



Impact of the Sunshine Act on Medical Affairs

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Background

The Physician Payment Sunshine Act is a component of the Patient Protection and Affordable Care Act (PPACA) that was signed into law by the Obama administration in 2010. The Sunshine Act is intended to enhance transparency between pharmaceutical manufacturers and healthcare providers by requiring that certain financial transactions be reported and made publicly available.¹ After several months of delay, the Centers for Medicare and Medicaid Services (CMS) finalized the Sunshine Act rule in early February 2013. Per final regulations, data collection will begin on August 1, 2013. All reportable data from August through December 2013 will need to be reported to the government by March 31, 2014 and will be available for public viewing on September 30, 2014.²

Pharmaceutical company personnel employed within medical affairs departments commonly interact with external physicians in the medical community. Appropriate understanding and execution of Sunshine Act practices is critical in an effort to prevent violations. It is unclear whether medical affairs employees are aware of the impending changes expected with the Sunshine Act. Very little data currently exists regarding this topic.

Objective

To measure the level of understanding and preparedness for the implementation of the Sunshine Act within Medical Affairs departments at pharmaceutical companies.

Methodology

An anonymous, web-based survey consisting of 28 questions via SurveyMonkey[®] was disseminated beginning on December 17, 2012 to medical affairs personnel at 35 pharmaceutical and biopharmaceutical companies. The survey was designed to capture demographics, Sunshine Act training, and the overall level of understanding of the Sunshine Act.

Evaluation of Survey Respondents

- Of the 210 industry representatives contacted, 60% responded to the survey (n=126).
 - 87% (n=109) completed the entire survey
 - 13% (n=17) did not complete all questions of the survey
 - Information provided from these respondents was included in the analysis
- All eligible respondents were industry-based medical affairs employees

Results

Background and Training

Figure 1: Functional Area (n=111)

Functional Area	%
Medical Information	26%
Medical Operations (ISS, CMEs, Ad Boards, Publications)	12%
Field-Medical Affairs (MSL)	46%
Health Economics Outcomes Research (HEOR)	8%
Pharmacovigilance	2%
Medical Director	6%

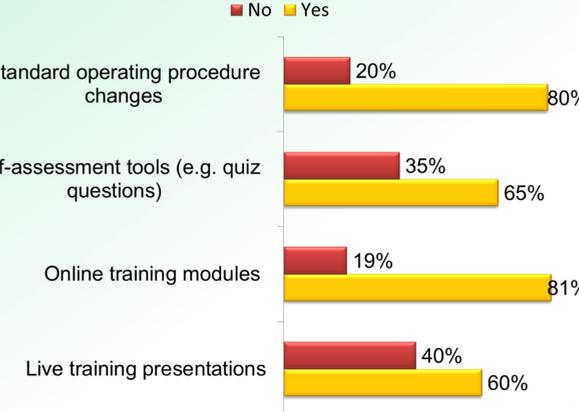
Figure 2: Length of time in Industry (n=122)

Time	%
<3 years	21%
4 - 6 years	24%
7 - 9 years	26%
>10 years	29%

Training

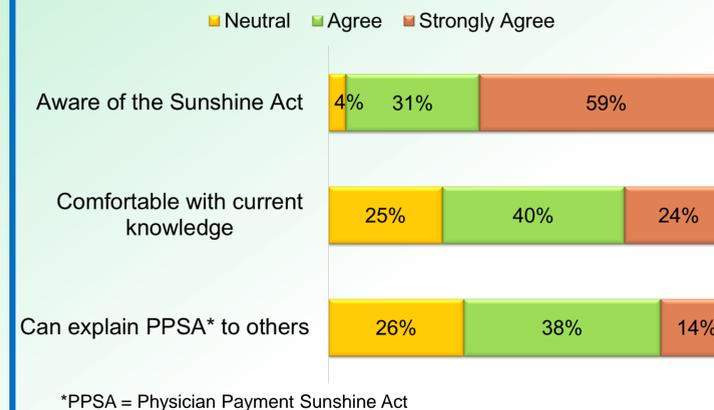
- 79% (n=95) of all respondents have received Sunshine Act training

Figure 3: Type of Training (n=105)



Understanding & HCP Interactions

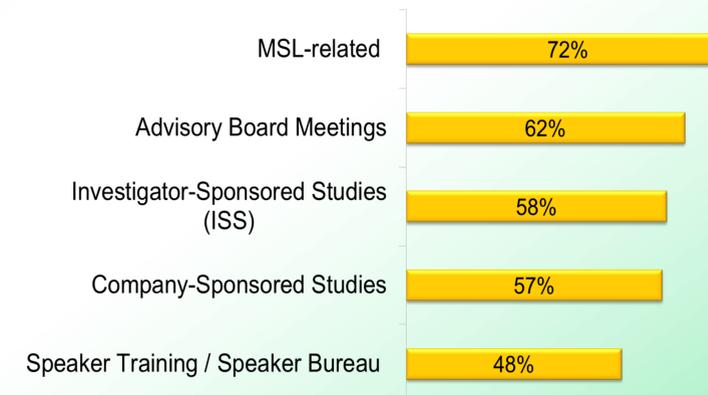
Figure 4: Sunshine Act Understanding (n=114)



*PPSA = Physician Payment Sunshine Act

- 44% (n=50) of respondents believe Sunshine Act reporting to the government is currently in effect
- 22% (n=24) do not know if their company has begun capturing transfers of value

Figure 5: Type of interactions with HCPs (n=89)



- 87% (n=114) of respondents interact with HCPs
- Reportable value items listed include:
 - Meals 80%
 - Consulting payments 56%
 - Investigator-sponsored studies 46%
 - Transportation 43%
 - Drug Information Literature 39%

Discussion

- A large proportion of medical affairs employees engage in reportable transfers of value with external HCPs
- The vast majority have received Sunshine Act training; however, the degree and magnitude of their understanding can be much improved
 - Many medical affairs employees falsely believe Sunshine Act reporting to the government is currently in effect
 - Only about half of all employees indicate that they would be able to explain the Sunshine Act to others
 - Some employees do not know if their company is currently tracking transfers of value made to HCPs
- Reasons for a suboptimal understanding of the Sunshine Act cannot be determined from this survey, but may include insufficient training tools, absence of government guidance, and delay in implementation
- Further evaluation should be conducted to measure the level of readiness for Sunshine Act implementation beginning in August 2013

Limitations

- Due to the sample size, substantial conclusions cannot be drawn from the data, nor can they be generalized across all pharmaceutical and biopharmaceutical companies
- This survey was not validated

Conclusion

Despite the fact that most employees are aware of the Sunshine Act, many do not have a thorough understanding of the processes involved. Sunshine Act training is being executed at most companies; however, employees may not have a sufficient understanding. Additional training strategies as well as assessment testing should be performed to identify whether trainees fully comprehend the details of the Sunshine Act. In addition, final guidance has changed since the time this study was completed. These changes will warrant additional training to all medical affairs employees across the industry.

References:

- Sullivan T. Physician Payment Sunshine Act: Center for Business Intelligence (CBI) Chart the State of Sunshine. *Policy and Medicine*. Retrieved Nov 6, 2012, <http://www.policyandmedicine.com/2012/10/physician-payment-sunshine-act-cbi-chart-the-state-of-sunshine.html>
- Centers for Medicare and Medicaid Services: Press Releases. Affordable Care Act "Sunshine" Rule Increases Transparency In Health Care. Retrieved February 8, 2013, from <http://www.cms.gov/apps/media/press/release.asp?Counter=4520&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&sr>

