
Common Questions

1. What is a transfer of value?

A "**transfer of value**" is defined as "*a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medical devices, pharmaceuticals or biologics*".

2. What is a "direct" transfer of value?

A "direct" transfer is one made directly by ACell to the recipient of the benefit.

3. What is an "indirect" transfer of value?

An "indirect" transfer is one "*made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient*".

Example: a third party conference organizer requests a Grant from ACell to support an Educational Conference. The Grant is to cover speaking fees, travel and lodging for HCPs to speak, AV equipment charges, and room rental fees at the educational conference. As part of the Grant, the third party organizer requests ACell to provide a recommended list of speakers on a particular topic. If ACell provides this speaker list and the organizer uses one of the speakers, the amount of the grant used to pay the HCP speaking expenses becomes a reportable transfer of value.

4. Can physicians review the specific data that concerns them prior to the data being reported to CMS for the respective reporting period?

Yes, physicians can review their data prior to it being reported to CMS. In addition to review, a dispute resolution process has also been established by CMS. If needing additional information concerning the dispute resolution process it can be found at www.cms.gov

5. What are the reporting timelines?

Open Payments reporting began in 2014 and occurs annually for transactions in each calendar year (January 1 through December 31). CMS is responsible for posting reports under Open Payments by July 1 of the following calendar year.

Example: 2016 data will be posted no later than July 1, 2017.

6. Who can review the data once it posted?

Anyone can review the transfer of value data once it is posted on the CMS public website (<https://openpaymentsdata.cms.gov/>).

7. If a Physician attends a business meeting and a meal is provided and paid for by ACell, is this a reportable event?
Yes, this would be considered a reportable event covered under the Food and Beverages reporting category.
8. If a Physician teaches a course for ACell and is compensated to do so, is this a reportable event?
Yes, this would be a reportable event covered under the Consulting Fees reporting category.
9. If a Physician pays for his/her own meal during a business dinner meeting, is this a reportable event?
No, if a Physician pays for their own meal, there is no transfer of value and therefore a reportable event has not occurred.
10. What items are generally excluded from reporting?
 - Speaking at a continuing education program if certain conditions are met:
 - Program meets accreditation/certification requirements;
 - The Manufacturer does not select the Physician Speaker and does not provide a list of individuals to be considered as speakers;
 - The Manufacturer does not directly pay the Physician Speaker.
 - Educational Items that directly benefit patients or are intended for patient use
 - In-kind items for the provision of charity care
 - Evaluation Product for which the quantity provided is less than a 90-day supply for a particular patient
 - Discounts and Rebates as applicable under the Anti-Kickback Discount and Rebate Safe Harbor