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SUNSHINE ACT LEGISLATION AND PROPOSALS

United States

The US Physician Payment Sunshine Act came into effect on 1 August 2013. The American Medical Association (AMA) notes the Act requires manufacturers of drugs, medical devices and biologicals (relevant organisations) that participate in US federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. The key provisions are discussed below.

Financial Transfers that are Subject to Reporting

There are two types of transfer that will need to be reported under the Act – Direct and Indirect.

Direct transfers are where relevant organisations make any direct payments of a value $10 or more to physicians and/or teaching hospitals. Examples[1] of direct payments include: gifts, travel expenses, charitable contributions, education, consulting fees, grants, and investment interests. However, there are 12 exceptions where a direct payment or transfer of value is not subject to reporting. These include product samples and educational materials that directly benefit patients.

Indirect transfers are those not made directly to physicians. There are two categories:

- Third party transfers are those where a physician does not receive the payment or transfer. For example, a physician (or someone acting on their behalf) may specify that a transfer of value should be given to another person or entity, such as a preferred charity.
- Other types of indirect transfers occur when an entity transfers value to a physician indirectly by way of a third party or intermediary. A good example would be when a pharmaceutical company makes a payment to a physician organization and then *requires, instructs, or directs* the payment or transfer of value to be provided to a specific physician or intended for physicians (in the latter case without regard to whether specific physicians are identified in advance).

Relevant organisations will need to keep their own record of those transfers or payments made with a value of less than $10, as when these reach an aggregated value exceeding $100 they must be reported.[3]

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[1] Silverman, E (2013) *Everything you need to know about the Sunshine Act*. *BMJ* 2013;347:f4704.

Ownership

Manufacturers and group purchasing organisations participating in federal health care programs will have to report certain ownership interests held by physicians and their immediate family members. However, there are certain ownership interests which are not reportable ownership interests.

Review & Public Reports

The majority of the information contained in the transparency reports will be available on a public, searchable website, which will be administered by the Centers for Medicare and Medicaid Services (CMMS). By statute, physicians are provided, at a minimum, 45 days to review their own consolidated transparency report and make corrections before the report is made public. Physicians have additional time, cumulatively two years, to dispute reports even after the reports are made public. If a physician utilises the dispute process, the public data will be marked as disputed in the public database.

Timescales[3]

Between 1 August and 31 December 2013, drug and device makers were required to start collecting and tracking payment and ownership information, and are now required to report the data for each full calendar year. The physician portal is expected to be opened in January 2014, which will; allow physicians to receive notice when reports are available for review.

By March 2014, drug and device makers are expected to report 2013 data to the CMMS and by June 2014, CMMS is expected to provide physicians access to individualized and consolidated reports for 2013.

Going forward, it is expected that in the June of each year reports for the prior year are will be made available, and by September 2014, CMMS is expected to release the data on the public website.

Administration and Costs

As noted above the CMMS is the body responsible for administering the programme. Despite requests for information on the programme and its associated costs, no reply has been forthcoming at the time of writing

France

Introduction of the French Sunshine Act

The French Law on the Strengthening of Health Protection for Medicinal and Health Products (known as the French Sunshine Act) was adopted on 29 December 2011, with the decree implementing the law being issued on 21 May 2013. The aim of the legislation is to specify the scope of disclosure obligations, which affect all agreements concluded between health care professionals (HCPs) and companies, as well as every benefit in kind or in cash exceeding €10.

Legal firm McDermott Will & Emery has published an article on the new law, and a partner from the firm has provided additional information.

Scope

The law affects a range of health care companies manufacturing medicines, medical devices and biologicals. The disclosure obligation affects any agreement concluded between companies manufacturing or distributing these products and French health care professionals (HCPs), or any benefit provided by those companies to French HCPs, including on:

- Research and development contracts e.g. clinical trials and observational studies
- Hospitality at conventions, e.g. invitations from individual HCPs to scientific or medical events, with the HCP paying incurred expenses such as travel costs, registration fees, etc.
- Other consultancy agreements e.g. speaking positions
- Any benefit in cash or in kind provided to French HCPs exceeding €10 (incl tax)

The only exceptions to the broad scope of this disclosure obligation are:

- Commercial sales agreements of goods and services concluded between companies and HCPs.
- Agreements concluded by companies manufacturing or distributing non-corrective contact lenses, cosmetic or tattoo products, as long as these do not relate to the conduct of health and safety work assessments and biomedical or observation research on these products.

