

Reporting under the Physician Payment Sunshine Act

The FDA's proposed Physician Payment Sunshine Act is due to come into force later this year. This will be important in the future as it affects sponsors giving any money to doctors working on clinical trials. Under the Act, data must be collected from August 1st 2013, with reports being sent to the CMS by March 31st 2014.

You only have until August 1st before you need to start collecting this data and a further eight months to submit it to the CMS. Remember, your company can be fined up to \$1,150,000 for failure to comply with the Sunshine Act so it's vital to get it right.



When in force, the following details will need to be reported:

- | | |
|---|----------------------|
| <input type="checkbox"/> Applicable manufacturer or GPO's name | <input type="text"/> |
| <input type="checkbox"/> Covered Recipient's | <input type="text"/> |
| <input type="checkbox"/> Amount of payment or other transfer of value | <input type="text"/> |
| <input type="checkbox"/> Date of payment or other transfer of value | <input type="text"/> |
| <input type="checkbox"/> Form of payment or other transfer of value | <input type="text"/> |
| <input type="checkbox"/> Nature of payment | <input type="text"/> |
| <input type="checkbox"/> The name of the related drug, device, biological or supply | <input type="text"/> |
| <input type="checkbox"/> National Drug Code (NDC) of related covered drug/biological, if any | <input type="text"/> |
| <input type="checkbox"/> Eligibility for delayed publication (research payments) | <input type="text"/> |
| <input type="checkbox"/> Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly (indirect payments) | <input type="text"/> |
| <input type="checkbox"/> Payments or transfers of value to physician owners or investors | <input type="text"/> |
| <input type="checkbox"/> Statement providing additional context for the payment or other transfer of value (optional) | <input type="text"/> |

Whitehall Training

The Physician Payment Sunshine Act is just one of the existing and future pieces of legislation in the new US GCP course from Whitehall Training. The course was researched and adapted by Dr Laura Brown, Director of the MSc in Clinical Research at Cardiff University, UK, and a trainer with over 11 years of experience of delivering technical, management and soft skills courses for the pharmaceutical industry.

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