

The Sunshine Act Inevitably Rises

2014's key implementation dates and how physicians can be better prepared for them.

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In order to help interventional physicians stay informed of legislative and medicolegal forces affecting their practices, Endovascular Today will be including ongoing coverage of developments related to physician compensation, compliance, and counsel. Steven J. Cagnetta, Esq., and Steven K. Ladd, founders of Primacea, Inc., will curate this column. If you have specific or general questions you would like covered in future editions, please contact us at evteditorial@bmctoday.com with the subject line "Physician Counsel."



The Physician Payment Sunshine Act, now referred to as Open Payments, is a small part of the otherwise mammoth Affordable Care Act (ACA) that received very little public attention when the ACA was passed in 2010. The first groups to take notice were the drug and medical device industries, as each manufacturer is required to develop a reporting system to provide the Open Payments data.

Most hospitals and nearly all physicians paid little attention, as the dates seemed too far off to offset their more immediate concerns. However, those dates are now here, and physicians and their hospitals need to understand how Open Payments works and how to manage their rights under the new regulations.

PHYSICIAN UNDERSTANDING OF OPEN PAYMENTS

QPharma recently completed a study of 300 physicians to determine their level of knowledge regarding Open Payments. The results paint a clear picture:

- Only 25% of specialists claim to fully understand the act.
- 30% of primary care physicians admitted to having minimal or no understanding.
- More than 60% of physicians who accept samples did not know that the Open Payment Act requires disclosure.

- A majority did not know that records of these samples would be provided to the Food and Drug Administration.

- A large percentage did not know that payments directed to charities will still be credited to the physician who directed the payments.

There is obviously work to be done, as very few physicians know the details about the Open Payments requirements.

As a refresher, the Open Payments law was intended to provide a system in which applicable "manufacturers of drugs, devices, biologicals, or medical supplies" would report to the Secretary of the Department of Health and Human Services payments or other transfers of value to physicians and teaching hospitals. These data would then be made available to the public via a website managed by the Centers for Medicare & Medicaid Services (CMS), with the stated goal of providing more transparency regarding physician interactions with industry. There are many blogs and articles written about the details of the act, so our focus here is on the items that particularly impact physicians.

Table 1 includes a listing of key implementation dates, many of which have already been revised. Although some of these dates may slip further in conjunction with other launching difficulties of the ACA, it is important to prepare for each step in the process leading toward full public disclosure.

INDUSTRY IS ALREADY COLLECTING DATA

Obligations under Open Payments began on August 1, 2013, when industry was required to start collecting data on virtually every payment to or on behalf of a physician. The first reporting period was the 4 months from August 2013 through December 2013. All future reporting periods will be calendar years.

Physicians need to understand that all payments received from industry must be reported. This is not just "compensation" but also reimbursement of expenses and even a proportionate share of costs relating to an event

TABLE 1. KEY OPEN PAYMENT IMPLEMENTATION DATES

Event	Original Date	Revised Date
Data collection begins	8/01/2013	8/01/2013 (underway)
Physician registration begins	1/01/2014	Early 2014
Data submission starts	1/01/2014	Early 2014
Data submission ends	3/30/2014	90 days after submission starts
Physicians can review data	4/01/2014	Day after submission ends
Physicians can initiate a dispute	5/15/2014	45 days after review begins
Dispute resolution ends	5/30/2014	60 days after review begins
Final data reported to CMS	6/01/2014	After dispute resolution ends
CMS discloses data to public	9/30/2014	9/30/2014

attended by a physician. There are more than a dozen different categories to consider, including:

- Consulting fees
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than an accredited continuing education program
- Honoraria
- Gifts
- Entertainment
- Food and beverage
- Travel and lodging
- Education
- Research
- Charitable contributions
- Royalty or license
- Current or prospective ownership or investment interest (including those held by immediate family members)
- Grants

As a result, even if you were never paid anything for work, there is a reasonable chance that you might show up on the CMS site if you performed industry-funded research or attended industry-sponsored events.

Industry has been working hard to develop computer-based systems and internal policies to adjust to this new reality. CMS estimates that companies will spend more than \$260 million in the first year refining accounting systems and processes to comply with Open Payments. As representatives of industry testified at a Senate Committee on Aging hearing in 2012, companies were surprised by the complexity of regulations. One early adopter said their firm spent 23 months to understand business processes and model 30 sources of data, concluding that most manufacturers would need 180 days

after final regulations were published to “to get 70% of payments under control.”

PHYSICIANS MUST TRACK PAYMENTS TOO

We believe all physicians should track their compensation in order to protect their reputations. Based on Primacea’s experience on behalf of physicians in academic medical centers and community hospitals across the country, approximately 10 hours are needed each year to maintain the physician accounting system and conduct the year-end reviews of industry data submissions.

As a result, physicians’ investment in Open Payments will be on par with industry. Using Primacea’s experience and CMS assumptions of 334,500 affected physicians whose time is worth \$72.52 per hour, the value of physicians’ time will exceed \$240 million per year.

PHYSICIANS CAN REGISTER IN EARLY 2014

Originally scheduled for January 1, 2014, CMS will open registration for physicians on its web platform (<http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-payment-Transparency-Program/index.html>) in “early 2014.” Given complex regulations and the sheer volume of data being processed by untested industry accounting systems, registration is in the best interest of every physician. Why? Registered physicians will be able to review and dispute industry data submissions before the data become public.

Physicians who do not register will not be able to see what is being disclosed about them until after the data become public, because industry is not required to directly provide physicians with the data being submitted to CMS.

PHYSICIAN DISPUTE PERIOD SCHEDULED FOR APRIL AND MAY

Industry was originally scheduled to upload all of its data to the CMS website between January 1, 2014 and March 31, 2014. Those dates are now “early 2014” and “90 days after submission starts.”

Physicians who register on the CMS platform will have the ability to review and dispute the industry submissions posted about them. Disputes may be initiated during the 45 days after data submission and must be resolved by 60 days after data submission. If disputes cannot be resolved within that period, CMS will report the data that were submitted by industry with a provision for noting that the value was disputed by the appropriate physician.

The ability to dispute submissions is a critical right for physicians and for the public at large. It goes hand in hand with the right for physicians to provide a description of the positive purposes for consulting, a right that Primacea succeeded in adding to the final CMS regulations. A future column will focus exclusively on how physicians can best make use of this crucial description.

EVERYTHING CHANGES ON SEPTEMBER 30, 2014

CMS has scheduled the public launch of the Open Payments platform for September 30, 2014. If all goes as planned, all of the information that has been loaded onto the site will be made available to the press and the public.

The Open Payments information is expected to enable patients and the public at large to better understand the importance of physician–industry relationships to the advancement of medicine. Done correctly, this knowledge will enhance public trust and support the patient–physician relationship.

Future columns will provide details of how physicians and their hospitals can best manage physician–industry relationships in the Open Payments era. ■

Primacea provides tools to physicians and leading hospitals to facilitate transparency in innovation and manage compliance obligations.

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