Failure to comply can lead to a range of penalties, including a fine of up to €45,000.

Disclosure Process

Companies must disclose the following:

- The name and address of the parties to the agreement.
- The qualifications and medical specialties of the parties.
- The date and subject matter of the agreement.
- The program of the event that is the subject matter of the agreement.

All companies must also publish the following information on benefits provided to HCPs that exceed €10 Euros including tax:

- The identity of the recipient and companies providing the benefit.
- The value of the benefits rounded up to the nearest Euro.
- The date and nature of every Euro received during the relevant period.
- The six months during which the benefit was granted.

Information regarding agreements should be passed on to the responsible authority (i.e. the Ministry for Health) within 15 days of the signing of each agreement. The information on benefits granted and agreements entered into should be provided to the responsible authority no later than 1 August for benefits granted and agreements entered into during the first half of the year and no later than 1 February for those granted and entered into during the second half of the preceding year. The authority will publish this information no later than 1 October and 1 April respectively.

Initially, the information on agreements has been published by companies on their own websites and transmitted to national boards for them to disclose the information on their own websites. However, the intention has always been that disclosure and publication would take place though a free public website, which would negate the need for publishing the information on company and other websites. A Ministerial Order specifying the how the website should function came into force on 20 December 2013, though the website may not be fully accessible to companies until 1 April 2014.

Administration and costs

As noted above, the Ministry for Health is the body responsible for the legislation. However, cost information concerning the scheme as a whole or in part (e.g. the public website) has not been published.

Australia

There have been two recent initiatives taking place in Australia, which have sought to arrive at a similar goal. However, one is based on statute and the other is based on industry regulation.

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

This Bill was introduced in the Australian Senate but did not progress past the second reading stage as it lapsed at the end of the last Parliament. The Bill had sought to amend an existing piece of legislation to place restrictions on the way that pharmaceutical companies may interact commercially with doctors, and create a requirement for more transparent reporting of such interactions. The Bill's proposals included:

- Making it an offence for a pharmaceutical company to arrange or sponsor a conference or educational seminar for Australian doctors that takes place overseas. This was intended to curtail the possibility of hosting an educational event in a tropical or otherwise exotic location which may act as an inducement.
- Specifying that the company could only spend $100 per head on catering and entertainment (this could be raised through regulations), which was intended to otherwise place limits on overly lavish hospitality.
- Specifying that a pharmaceutical company could not pay for a medical practitioner to attend a conference or seminar, including travel or accommodation costs, unless that medical practitioner was a representative of the company sponsoring the event. In the event that a company did provide travel, accommodation or other recompense to a medical practitioner to attend the event on their behalf, that compensation was a reportable payment.
- Clarifying what it meant for a sponsoring company to make a payment to a registered medical practitioner, including paying for a practitioner to attend an event, paying a fee, paying for research, making a donation or giving a gift.

- Specifying that regulated corporations, i.e. pharmaceutical companies would be required to prepare an annual report and make it public, and to provide for timescales for these to be published and what it should contain.
- Detailing which payments constitute reportable payments. This would have included: any fee or honorarium paid to a medical practitioner or their employer; providing a service; paying travel or accommodation; providing funds to be used for research; making a donation to charity or giving any gift with a value over $25.

The documents accompanying the Bill did not make reference to the financial implications of the proposal.

Medicines Australia Transparency Working Group

In August 2012, Medicines Australia established the Transparency Working Group to develop measures and policies that would further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. The working group has developed a Transparency Model, which is based on a series of principles, is largely based on the scheme developed in the United States through the Physician Payments Sunshine Act. The working group did not reach a consensus of every part of the model, but has been published as a basis of discussion as part of the wider consultation on Medicine Australia's Code of Conduct Review. The consultation began in July 2013.

Medicines Australia in a submission on the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013, believed that initiatives such as the Transparency Model, which were based on existing industry self-regulation, were the best way of dealing with such matters rather than using legislative means.

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