Independent Grants for Learning & Change (IGLC)

Sunshine Act Reporting Requirements for Pfizer Independent Grants Program

Frequently Asked Questions

[Section added Feb 2015]

Reactive Q&A: Center for Medicare and Medicaid Services (CMS) dropping Continuing Medical Education (CME) exclusion for Sunshine Reporting

CMS recently deleted the Sunshine Act regulation’s express exclusion for accredited/certified CME payments. Will that change affect how Pfizer supports CME through independent grants?

No. On November 13, 2014, CMS announced that it was deleting the express exclusion for accredited/certified CME payments. That change will take effect in 2016. Nonetheless, CMS explained that “if an applicable manufacturer . . . provides funding to support a continuing education event but does not require, instruct, direct, or otherwise cause the continuing education event provider to provide the payment or other transfer or value in whole or in part to a covered recipient, the applicable manufacturer . . . is not required to report the payment or other transfer of value. When it supports CME through independent grants, Pfizer does not require, instruct, direct, or otherwise cause the continuing education event provider to provide a payment or other transfer of value to a covered recipient. Consequently, CMS’s deletion of the express exclusion for accredited/certified CME payments will not affect Pfizer’s support for CME through independent grants.

Will CMS’s change to the Sunshine Act regulation affect how Pfizer reports support for CME through independent grants?

Not for 2015. As for 2016 and beyond, Pfizer is evaluating how CMS’s change affects its responsibilities under the Sunshine Act. Pfizer is also monitoring the 21st Century Cures legislation and H.R. 5539, each of which would create an exemption regarding continuing education.

Will CMS’s change to the Sunshine Act regulation affect how Pfizer reports independent grant support for non-CME programs?

Pfizer currently considers such non-CME grants to covered recipients reportable under the Sunshine Act, notwithstanding CMS’s recent revisions to the Sunshine Act regulation. That approach will not change at this time.

[Last updated Oct 2014]

Definitions:


Payment or transfer-of-value: This refers to a payment or transfer of anything that has value on the open market, even if the payment or transfer-of-value has no value to the recipient. Common kinds of payments or transfers-of-value are honoraria, compensation, consulting fees, meals, travel/lodging, expense reimbursements, educational items and materials (except for those exclusively used by or with patients), space rental fees, charitable contributions, and grants.
Direct payment or transfer-of-value: A payment or transfer-of-value made by a pharmaceutical or medical-device manufacturer to a covered recipient.

Indirect payment or transfer-of-value: This refers to (1) a payment or transfer-of-value by a pharmaceutical or medical-device manufacturer to a covered recipient through a third party, even if the third party is not a covered recipient; and (2) when a pharmaceutical or medical-device manufacturer requires, instructs, or directs a third party to make a payment or transfer-of-value to a covered recipient. A manufacturer may be required to report the payment or transfer-of-value even if it does not know the name of the covered recipient when it gave the grant to the third party.

General FAQs

What is the Sunshine Act?
Originally called the Physician Payments Sunshine Act and passed as part of the Affordable Care Act, the Sunshine Act requires pharmaceutical and medical-device manufacturers, such as Pfizer, to annually report to the Centers for Medicare and Medicaid Services ("CMS") payments and other transfers-of-value given to covered recipients.

How does the Sunshine Act impact the Pfizer grant process, and what does it mean for my organization as a grant recipient?
The Sunshine Act has not changed Pfizer’s grant process. But it has created new reporting obligations for Pfizer, which, in turn, require additional recordkeeping and reporting by grant recipients. By accepting an IGLC grant, an organization may become responsible for collecting and submitting to Pfizer specific data about how the organization spent Pfizer’s grant. Each letter of agreement will explain a grant recipient’s responsibility for providing Sunshine Act data to Pfizer. When planning how to carry out the subject of your grant application, you will now want to consider whether you will have to track and report Sunshine Act data and, if so, how you will fulfill that duty.

What will Pfizer do with the information provided by grant recipients? What will CMS do?
Pfizer, as required by law, will provide that data to CMS. CMS will make that data available to the public.

