



SUNSHINE IN PRACTICE, NOW AND IN THE FUTURE
THE DISCUSSION

A summary of the questions, answers and debate at a
MedComms Networking afternoon workshop - 12 February 2014, Oxford -
which explored transparency and disclosure requirements with
particular reference to medical communications activities.

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THE PHYSICIAN PAYMENT SUNSHINE ACT – WHERE ARE WE NOW?

The Physician Payment Sunshine Act, commonly referred to as “The Sunshine Act” was enacted by Congress in 2010, part of President Obama’s Healthcare reform, the Patient Protection and Affordable Care Act. The aim is transparency in financial relationships between the healthcare industry and physicians¹.

According to the Sunshine Act, the following information must be reported²:

- the name and address of the physician
- the amount and date of the payment
- the form of the payment, such as cash or stocks
- the nature of the payment, such as consulting fees, gifts, or entertainment expenses

The Sunshine Act requires^{1,2} that “transfers of value” of more than \$10 to physicians and teaching hospitals must be reported to the Centers for Medicare and Medicaid Services (CMS). In addition, companies and group purchasing organizations (GPOs) must annually report information about ownership and investment interests held by physicians and members of their immediate families.

Small transfers of value e.g. a cup of coffee are not reported to the CMS except when the aggregate annual total of small items for a physician exceeds \$100 in a year. The following are some of the exemptions from reporting requirements: product samples, certain educational materials, some payments that support continuing medical education (CME) and in-kind items for charity care, provided in all cases that certain conditions are met.

Although it was enacted back in 2010, it wasn’t until February 2013 that that the CMS released the final regulations to implement the act. These regulations required companies to begin tracking transfers of value from 1st August 2013 to December 31st 2013. This information has to be reported to the CMS by 31st March 2014. This data will be published by CMS on a searchable public website by September 30, 2014. In subsequent years companies will be required to report for each full calendar year.

NOTES

The discussion was held under the Chatham House Rule: “Participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.”

You should also refer to the presentations, the pre-meeting survey and reference material provided at the [MedComms Networking Sunshine meeting](#) webpage.

The authors have picked the points of debate that were, to them, the most interesting. We hope you also find them of interest. We have reflected our understanding of the debate and comments made but that doesn’t mean we necessarily agree with all the points made.

[Pharmacodes Compliance](#) provides consultancy services to Pharmaceutical Companies, Medical Communications Agencies and others on compliance matters. A newly revised edition of ‘Compliance Codes and Communications’ – a practical guide to the 2014 ABPI Code (and which covers UK disclosure requirements) by Judith Grice is now available: www.pharmacodes.com

USEFUL LINKS

The presentations and further Information on the event can be found here:

[MedComms Networking Sunshine meeting](#)

Useful references:

- [IFPMA Code of Practice, 2012 \(PDF\)](#)
- [EFPIA Disclosure Code, 2013](#)
- [ISMPP Suggestions Document, August 2013 \(PDF\)](#)
- [PMCPA Code of Practice, 2014 \(PDF\)](#)
- [Policy and Medicine - commentary about US Sunshine Act](#)
- [CMS.gov: Open Payments - Frequently Asked Questions](#)

In the lead up to the event we ran a simple, anonymous, online survey and collected responses from 200 specialists, which provided some interesting insights into how the community regards the impact of the various Sunshine developments on the MedComms business. The top line data was included in the presentation given by Peter Llewellyn, but the full data set is freely accessible for you.

[Access data set here](#)

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QUESTIONS AND ANSWERS

Q: Why all this fuss about disclosure of transfers of value to HCPs?

A: This has its roots in the lack of trust and damaged reputation of healthcare companies. This has been exacerbated by books such as 'Bad Pharma' by Ben Goldacre which by their very title paint the pharmaceutical industry as inherently bad. Enhanced transparency commitments, particularly in clinical trials' data and 'transfers of value' is seen as a way of improving trust, or maybe just limiting the decline. It's all about trust.

Q: Will increased transparency halt bad practice?

A: There are fewer examples of bad practice nowadays and some feel they are more likely to occur with smaller companies that have not devoted a great deal of resource to compliance – although not all agree.

Q: Why the varying approaches from companies?

A: Some felt that you get a very different approach between companies. It could be an oversimplification but there might be a 'US lawyer led / compliance' approach and a rather different 'European Code / do the right thing' approach.

Q: What good does transparency of 'transfer of value' do?

A:

- It allows patients to see who is paying their doctors for what – and judge whether their treatment might have been influenced by those payments. Some doubted that this would happen to any significant degree.
- It could be more about providing fodder for industry critics and journalists who could use the figures selectively to support their 'stories'.
- 'Fair Market Value' rules are there to ensure that opinion leaders only get a fair return for the work they do for companies and that excessive payments aren't used to inappropriately influence prescribing or recommendations – transparency just reassures 'the world' that the FMV rules are being kept
- It could help companies to 'self control'. Sometimes big companies don't realize how much different parts of the organization are engaging with a particular HCP.

