

Sunshine Act:

Physician financial transparency reports

Since Aug. 1, 2013, the Physician Payments Sunshine Act (Sunshine Act), requires manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal health care programs to track and then report certain payments and items of value given to physicians and teaching hospitals. Manufacturers will submit the reports to the Centers for Medicare & Medicaid Services (CMS) on an annual basis. In addition, manufacturers and group purchasing organizations must report certain ownership interests held by physicians and their immediate family members. CMS refers to this program as the Open Payments Program.

The majority of the information contained in the manufacturers' reports will be available on a public, searchable website. Physicians have the right to review these reports and to challenge those reports pertaining to them that are false, inaccurate or misleading. This American Medical Association resource gives physicians important information that can help them navigate the road ahead.

Learn more at ama-assn.org/go/sunshine



TRENDS IN TRANSPARENCY LAWS

The convergence of media coverage, calls from within medicine for greater transparency, intense governmental scrutiny (including investigations), and the rapid growth in states passing laws requiring transparency or implementing bans, created significant momentum for the inclusion of a transparency requirement in the ACA. It also reflected a broader trend in passage of transparency laws including those governing federal elected officials and lobbyists, for example. The foregoing created significant challenges to AMA efforts to ensure that transparency reporting would be fair and accurate and would not impose burdens or penalties on physicians.

AMA POSITION ON TRANSPARENCY

The AMA has consistently advocated that transparency reporting should: (1) not impose a regulatory and paperwork burden on physicians; (2) protect physician rights to challenge false and misleading reports; and, (3) provide a meaningful, accurate picture of physician-industry interactions. The AMA secured significant modification to the ACA transparency requirements and final regulations to ensure fairness and accuracy. AMA advocacy remains ongoing.

Purpose of transparency reports

There are many interactions between physicians and manufacturers of drugs, medical devices, and medical supplies that benefit patients and advance the art and science of medicine. The Sunshine Act transparency reports provide patients and the public with information on the financial interactions of physicians and industry. These interactions often drive innovation, discovery and changes in medical practice that promote better patient outcomes. The congressional sponsors of the Affordable Care Act (ACA) reporting provisions have stated that this process is not designed to stop, chill, or call into question beneficial interactions between physicians and industry, but to ensure that they are transparent.

Public release of data

Reports on data from the previous year are released to the public June 30 and are available at cms.gov/openpayments. Be prepared for inquiries from the media, your patients and your friends:

- Know what is reported about you. If you have not already completed the three-step registration process to review your data, you should do so now (see key steps and dates below).
- Be ready for questions by providing context on the reported items. Download customizable talking points, available at ama-assn.org/go/sunshine, to use in your conversations with the media, patients and friends

Sunshine Act: Is your data accurate? Take these steps to make corrections.

Step 1: Complete CMS e-verification process today

You must complete CMS' e-verification process via the CMS Enterprise Portal (EIDM). New users will be required to complete a one-time EIDM registration process.

Step 2: Register with CMS' Open Payments System

Register in CMS' Open Payments System via EIDM and review your data.

Step 3: Review and dispute data by Dec. 31

You can still dispute your data after the public release. Corrections will be made the next time CMS updates the Open Payments System.

Top tips to ensure accurate reporting

Update your disclosures regularly. Ensure that all financial disclosures and conflict of interest disclosures required by employers, advisory bodies and entities funding research, for example, are current and updated regularly.

If you have a NPI, update the information and ensure your specialty is correctly designated. Physicians who have a National Provider Identifier (NPI) should ensure all information in the NPI enumerator database is current and regularly updated as needed. This information will be used by industry, among other unique identifiers, to ensure that they have accurately identified you.

Inform your industry contacts that you want ongoing notice of what they report to the government. Ask all manufacturer and group purchasing organization representatives with whom you interact to provide you with notice and an opportunity to review and, if necessary, correct all information

that they intend to report before it is submitted to the federal government.

