

Perceived Impact of Physician Payment Sunshine Act on MSL Interactions

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Introduction

- The Physician Payment Sunshine Act (PPSA) was passed under the Patient Protection and Affordable Care Act in 2010. The Centers for Medicare and Medicaid Services (CMS) issued proposed regulations for the sunshine act provisions in December 2011. Final regulations were published in the Federal Register on February 1, 2013.
- The rule requires manufacturers of drugs, devices, biologics, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS payments or other transfers of value made to physicians and teaching hospitals.
- Payments exceeding \$100 annually to covered recipients must be reported to CMS. Any item or monetary exchange greater than \$10 must also be reported, even if the payments are not related to drug, device, biological, or medical supply.
- Reporting goes into effect August 1, 2013 for covered transactions. All reports must be sent to CMS by March 31, 2014 for the first reporting period.
- All reported payments must fall within the categories specified in the Act, which includes: consulting fees, compensation for services other than consulting, honoraria, gift, entertainment, food and beverage, travel and lodging, education, research, charitable contribution, royalty or license, current or prospective ownership or investment interest, speaking fee, grant, and space rental or facility fee.
- Exempted items include any material used directly by patients such as drug samples and patient education material where the patient is the ultimate user.

Objective

- Primary Objective:** To assess MSL perception of the Physician Payment Sunshine Act's impact on industry relationships with physicians, and possible barriers to collaboration.
- Secondary Objectives:**
 - To assess MSL perception of manufacturer awareness of regulation requirements and current preparedness.
 - To determine if manufacturers have implemented training and payment capture systems.

Methods

- An electronic questionnaire was sent via Google survey software from late January 2013 to the end of February 2013 to MSLs representing more than 40 companies.
- The survey was distributed through MSL professional networking groups, internal field medical directors of pharmaceutical companies, and alumni of the Rutgers Pharmaceutical Industry Fellowship program in MSL or field medical positions.
- Survey participants were informed that all responses were strictly confidential. The names of individuals or companies represented were not captured.
- The survey collected the following information:
 - Demographics including company size, educational background, and therapeutic area
 - Company preparedness for implementation of reporting systems and training programs
 - Perception of current awareness among physicians of reporting requirements
 - Anticipatory landscape of working interactions with physicians and potential impact on the health care environment

Results

MSL DEMOGRAPHICS (N=103)

Table 1. Professional background

RPh, PharmD	64%	RN, NP	4%
PhD	19%	PA	2%
MD, DO	4%	Other (MS, MPH)	7%

Table 2. Years of experience as a MSL

< 1	6%	10-15	21%
1-5	33%	15-20	7%
6-10	29%	> 20	3%

Table 3. Company classification

Large pharma	26%	Biotech	18%
Medium pharma	31%	Medical Device	2%
Small pharma	17%	Specialty Lab	1%

Table 4. Geographic regions

Northeast	29%	Southeast	13%
Midwest	22%	Southwest	13%
West	20%	Other regions	10%

Table 5. Therapeutic area(s)

Oncology/Hematology	37%	Infectious Diseases/ Virology	14%
Endocrinology/Metabolics	21%	Rheumatology/Arthritis	12%
CNS/Neurology	15%	Allergy/Immunology	7%
Cardiovascular	15%	Other TAs	44%

Table 6. Number of HCPs interactions per month

1-10	8%	20-25	17%
10-15	18%	25-30	10%
15-20	23%	>30	23%

MANUFACTURER & MSL PREPAREDNESS

Figure 1. Company implementation of reporting system to capture physician payment

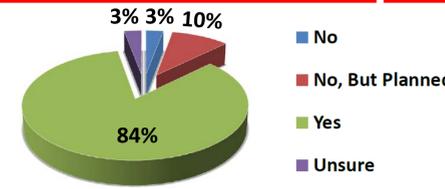
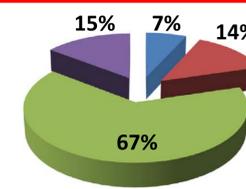


