



Open Payments – Attestation Statements

Centers for Medicare & Medicaid Services

May 2014

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY
INTO INDUSTRY-PHYSICIAN
FINANCIAL RELATIONSHIPS

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This document contains the attestation statements presented in the Open Payments system. Applicable manufacturers and applicable group purchasing organizations will be required to confirm the attestation statements prepopulated by the Open Payments system by selecting the checkboxes next to each of the applicable statements. The user must, at a minimum, select the first two checkboxes to proceed with the attestation process.

- I am attesting that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization with the authority to attest to the information submitted to the Open Payments system.
- I am attesting that the information reported is timely, accurate, and complete to the best of my knowledge and belief.
- I am attesting that my entity is only reporting payments or other transfers of value associated with covered drugs, devices, biologicals, or medical supplies based on one or more of the reasons listed below.

If yes to statement 3 above, indicate the reason by selecting at least one of the following reporting limitation statements:

- My entity's gross revenue from covered drugs, devices, biologicals or medical supplies constituted less than 10 percent of gross revenue during the fiscal year preceding the reporting year.
- My entity is under common ownership, as defined by 42 C.F.R. § 403.902, with an applicable manufacturer and provides assistance or support to an applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological, or medical supply. Therefore, my entity is only required to report payments or other transfers of value associated with covered drugs, devices, biologicals or medical supplies which my entity provided assistance and support to an applicable manufacturer.
- My entity has a separate operating division that does not manufacture any covered drugs, devices, biological, or medical supplies. Therefore, my entity is only required to report payments or other transfer of value to covered recipients related to the activities of these separating operating divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply.
- The only covered drug, device, biological or medical supply manufactured by my entity is pursuant to a written agreement to manufacture a covered drug, device, biological, or medical supply for another entity. My entity does not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and is not involved in the sale, marketing, or distribution of the covered drug, device, biological or medical supply. Therefore, my entity is only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.
- My entity only manufactures covered drugs, devices, biologicals, or medical supplies.

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- I am attesting that my entity is requesting a delay in publication for one or more payments or other transfers of value.

If yes, to statement 4 above, indicate one or more of the reasons listed below.

- The payment or other transfer of value is related to research or development of a new drug, device, biological, or medical supply.
 - The payment or other transfer of value is related to research or development of a new application of an existing drug, device, biological, or medical supply.
 - The payment or other transfer of value is related to clinical investigations regarding a new drug, device, biological, or medical supply.
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- I am attesting that my entity is submitting a consolidated report because it is under common ownership, as defined by 42 C.F.R. § 403.902, with a separate entity or entities that are also applicable manufacturers.