

FREQUENTLY ASKED QUESTIONS

Table of Contents:

- **General Information**
- **When to Report**
- **Reporting Requirements**
- **Contact Information**

General Information:

- What is Open Payments Program?
 - As of August 1, 2013, pursuant to a section of the Patient Protection and Affordable Care Act known as Open Payments, certain pharmaceutical and medical device manufacturers are required to track payments or transfers of value (PTOV) provided directly or indirectly to U.S. licensed physicians and U.S. teaching hospitals (“Covered Recipients”), and report information about these PTOV to the Centers for Medicare and Medicaid Services (CMS). Covered recipients include the following healthcare professionals: podiatrists, dentists, optometrists, chiropractors, doctors of osteopathy, and medical doctors. CMS publishes the information submitted by manufacturers on a publicly accessible website.
- What categories of payments or transfers of value (PTOV) are considered reportable to CMS under the Open Payments Program?
 - Among the many categories of PTOV that are reportable under the Open Payments Program are:
 - Grants or payments to teaching hospitals (direct or indirect), including fellowship grants;
 - Payments or transfers of value to US physician faculty of educational programs (in certain circumstances); and
 - Meals and refreshments for US physician attendees of educational programs (in certain circumstances).
- If a grantee does not pay a U.S. licensed physician directly but coordinates and pays for the physician’s travel through a third party (e.g., a travel agency or transportation service), is that transaction reportable under the law?
 - Yes, because the physician is receiving a transfer of value. The Open Payments program requires manufacturers to report PTOV provided both directly and indirectly to covered recipients.

When to Report:

- When does Janssen require grantees to submit Open Payment information?
 - Janssen requests information from grantees within the Grant Management System (GMS) as part of the grant reconciliation process. Submitting Open Payments data is one requirement of the grant reconciliation process, along with final budget reconciliation and other requirements. Grantees may enter information into the system at any time following signature of the Letter of Agreement (LOA), however, information will not be submitted to Janssen until the grantee submits the final reconciliation for the program. Grantees may update or change the information within the system up until the point they click “Submit”. The deadline for submitting Open Payment information is the reconciliation due date (i.e., 60 days post-activity).

- Will grantees be notified in advance if tracking and reporting is required?
 - In some circumstances, Janssen may notify grantees in advance if certain types of payments or transfers of value must be tracked (e.g., attendee meals). However, failure to receive advance notification does not excuse a grantee from the tracking and reporting requirements. All grantees should keep detailed records of all payments and transfers of value made to U.S. licensed physicians and teaching hospitals in association with a Janssen-funded activity.

- How will grantees know what information they are required to report?
 - The Open Payments reporting module (completed as part of the reconciliation process) includes a set of screening questions that will help grantees identify what information, if any, is required according to Janssen’s policy. For more information about the reporting process, see the “Process” section of this FAQ document.

- What happens if a grantee does not report Open Payment information by the company’s deadline?
 - Janssen reserves the right to deny future grant funding to any organization that does not comply with the terms of the Letter of Agreement (LOA) and the company’s Open Payment reporting requirements.

Reporting Requirements:

- How do grantees report Open Payment information?
 - Grantees are required to complete several questions to determine their eligibility and requirements. If data are required to be submitted to Janssen, grantees may enter the

information directly into the GMS and submit to Janssen along with their final budget reconciliation.

- Can grantees update Open Payment information at multiple time points?
 - Yes. Grantees may record information within the system at any time following signature of the LOA, however, information will not be submitted to Janssen until the grantee submits the final reconciliation for the program. Grantees may update or change the information within the system up until the point they click “Submit.” The deadline for submitting data is the reconciliation due date (i.e., 60 days post-activity).

- What type of information is required for payments to U.S. physicians?
 - Physician first and last name
 - Physician address
 - Physician degree
 - Physician NPI number (optional)
 - Amount of payment or transfer of value (PTOV)
 - Date of PTOV
 - Form of PTOV (e.g., cash, in-kind item)
 - Nature of PTOV (e.g., speaker payment, attendee meal)
 - Name and Tax ID of institution if physician directed payment to his or her institution

- What type of information is required for payments to teaching hospitals?
 - Institution (teaching hospital) name
 - Tax ID
 - Organization address
 - Amount of payment or transfer of value (PTOV)
 - Date of PTOV
 - Form of PTOV (e.g., cash, in-kind item)

- How do grantees submit Open Payment information?
 - Once all of the required information has been entered, grantees submit data to Janssen by submitting their final reconciliation. The final reconciliation also includes evaluation forms and full budget reconciliation, among other information.

- Who can grantees contact with questions?
 - HIV/HCV: TTGrantInfo@its.jnj.com
 - Immunology/Oncology: JBIgrantsoffice@its.jnj.com
 - CNS: JanssenIME@its.jnj.com
 - Cardiovascular/Metabolism: JanssenIME@its.jnj.com