Figure 2. Company provision of PPSA training program for MSLs



MSL PERCEPTION OF PHYSICIAN AWARENESS

Figure 3. Physician awareness of payment tracking and reporting

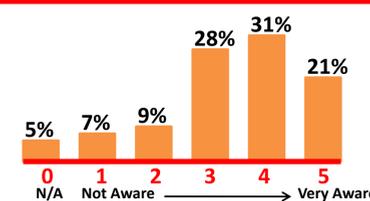


Figure 4. Physician awareness of public disclosure of payments

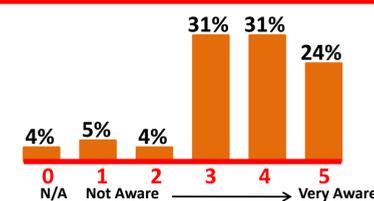


Figure 5. Physician interest in reviewing and correcting payment reports

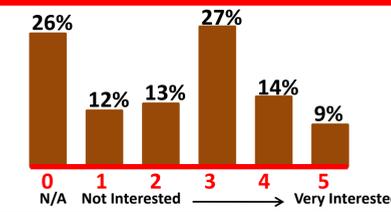
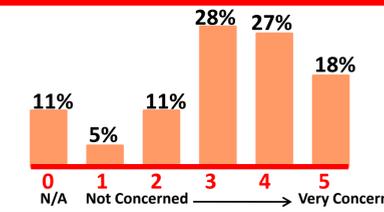


Figure 6. Physician concern regarding the implications of the PPSA



MSL PERCEPTION OF IMPACT ON PHYSICIAN INTERACTIONS

Figure 7. Impact of accurate public disclosure of payment information on MSL-physician interactions

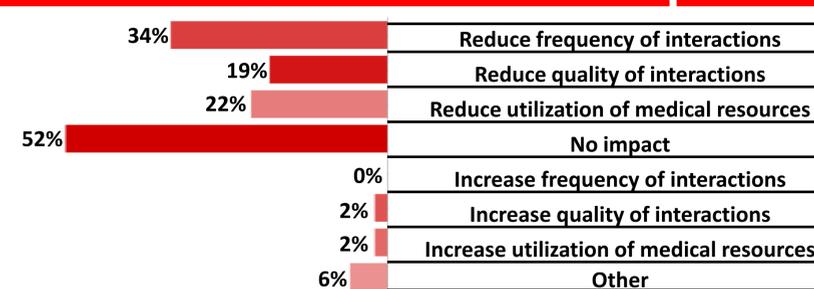
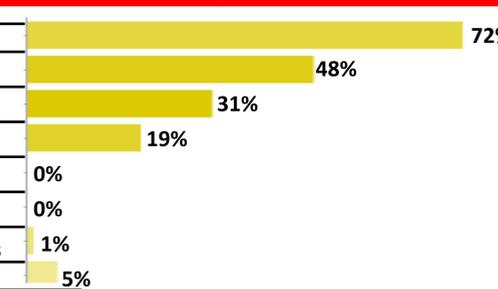


Figure 8. Impact of false or incorrect public disclosure of payment information on MSL-physician interactions



Discussion

- Awareness of the act varies between physicians. Most are aware of general provisions and may be less likely to meet with MSLs at dinner venues or where a potential cause for reporting would be triggered. Many are concerned about public posting and the potential for error or patient misunderstanding.
- Participants noted that physicians are concerned how generic information may give the public the wrong perception of how physicians work with manufacturers. The general public may inappropriately assume dollar values are kickbacks for physicians promoting certain products, and not take into account payments made to physicians for speaker series, clinical research, and educational material.
- Medical Science Liaisons are concerned that the Act could have a negative impact on research and development of new drugs, biologics, and medical devices. Physicians may be less likely to participate in clinical research and clinical trials as a result of the stigma associated with manufacturer dollars in the public domain. Physicians may also be less likely to participate in speaker series for promotional programs. Educational interactions with physicians benefiting patients and patient outcomes may be reduced. Comments from the survey noted that payments made for certain services like conducting a clinical trial should be clearly distinguished from meals or activities promoting a manufacturer's product.
- MSLs anticipate the Act may have less impact on MSL interactions than sale representatives. As access to physicians become increasingly restricted, 'lunch and learns' have become a primary vehicle for sales representatives to obtain quality product discussion time with physician customers. Many physicians place a greater value with MSL interactions, so lunches are often not necessary.

Limitations

- In order to maintain anonymity, the survey did not capture participant affiliations with manufacturers.
- The final rule was published during the time the survey was open. Some responses (n=8) recorded before February 1, 2013 were based on perception from the proposed rule. Because the rule was published during the time the survey was distributed, awareness of provisions and company response may have been heightened.
- The survey was designed to capture MSL perception and not actual physician perspective.

Conclusion

- Overall, most Medical Science Liaisons (52%) have agreed that the Physician Payment Sunshine Act will not have an impact on their relationships with physicians. However, some MSLs have noted that the act could reduce the frequency and quality of interactions and negatively impact the utilization of medical resources.
- The majority of manufacturers have PPSA training programs for MSLs (81%) and payment capture systems (94%) already in place or planned.

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