What types of payments or transfers-of-value do I need to report to Pfizer?
All non-excluded payments and transfers-of-value that your organization provides to a covered recipient must be reported to Pfizer. Examples of reportable payments or transfers-of-value include honoraria, compensation, meals, travel/lodging, consulting fees, or expense reimbursement provided to faculty (planners, speakers, investigators, project leads, etc.) and “items of value” (items that possess a discernible value on the open market, such as textbooks) provided to faculty and learners/participants, if such faculty and/or learners/participants meet the definition of covered recipient. NOTE: Funds from Pfizer may not be used for food or beverages for learners/participants in any capacity; this applies across all grant types supported by IGLC. Additionally, for Track 2 grants, funds from Pfizer may not be used to provide items of value to faculty or learners/participants. Refer to the Policy section for further details. If you have any doubt about whether a payment or transfer-of-value is reportable, please contact us at IGLC@pfizer.com.

What is NOT reportable under the Sunshine Act for accredited and/or certified CME?
Payments or other transfers-of-value provided as compensation for speaking at a CME program are not required to be reported if all of the following conditions are met:
- the CME activity meets the accreditation or certification requirements and standards of the ACCME, AAFP, ADA CERP, AMA, or AOA;
- the pharmaceutical or medical-device manufacturer does not pay the covered recipient directly; and
- the pharmaceutical or medical-device manufacturer neither selects the covered recipient nor provides a distinct, identifiable set of individuals to be considered as faculty for the CME activity.

Reminder: At this time the exclusion criteria above do not apply to activities offering credit by other accreditation organizations not named above.
My organization is accredited by the CMA/IMQ organization which is accredited by ACCME. Does this qualify for the exclusion?
Yes, if the activity is also accredited through ACCME and all the criteria listed above are met.

**Policy FAQs**

**Does Pfizer IGLC prohibit the coverage of food and beverages (F&B) in all grant types?**
You cannot use funding from Pfizer IGLC towards food or beverages for learners/participants in any way or for any reason. That prohibition applies to Track 1 grants, Track 2 grants, and Healthcare Charitable Contributions. When applying for support, organizations will be required to certify that no Pfizer funds will be used for food or beverages for learners/participants. If approved for a grant, organizations must sign a letter of agreement that includes this prohibition. NOTE: F&B are permitted for faculty which includes, but is not limited to, planners, speakers, content developers, investigators, project leads, etc. When applicable, to comply with Sunshine Act reporting your organization is required to report F&B (and any other payments) for all faculty who meet the definition of covered recipient.

Because IGLC does not support F&B, is it acceptable to serve F&B to learners but exclude this specific line item in the budget included in a grant request? My organization would use IGLC funds for other expenses (e.g., Audio/Visual) and use non-Pfizer funds, such as registration/exhibit fees, to cover the cost of F&B.
Yes, this is acceptable. Remember, by signing a letter of agreement, your organization agrees that Pfizer IGLC funds will not be used for F&B for learners/participants.

May we still include F&B in our total project budget with a note that Pfizer IGLC funds will not be used for that purpose, or should our budget not reference F&B expenses?
It is acceptable for your budget to include F&B expenses. But remember: by signing a letter of agreement, your organization agrees that Pfizer IGLC funds will not be used for F&B for learners/participants.

If our program qualifies for the Sunshine Act’s CME exclusion criteria, does the prohibition on F&B for learners/participants still apply?
Yes. This is a policy decision that applies to all Pfizer IGLC grant types.

Do all Pfizer IGLC grants prohibit using Pfizer funds to pay for items of value (e.g., textbooks)?
That prohibition applies only to Track 2. No portion of a Track 2 (Knowledge Gap) grant may be used to purchase/distribute “items of value,” which are items that possess a discernible value on the open market, such as textbooks for faculty or learners/participants. When applying for Track 2 support, organizations will be required to certify that no Pfizer funds will be used for items of value for faculty or learners/participants. If approved, organizations must sign a letter of agreement that includes this prohibition.

