Frequently Asked Questions

Q. **What is the Sunshine Act?**
The Physician Payments Sunshine Act, commonly called the Sunshine Act, was enacted by Congress in March 2010 as part of the Patient Protection and Affordable Care Act, or the healthcare reform law. The law is intended to make the relationships between the healthcare industry and healthcare professionals more transparent.

The Sunshine Act requires applicable manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP) to report certain payments or other “transfers of value” provided to physicians or teaching hospitals and other research entities to the Centers for Medicare & Medicaid Services (CMS) on an annual basis.

Q. **What is Open Payments?**
Open Payments is a national disclosure program designed by CMS to administer the transparency requirements of the Sunshine Act. Beginning in 2014 and annually thereafter, applicable manufacturers will submit transparency reports to CMS through the Open Payments portal, and CMS will make that information publically available on the Open Payments website. [http://go.cms.gov/openpayments](http://go.cms.gov/openpayments)

Q. **When did the Sunshine Act take effect?**
Companies began tracking reportable payments on August 1, 2013, and submitted data for August 1 - December 31, 2013, to the government which was subsequently published on the Centers for Medicare and Medicaid Services (CMS) Open Payments Web site at [http://go.cms.gov/openpayments](http://go.cms.gov/openpayments) on September 30, 2014. The data made available on June 30, 2016, reflects reportable payments and transfers of value for January through December 2015, as well as any adjustments made to previously published 2014 data.

Q. **What are “payments” and “transfers of value”?**
“Payments” are fees for services rendered such as for speaker programs or consulting, and for associated approved out-of-pocket reimbursements (e.g., mileage and parking).

“Transfers of value” are in-kind items such as meals, airfare, and/or educational materials that Novartis Pharmaceuticals Corporation (NPC) pays for or provides in connection with medically relevant interactions with healthcare professionals and healthcare organizations.

Q. **Why does NPC make payments and transfers of value to physicians and hospitals?**
We believe that collaborations with physicians and teaching hospitals have a critical role in advancing patient care and helping ensure that medicines are being used appropriately. We support the Sunshine Act and other initiatives that promote transparency around these types of interactions and related payments and transfers of value. It is our hope that this will encourage a constructive dialogue about the relationships between healthcare companies and healthcare professionals and help people better understand the importance of these relationships to quality patient care.
NPC interacts with physicians and teaching hospitals in many important ways. We consult doctors to get their insights and advice on diseases and products to help ensure we’re developing medicines that meet the needs of patients. We facilitate programs where physicians who are experts in their fields meet with their peers to help educate them about the appropriate use of FDA-approved medicines; this helps them make informed prescribing decisions with their patients. Our comprehensive compliance program provides the policies, training and tools to help ensure we consistently conduct these activities responsibly and in compliance with legal and regulatory standards.

We also engage physicians as clinical trial investigators and work with hospitals to conduct clinical research studies, which are fundamental to the development of innovative medicines, vaccines and medical devices that treat and prevent illness. Clinical trials are essential to help us understand the effectiveness and safety profiles of new treatments.

Q. **How does NPC track and report payments and transfers of value?**

Novartis has a comprehensive program in place to help collect, track and report payments and transfers of value to physicians, teaching hospitals and research entities across all the Novartis Group companies covered by the Act. We believe that disclosing payments and transfers of value related to interactions with physicians and teaching hospitals helps foster trust with patients, healthcare professionals and government officials, and reinforces our commitment to high ethical business standards.

Under its Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services, NPC is required to post its payments and transfers of value to U.S.-based physicians and healthcare organizations on its [www.pharma.us.novartis.com](http://www.pharma.us.novartis.com) website. NPC’s CIA reporting is aligned with the final Sunshine Act requirements. However, CMS may choose to publish more information than does NPC related to these payments and transfers of value (e.g., physician’s specialty, licensure state, drug associated with the spend or payment amount, date of payment/transfer of value, etc.). Additionally, some records may appear on the NPC CIA website, but not on the Open Payments website if they didn’t pass the Open Payments validation process.

We stand by this commitment to transparency and our rigorous data collection efforts. We also recognize what a complex undertaking tracking and reporting this volume of data is, and we are committed to ongoing collaboration with the Centers for Medicare & Medicaid Services (CMS), physicians, teaching hospitals and research entities to help ensure we report the information requested.

