

AstraZeneca Data Requirements for Payments and Transfers of Value to Covered Recipients

The US Centers for Medicare and Medicaid Services (CMS) has been charged with implementation of the Physician Payment Sunshine Act, legislation that requires drug and device manufacturers to track and report all non-exempt Payments and Transfers of Value to US-licensed physicians and US teaching hospitals (“Covered Recipients”). A “Payment or Transfer of Value” is any payment or transfer of value as defined in the Sunshine Act (42 USC 1320(e)(10)), and implementing regulations (42 CFR 403.900 et seq.), and includes compensation, reimbursement for expenses, meals, travel, medical journal reprints, study drug, study supplies and medical writing and publications assistance. Detailed information about the Act is located on CMS’s OPEN PAYMENTS website: <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

Importantly, AstraZeneca’s transparency reporting obligations extend to direct and indirect payments and transfers to Covered Recipients by our research partners, suppliers and vendors. It is therefore critical that these partners collaborate with AstraZeneca in fulfilling these obligations.

There are also a number of US states that have transparency reporting laws that impose additional obligations. Where applicable, vendors working with AstraZeneca may be required to submit additional payment information to satisfy these state requirements.

In accordance with OPEN PAYMENTS reporting specifications, the data required from our partners will vary depending upon whether a payment or transfer is made in connection with medical or scientific research.

At a minimum the following information is required to be provided:

- Name of recipient receiving payment or transfer of value
- Address of recipient receiving payment or transfer of value
- Tax ID number, NPI or SLN
- Type of payment or transfer of value (fee, meal, travel, etc.)
- Name of AZ product
- Date of payment or transfer of value
- Amount of payment or transfer of value
- Currency of payment or transfer of value

Additional requirements if related to research:

- Principal investigator name
- Principal investigator address
- Principal Investigator NPI or SLN
- AZ study code

For exact data requirements, or for additional details regarding AstraZeneca's transparency reporting requirements, please visit the CMS OPEN PAYMENTS website or contact your AstraZeneca project manager.

The Research Report and General Report data specifications use the following definitions:

- Covered Recipient (CR) – a US licensed physician or US teaching hospital.
- PTOV – a payment or transfer of anything of value to a Covered Recipient unless exempted.
- Exempt PTOV – a payment or transfer of value not required to be tracked or reported. Exempt PTOVs include: (i) patient education materials, (ii) samples/coupons/vouchers, (iii) discounts and rebates, (iv) buffet-style meals or snacks made available to participants at large-scale conferences or events, and (iv) items of value under \$10 made available to participants at large-scale conferences or events.
- Items of Value (IOV) – items that possess a value on the open market, such as textbooks, study drug and journal subscriptions.
- Research Payments – payments or transfers of value made pursuant to a written agreement or protocol covering the conduct of a research study or project. These payments will follow the CMS Research Report format.
- General Payments – payments or transfers of value that do not qualify as Research Payments. Payments related to research that are not covered by a written study agreement or protocol are General Payments. These payments follow the CMS General Report format.
- Indirect Payments – payments to a Covered Recipient through one or more third parties.
- Related Entity Payments – a payment to a third party on behalf of, or at the request of, a Covered Recipient. This would be the case when a physician directs a vendor to pay the physician's employer or practice group instead of the physician directly.
- Entity Paid – the name of the organization that received the Related Entity Payment on behalf of the Covered Recipient (e.g., employer name, group or individual practice name).
- Site – the location where the research activity is taking place, including teaching hospitals, nonteaching hospitals, laboratories, medical offices and other healthcare facilities.
- Principal Investigator (PI) – the lead scientist with primary responsibility for the design, execution or management of a research project at a research site.