**Pfizer participates in several alliances that fund education, such as the Bristol-Myers Squibb/Pfizer Alliance and the REMS Collaboration. What rules will be in place under these arrangements?**
Grant recipients will be informed of the rules that apply to their particular grant. The rules that will apply will be the rules of the Alliance partner funding the grant recipient.

**The Sunshine Act is a regulation in the United States. How does it apply to U.S.-licensed physicians who attend educational activities outside the U.S. or to organizations based outside the U.S.?**
Organizations who receive support from Pfizer IGLC, including those who operate outside the U.S. or conduct educational activities outside the U.S., will be obligated to supply specific information about payments or transfers-of-value to covered recipients. The covered recipients may include U.S.-licensed physicians serving as faculty (planners, speakers, investigators, project leads, etc.) and U.S.-licensed physician attendees (learners/participants).

If my organization has a multi-year grant and the Pfizer IGLC policy/interpretation changes midway through the term of the grant, do I report under the policy in effect at the time of funding or at the time of reconciliation or Sunshine reporting collection?
You should collect or report data according to the law and policy in effect when you are collecting or reporting data. All grant recipients will be informed through an email communication if changes are made to any policy and/or reporting requirements related to the Sunshine Act. That communication may also be posted at www.pfizer.com/independentgrants in the Grants Process section, refer to “Policies & Announcements” tab.
Report Submission Process FAQs

What type of data will Pfizer collect? How do I report the data back to Pfizer?
You must report the information specified in Pfizer’s Sunshine Data Template, which Pfizer will provide you. Among other things, you must identify each covered recipient’s name, business address, and NPI; the amount and date of each payment or transfer-of-value; and the payment’s category. You will submit the data to Pfizer by uploading the Sunshine Data Template to the Grant Management System.

Why is Pfizer requesting information such as an NPI, state license number, middle name, and credential?
Because there may be more than one physician with the same first and last name, Pfizer requires this information so it can accurately match payment information with the correct individual.

How can I access the Sunshine Data Template and when will I be required to complete this template?
The Sunshine Data Template can be accessed in the Grant Management System, but the availability depends on the type of support provided by Pfizer.

- **Track 1 – Learning & Change:** Education grants approved through the Request for Proposal (RFP) process to support multi-year projects to execute learning & change strategies.
  - The Sunshine Data Template can be accessed during the collection process at periodic intervals (currently collected by Pfizer semi-annually) as well as during the closeout process following the completion of the supported project. The Sunshine Data Template may also be required earlier in order to meet specific Sunshine Act reporting commitments, upon Pfizer’s request.

- **Track 2 – Knowledge Gap:** Education grants to support annual meetings for healthcare professionals; and education grants to support other activities to close gaps in knowledge reviewed through the Call for Grant Applications (CGA) process.
  - The Sunshine Data Template can be accessed during the reconciliation process following the conclusion of the supported activity or made available earlier in order to meet specific Sunshine Act reporting commitments, upon Pfizer’s request.

- **Healthcare Charitable Contribution:** Charitable contributions to support patient programs.
  - The Sunshine Data Template can be accessed during the acknowledgment process following the conclusion of the supported program or made available earlier in order to meet specific Sunshine Act reporting commitments, upon Pfizer’s request.

You may also request a copy of the template by sending an email (please include your name, organization and request ID) to IGLC@pfizer.com.

If my organization is a teaching hospital, how do I report the grant my organization received from Pfizer? What about payments my organization made to another teaching hospital?
If your organization is a teaching hospital, be advised that Pfizer will report to CMS the grant your organization received from Pfizer as a direct payment to a covered recipient; do not include the grant you received from Pfizer in the template.

If your organization is a teaching hospital and you made a payment or transfer-of-value to another teaching hospital or U.S.-licensed physician, you should enter that payment or transfer-of-value in the Sunshine Data Template. Pfizer will report that payment or transfer-of-value as an indirect payment or transfer-of-value to a covered recipient.