Q. **Are all of the submitted by NPC to date available on the Open Payments website?**

Novartis has a comprehensive program in place to help collect, track and report payments and transfers of value to physicians, teaching hospitals and research entities across all the Novartis Group companies covered by the Act. We have worked diligently in an effort to ensure we reported the information requested.

However, the data we reported differ from what is publicly available on the Open Payments website for the following reasons:
Some reported payments aren’t available yet on the CMS website because the Sunshine Act allows companies to request delayed disclosure of payments related to investigational products/compounds that have not yet received FDA approval for any indication. Novartis requested this delayed disclosure related to research payments for our investigational products in order to maintain the confidentiality that is necessary to protect innovation in medicines. These payments will be reported once the compound receives FDA approval or four years have passed since the payments were made, whichever comes first.

Some reported payments aren’t available yet on the CMS website because the data has not yet been made available by CMS for review and dispute.

CMS did not accept any records that they were unable to match to a single physician or teaching hospital due to what they considered to be missing or inconsistent information.

Tracking and reporting this volume of data is a complex undertaking; however, Novartis stands by the rigor of our data collection and reporting efforts. We continue to work to understand the nature of these discrepancies and provide additional detail to resolve them.

We are committed to ongoing collaboration with CMS, physicians, teaching hospitals and research entities to help ensure we report the information requested.

Q. Who is considered a “physician” under the Sunshine Act?
A physician will be considered a reported “Covered Recipient” if they have an active license in the US and possess any of the following degrees, even if the physicians are not actively practicing: Medical Doctor (M.D.), Doctor of Osteopathy (D.O.), Doctor of Dental Surgery (D.D.S.), Doctor of Dental Medicine (D.M.D.), Doctor of Optometry (O.D.), Doctor of Podiatry (D.P.M.) or Doctor of Chiropractic Medicine (D.C.).

Q. How does the Sunshine Act define “teaching hospital?”
CMS has defined a “teaching hospital” as any hospital that receives indirect medical education (IME), direct graduate medical education (GME), or psychiatric hospital IME. Every year, CMS provides a list of teaching hospitals identified as reportable “Covered Recipients.” For more information please check the CMS list of teaching hospitals, available at www.cms.gov.

Q. What are some of the payments and transfers of value that NPC will report to fulfill Sunshine Act reporting requirements?
NPC reports certain payments made and the value of items provided directly or indirectly to physicians, teaching hospitals and research entities such as:
   • Meals provided to physicians by NPC associates during medically relevant discussions and presentations
   • Consulting fees and related expenses paid to physicians
   • Research fees and trial site payments made by clinical research organizations on Novartis’s behalf
   • Hospital-hosted convention fees and other payments to teaching hospitals
   • Educational items such as books and reprints
Q. **Does NPC have to report every payment or transfer of value to a physician or teaching hospital to comply with the Sunshine Act?**
   For 2013 reporting, companies do not have to report amounts less than $10 unless the combined total of all payments or transfers of value to any individual physician or teaching hospital totals $100 or more in the reporting year. However, if the combined total of all payments or transfers of value to any individual physician or teaching hospital is less than $100, any payment or transfer of value more than $10 must be reported.

For 2014 and subsequent years, these thresholds will adjust, based on the consumer price index.

The 2014 thresholds are: $10.18 / $101.75.
The 2015 thresholds are: $10.21 / $102.07.
The 2016 thresholds are: $10.22 / $102.19.

Q. **If I have a question about the data that NPC has reported, what can I do?**
   If you have any questions about the Sunshine Act, Open Payments or published data, please contact (866) 356-8735 to speak with a member of our customer relations team or email us at cic.open_payments@novartis.com.

Q. **How are reporting disputes resolved?**
   CMS has provided physicians with access to a secure website so they can review the payments and transfers of value attributed to them and dispute them if necessary.

   We stand by our commitment to transparency and our rigorous data-collection efforts. But we also recognize what a complex undertaking it is to track and report this volume of data. Where disputes or discrepancies related to what has been reported or published are brought to our attention, we will work quickly with the individuals or institutions involved to provide additional detail and resolve any discrepancies and provide CMS with a revised submission, as appropriate.

For more information about the Sunshine Act and the Open Payments Website, visit [www.cms.gov](http://www.cms.gov).

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