. It also requires manufacturers to report certain ownership and investment interests held by physicians and their immediate family members. The main purpose of the law is to provide patients with greater transparency into the relationships their health care providers have with life science manufacturers, including health care product companies. The law does not restrict industry-physician collaboration or interactions, nor prohibit payments or transfers of value. Rather, the law requires tracking and reporting of payments and transfers of value that result from these transactions.

In August 2013, health care product companies began collecting information about payments, transfers of value, and ownership interests of physicians and their immediate families. On August 1, 2014, physicians may access their own data inside the Open Payments System in order to review and correct any errors. They will have until September 30, 2014, to initiate and resolve any disputes, for on September 30, 2014, the data will be published on a public website by the Center for Medicare and Medicaid Services (CMS). This first disclosure period will cover the last five months of 2013, and will follow a calendar year in the future.

The Law is specific about which entities it will require to report payment data. Manufacturers of medical devices, drugs, biologicals, and medical supplies operating in the U.S. must submit Transparency Reports annually to CMS on payments and transfers of value given to physicians and teaching hospitals. Furthermore, Group Purchasing Organizations (GPOs) and manufacturers must report ownership and investment interests held by physicians or their immediate family members and any payments or transfers of value to physician owners/investors.

Should the physician choose to review their data before the September 30th publication date, they must register within the CMS database referred to as "Enterprise Identity Management System", also known as EIDM. CMS will initiate a full identity check to verify the registrant is, in fact, the physician. Once the registration with EIDM is satisfied, the physician will be asked to register within the Open Payments System. When the dual-step process is complete, the physician will have access to the data submitted by all U.S. health care product companies related to themselves and may review the data for accuracy. Without the express permission of the physician, the University may not access or review the payment data or initiate any corrections through the dispute process. The physician may nominate a SLUCare Administrator to access, review, and coordinate corrections on their behalf as part of the formal registration process in the Open Payments System within EIDM. Even when nominating a proxy, the physician must still register and submit to an identity check.

The University Policy on Medical Center Conflicts of Interest in Patient Care and Service identifies non-allowable interactions with health care companies due to the inherent bias they pose, and limits or defines acceptable methodologies for allowable interactions. The Policy requires faculty to report certain interactions with health care product companies, and requires SLUCare administration to assure overall integrity of patient care, service and trainee learning environments. The Policy requires that the University collect this data and reconcile it with that which is reported by CMS, so as to identify discrepancies and proactively work with the physicians for accurate financial transparency with health care companies. Furthermore, the University will coordinate responses to all external party questions (including media requests) after the payments to our physicians becomes public information.

The official CMS Website for the Sunshine Law, also referred to as the National Physician Payment Transparency Program, Open Payments has created a variety of guidance for physician and teaching hospital use, and can be found at <http://go.cms.gov/openpayments>. Also, information from the American Medical Association can be found at www.ama-assn.org/go/sunshine. The Saint Louis University School of Medicine is committed to assisting you navigate the Sunshine Law. Please direct your questions to the Graduate Medical Education Office at (314) 977-9853.

2014 Annual Compliance Update

Coming to a computer near YOU!



The Mandatory 2014 Annual Compliance Update will be available online starting August 1, 2014. Look for an email from the Office of University Compliance containing instructions on how to access the update.

Research Compliance



This month we bring you an [update](#) from the Iowa State case we brought to your attention in [January](#).

Dr. Dong-Pyou Han was accused last year of falsifying HIV/AIDS research blood samples by adding human blood—containing HIV antibodies—to rabbit blood in order to make it appear as though the rabbits on which a trial AIDS vaccine was being tested were producing HIV antibodies on their own as a result of the vaccine. Dr. Han now faces four felony charges as a result of his fraudulent research. He faces up to 20 years in prison. He has pleaded not guilty to the charges.

The research team at ISU, of which Dr. Han was a part, received a \$19 million grant for the vaccine research, much of which was awarded after the faked results were reported. The National Institutes of Health has announced that it will not make its final \$1.38 million grant payment to the ISU team because of Dr. Han's actions. Additionally, ISU has agreed to repay the NIH \$496,000 that it received for Dr. Han's salary and related costs.

Criminal and financial repercussions of this nature are somewhat unusual in the realm of research misconduct cases and can be attributed to the reckless nature of Dr. Han's falsification of research data. His case garnered wide-spread media attention and a direct response from Iowa's US Senator, Charles Grassley, who demanded refunds in the name of accountability.

Compliance administrators at Saint Louis University have watched the case with interest as it showcases an increase in federal agency enforcement despite the limited movement on initiatives within US Congress.