If my organization used funds received from Pfizer to make a payment to a teaching hospital that ultimately was provided to physicians, how do I report the payment?
In this scenario, the teaching hospital is serving as an intermediary. If the payment your organization made to a teaching hospital was ultimately provided to physicians, you should report the payments made to each physician—do not report the payment made to the teaching hospital when the teaching hospital is only serving as intermediary.
If my organization is not a teaching hospital, do I have to report payments my organization made to covered recipients?
Regardless of whether your organization is a teaching hospital, if your organization made non-excluded payments or transfers-of-value to covered recipients using funds received from Pfizer, you must provide the required information to Pfizer within the specified timeframe. This data will be collected according to the terms and conditions included in the letter of agreement signed at the time Pfizer approved your grant.

Are research grantees also required to complete the Sunshine Data Template?
You must appropriately complete the Sunshine Data Template. Please know that grant support from Pfizer IGLC will NOT be reported as research under the Sunshine Act.

If my organization used funds received from Pfizer to support a covered recipient’s salary/fringe, where do I enter this data in the template?
Please report this data in the spend type “Compensation – services other than consulting” in the Sunshine Data Template. The amount you will report will equal the amount of salary/fringe for the respective reporting period and that you paid out of Pfizer funds. For projects spanning more than one year, which is often the case with Track 1 grants, this reporting will continue over the project’s lifecycle.

If my organization made multiple payments to a covered recipient, what do I enter in the “Date of Interaction” field in the template?
When multiple payments were made over the course of the respective reporting period, which is often the case with Track 1 grants, enter the most recent date a payment was made or the last date of the reporting period.

Do I need to provide supporting documentation or receipts for the reportable payments?
You do not need to provide Pfizer with documentation or receipts when you give Pfizer the completed Sunshine Data Template. However, you must retain the supporting documentation and receipts in the event Pfizer requests that information.

May I use my own format instead of the Pfizer reporting template?
No. You must use the Sunshine Data Template provided by Pfizer. Pfizer must submit reportable data to CMS in a uniform, consistent format.

How do I send the reportable information back to Pfizer?
When prompted to take action related to Sunshine Act reporting, you must log in to the Grant Management System and complete the online form. Further, if you have reportable data to submit, you must download the Sunshine Data Template (accessible within the online form), enter the required information, save the file to your computer, and, finally, upload the completed file to the Grant Management System. Similar instructions are included in the Grant Management System for your convenience.

Why does Pfizer collect information periodically or earlier than the CMS deadline?
Pfizer must collect and consolidate a high volume of data across its various divisions, business units, and departments who are all interacting with numerous external organizations. Collecting data before the CMS deadline or periodically aids us with that process.

Non-Compliance FAQs

What happens if my organization elects not to report the required information? Or within the timeframe set by Pfizer?
By signing a letter of agreement, your organization undertakes an obligation to provide Pfizer with specific information about payments or transfers-of-value to covered recipients that come from grant funds you received from Pfizer. Failure to submit the required information to Pfizer within the specified timeframe is viewed as non-compliance with the terms and conditions in the letter of agreement; in other words, it is a breach of your contract with Pfizer. In addition to other legal remedies, failure to provide Pfizer with the required information in a timely manner may result in Pfizer canceling the grant or seeking recovery of the funds. Pfizer may also deny future grants to your organization.

Can U.S.-licensed physicians opt out of the reporting requirement?
No. The Sunshine Act requires pharmaceutical manufacturers, such as Pfizer, to report non-excluded payments or transfers-of-value made to covered recipients. If a U.S.-licensed physician does not wish to be reported, he or
she should not accept any payment or other transfer-of-value provided directly or indirectly by a pharmaceutical manufacturer, such as Pfizer. An example of an indirect payment is one made by your organization to a covered recipient, using the funds received from Pfizer.

Resources

Who should I contact if I have a question about the reporting requirements with regard to the Pfizer independent grants program?
Please email IGLC@pfizer.com.

Where can I find the NPI for a covered recipient?

Where can I find more information about the Sunshine Act?
To learn more about the Sunshine Act, please refer to the following:

The Official Website for Open Payments (Sunshine Act)

42 C.F.R. §§ 403.900-.914 Transparency Reports and Reporting of Physician Ownership or Investment Interests
http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=1f1f886d8bc4bf8f81beea7d2d5903a6&n=sp42.2.403.i&r=SUBPART&ty=HTML