Q: How are companies dealing with disclosure requirements?

A: In a variety of ways. Some have put in place very expensive IS solutions customized to interact with their existing data collections systems. Others seem to be relying on simple Excel spreadsheets.

Q: Are companies involving HCPs in their disclosure requirements?

A: Many companies are including within their contracts the fact that fees will be made public as part of the current disclosure requirements. Additionally companies may make it a requirement that when an HCP speaks in public or makes a public announcement, they should disclose their affiliations or sponsorships.

Q: What is actually changing?

A: In the US the sunshine provisions are now in place. In Europe the EFPIA code calls for listing of transfers of value starting with 2015 data but some European countries already have disclosure requirements which may need adjustment to fit with the EFPIA Code – but the Code won't trump legislation such as that in France.

On a practical note, some companies now avoid using US KOLs for European activities due to the Sunshine Act.

Q: Is the platform for disclosure clear?

A: Not yet in all countries. The UK is considering a single multi-company platform but the final decision hasn't been taken.

Q: We have heard that GSK is intending to make changes to the use of HCPs as consultants, what are these changes?

A: Glaxo said in a statement³ that the company will no longer pay health care professionals to speak on its behalf about its products or the diseases they treat "to audiences who can prescribe or influence prescribing," it. It will also stop providing financial support directly to doctors to attend medical conferences, a practice that is prohibited in the United States through an industry-imposed ethics code but that still occurs in other countries. GSK intends to complete these changes worldwide by 2016. Payments will still be made for market research purposes.

It remains to be seen whether other pharmaceutical companies will follow this lead.

Q: What about HCPs' responsibilities?

A: Well yes! In some countries HCPs do themselves have a responsibility to declare receiving 'value' or payment – but not in most countries. Perhaps they should have a universal responsibility? EFPIA have 'gone it alone' making declarations of transfers of value an industry responsibility. However it was pointed out that the original stimulus for this transparency came from a European Commission communication and that envisaged sector wide initiatives with both givers and recipients involved – that hasn't happened.

Q: Doesn't privacy and data protection have any influence?

A: Yes. Data privacy laws differ in detail between EU states and the US is very different from Europe. In Europe HCPs could refuse to sign contracts that require their personal data to be made public. The European disclosure code does allow for aggregate information to be declared when that happens. Not really supporting the spirit of transparency though and companies may refuse to engage with HCPs that insist on anonymity – we'll see! However care has to be taken with respect to EU competition law. Refusing to deal with physicians who insist on upholding their data protection rights with respect to non-disclosure could be viewed as contrary to EU competition law.

Q: What we really want to know is whether medical writing is a 'transfer of value'?

A: Maybe! Most big companies seem to be treating it as a transfer of value under the US provisions – but not all companies agree and there's no definitive guidance. For sure, some transfer of value is taking place and money is changing hands. Companies are paying for professional skills in writing papers but who is receiving the benefit is open to debate.

Q: So are the authors really receiving something of value?

A: Some people think they are. They argue that the authors career is enhanced by the list of publications they can boast. Others argue that the real value is to the company who pays for the writing skills and the authors get nothing that can be quantified.

Q: If the authors are receiving a transfer of value does that mean that they should declare it on their tax form – and if so, how much?

A: Who knows! Call in the tax lawyers. Many people don't think authors actually receive a quantifiable benefit with respect to the medical writing services.

Q: Have you forgotten that authors may receive a fee?

A: No, of course not. They, or the company who paid it, would have to disclose that under the various national transparency rules.

Q: Is there any guidance we can turn to?

A: Quite a bit from various sources in the US – but no definitive guidance on whether medical writing is a ‘Transfer of Value’. In Europe EFPIA has produced some Q&As but these are not made public. That’s not exactly helpful but actually in Europe the rules are operated at a national level through national codes so we eagerly await guidance from national code bodies on what counts as a transfer of value.

Q: And while we are waiting for guidance?

A: The EFPIA code does require that companies include a statement that describes their methodology so companies can make their own decision as long as they state publicly what it is.

Q: Do these transparency requirements cross national borders?

A: Generally yes. If an overseas affiliate or headquarters provides something of value to an HCP then companies should have systems to capture that so that disclosure requirements in the HCPs home country can be met.

Q: Will these disclosure requirements lead HCPs to stop or reduce the amount of work they do for Pharma?

A: Maybe. Some people thought this was happening already. HCPs may not be comfortable revealing how much they receive from Pharma but as mentioned earlier data protection and anti-competition law must be taken into account.

References

1. American Medical Association <https://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page>.
2. Peterson: What do you know about the Sunshine Act? www.aaos.org/news/aaosnow/apr13/advocacy6.asp.
3. Katie Thomas New York Times December 16th 2013.



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