Product Information Reporting Summary (for General and Research Payments)

Applicable to data collection beginning on January 1, 2016, with reporting to CMS in 2017

Payment or Other Transfer of Value Scenario Description	Data Elements					
	Payment or other Transfer of Value Related to a product?	Covered or Non-Covered Product Indicator	Drug, Biological, Device, or Medical Supply Indicator	Marketed Name	Therapeutic Area or Product Category	NDC
Scenario 1: A payment or other transfer of value that relates to a Covered Product	Required Response Type: "Y" for Yes	Required Response Type: "1" for Covered"	Required Response Type: "1" – Drug "2" – Device "3" – Biological "4" – Medical Supply	Conditionally Required Special rules for responses "1" or "3" (drugs and biologicals): If the drug or biological does not have a marketed name – use the name from clinicaltrials.gov Special rules for responses "2" or "4" (devices and medical supplies): Leave blank if the device or medical supply does not have a marketed name	Required for all product types (drugs, devices, biologicals and medical supplies)	Required for drugs and biologicals (if the drug or biological has an NDC) Leave blank if reporting about a device or medical supply
Scenario 2: A payment or other transfer of value that relates to a Non-Covered Product	Required Response Type: "Y" for Yes	Required Response Type: "2" for Non- Covered"	Optional If responding, see guidance for Scenario 1	Optional If responding, see guidance for Scenario 1	Optional If responding, see guidance for Scenario 1	Optional If responding, see guidance for Scenario 1
Scenario 3: A payment or other transfer of value that does not relate to any product	Required Response Type: "N" for No	Do not report	Do not report	Do not report	Do not report	Do not report

November 2015

KEY: Designates actions to be taken in the Open Payments System

OPEN PAYMENTS
CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

Product Information Reporting Process Flow (for General and Research Payments)

Applicable to data collection beginning on January 1, 2016, with reporting to CMS in 2017

KEY: and Designates actions taken within the Open Payments System.

Payment or transfer of value (POTOV)

Is the POTOV related to one or more products?
Products:
- Drugs
- Devices
- Biologicals
- Medical supplies

NO → Indicate that payment is not related to a product: Respond **"N"**

YES ↓

Is the POTOV related to a **covered** product?

NO ↓

Respond **"2" for Non-Covered**

↓

**** NOTE:** You have the **option** to indicate the type of product if you respond **"2" for Non-Covered** and report additonal product information.

YES →

POTOV related to a covered product

Respond "1" for Covered →

Indicate type of product:
"1" for drug
"2" for device
"3" for biological
"4" for medical supply

For "1" Drugs and "3" Biologicals

Does product have a marketed name?

NO ↓

Report:
1. Clinicaltrials.gov Name (if available)
2. Therapeutic Area or Product Category
3. NDC (if the product has an NDC)

YES ↓

Report:
1. Marketed Name
2. Therapeutic Area or Product Category
3. NDC (if the product has an NDC)

For "2" Devices and "4" Medical Supplies ↓

Report:
1. Marketed Name (Required if the product has a marketed name)
2. Therapeutic Area or Product Category (Required)

NOVEMBER 2015

OPEN PAYMENTS
CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS