ABSTRACT

Objective: Physicians often turn to their professional associations for guidance on clinical and ethical issues. We identified and analyzed recently published guidance from professional medical associations regarding the Sunshine Act.

Research design and methods: Using "Sunshine Act" as a search term, we surveyed the peer-reviewed literature in PubMed (February 2013–November 2014). Based on subject matter expertise, "gray literature" was retrieved (12 articles) using search engines (Google/Google Scholar). Online information was extracted from websites of 17 professional medical societies. Articles were reviewed by 6 publication professionals and all discrepancies regarding relevance or categorization were resolved by discussion leading to agreement.

Results: Some professional medical associations have published peer-reviewed recommendations (5 reviewed), position statements (3 reviewed), or general advice on their websites (17 reviewed). Associations had broad online educational resources for physicians around Sunshine Act. There was agreement between peer-reviewed publications, including guidelines, for full transparency and disclosure of industry support. Surveys by professional associations (eg, ACOs) showed variance in opinion on the forecasted impact of the Act on physician-industry relationships. Although the literature from professional associations contained general guidance, there was insufficient consistent guidance from associations around specific concerns, including transfers of value for publications.

Conclusion: There is a shortage of clear guidance from professional associations around the Sunshine Act. Presently, information is fragmented, open to diverse interpretations and incomplete. The literature debates potential impact of the Act and highlights concern that physician-enabled innovation may be hindered.

INTRODUCTION

• Transparency, in terms of financial relationships between industry and healthcare practitioners (HCPs) is essential in order to maintain public trust

• The Patient Protection Affordable Care Act (PPACA), which includes the Sunshine Act (Section 6002; also known as Open Payments (the Act)), was the first transparency legislation for payments from industry to HCPs and teaching hospitals to be enacted at the US Federal level

• The laws and guidelines associated with reporting requirements cover direct and indirect payments and in-kind services, the latter also known as transfer of value (TOV)

• The HCPs who participate in industry-sponsored research are frequently authors of the publications that disseminate the clinical trial results

• Industry may provide support for the development of the clinical trial publication, which could be considered a reportable TOV

METHODS

Search strategy

• Using “Sunshine Act” as a search term, we reviewed peer-reviewed publications indexed in PubMed (February 2013 [issue of final rule] to November 4, 2014)

• “Grey literature” was surveyed using Google/Google Scholar with “Sunshine Act” as the search term

• Websites of pre-identified professional medical societies were manually searched for guidance on the Act

Data extraction

• Articles were initially assigned to categories and assessed by content type (Figure 1)

• In-depth reviews and data were consolidated into a central repository housed centrally at ISMPP

• Articles were reviewed by 6 medical publication professionals and all discrepancies regarding relevance or categorization were resolved by discussion leading to agreement

RESULTS

• The majority of publications in the peer-reviewed and grey literature focused on industry-investigator relationships and within that category, most were considered either editorial or opinion (Figures 1 and 2)

• Of the medical society websites assessed, most of the information about Sunshine describe details about the Act, and recommends that HCPs review their data. There is little in terms of recommendations or guidelines with respect to Sunshine and medical publications (Table 1)

Figure 1. Disposition of Publications Retrieved for Review*

![Disposition of Publications Retrieved for Review*](image)

<table>
<thead>
<tr>
<th>Articles retrieved based on search criteria</th>
<th>Articles considered relevant by reviewers for inclusion and fall into 3 categories and 5 content types</th>
<th>Articles considered relevant by reviewers to be outside the scope of the research question</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>26 articles related to reviews for inclusion and fall into 3 categories and 5 content types</td>
<td>31 articles considered relevant by reviewers to be outside the scope of the research question</td>
</tr>
</tbody>
</table>

Figure 2. Most Frequent Content in Publications by Content Type

![Most Frequent Content in Publications by Content Type](image)

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opinion</td>
<td>70%</td>
</tr>
<tr>
<td>Editorial</td>
<td>20%</td>
</tr>
<tr>
<td>Guideline</td>
<td>8%</td>
</tr>
<tr>
<td>Position</td>
<td>2%</td>
</tr>
<tr>
<td>Opinion</td>
<td>2%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• There is a shortage of clear guidance from professional associations around the Sunshine Act

• The literature debates potential impact of the Act and highlights concern that physician-enabled innovation may be hindered

• Of importance for medical publication professionals is the lack of guidance to clinicians regarding the interpretation of the reportability of support for medical publications

DISCLAIMER

The views expressed in this publication represent the authors’ opinions and not those of their employers or of ISMPP. The authors are fully responsible for the design of the research, analysis of the results, and writing of the paper.

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