Check the AMA website ama-assn.org/go/sunshine. We will provide regular updates that can help you prepare for reporting.

Download and use OPEN PAYMENTS Mobile for Physicians smartphone app to control and track your transfers. Designed to help physicians and health care industry users to track payments and other financial transfers that industry will report to the government, you can download this free app through the Apple™ Store and Google Play™ Store. Compatible with the Apple™ and Android platforms, the OPEN PAYMENTS Mobile for Physicians app offers both on-the-go convenience and security features to protect the privacy of the data you capture. Urge your industry contacts to use the app so you are able to capture information you may need to ensure accurate reporting.

RESOURCES

For more information on the Sunshine Act reporting requirements and the dispute process, visit the AMA's Web page at ama-assn.org/go/sunshine. Please email questions to Medicare's Open Payment Help Desk at openpayments@cms.hhs.gov, or call (855) 326-8366.



Being transparent with your patients

Your patients may wish to know whether you have or have had financial interactions with industry. When a patient asks about this topic, it is important that you discuss the matter candidly in a way that will enhance the patient's understanding without compromising trust or the patient-physician relationship. Some of the issues you might want to address with the patient are what sources you rely on for information about medical innovations and new evidence, your role in medical research, and how you believe research will improve outcomes for patients. Download customizable talking points, which can help you respond to general inquiries about the Sunshine Act, on the AMA's Sunshine Act website.

Sunshine laws at the state level

Prior to the ACA, several states enacted *Sunshine-type* laws. It is important for physicians to recognize that the federal Sunshine Act, when fully implemented, may create additional requirements for physicians in states that already have a state law. In states where there is no state law, federal law will govern. The AMA has a chart with states that have sunshine-type laws available at ama-assn.org.

Learn more at ama-assn.org/go/sunshine

Summary of key provisions of the Sunshine Act

Financial transfers

Direct. Manufacturers of a drug, device, biological, or medical supplies participating in federal health care programs will have to report to CMS any direct payments or transfers of value to physicians and/or teaching hospitals of \$10 or more. However, there are 12 exceptions where a direct payment or transfer of value is not subject to reporting. These include product samples and educational materials that directly benefit patients.

Indirect. Transfers that are not made directly to physicians are categorized as third-party transfers or other types of indirect transfers.

- Third-party transfers are those where a physician does not receive the payment or transfer, but the payment is provided to another person or organization on the behalf of the physician.
- Other types of indirect transfers occur when an entity transfers value to a physician indirectly by way of a third party or intermediary. An example would be when a pharmaceutical company makes a payment to an organization and then requires that the payment be provided to a specific physician or physicians (in the latter case without regard to whether specific physicians are identified in advance).

Ownership. Manufacturers and GPOs participating in federal health care programs will have to report to CMS certain ownership interests held by physicians and their immediate family members. However, there are certain ownership interests, such as securities, which: (1) may be purchased on terms generally available to the public; (2) are listed on a stock exchange; and (3) have quotations that are published on a daily basis. These are **not** reportable ownership interests.

Review and dispute public reports

The majority of the information contained in the transparency reports has been made available on a public, searchable website at cms.gov/openpayments. You can initiate disputes until Dec. 31.

What is exempt from reporting?*

- Certified and accredited continuing medical education (CME) that adheres to standards of independence¹
- Buffet meals, snacks, soft drinks or coffee generally available to all participants of large-scale conference or similar large-scale events (such as at industry trade shows) where it is difficult for the manufacturer to establish definitively the identities of the physicians partaking in the food or beverage. (It is prudent to inquire whether this type of activity will be reported from the event sponsors/planners/hosts.)
- Product samples that are not intended to be sold and are intended for patient use
- Educational materials that directly benefit patients or are intended for patient use (Note: CMS narrowly interpreted this exemption. Textbooks and reprints are **not** excluded under this provision.)
- The loan of a medical device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device
- A transfer of anything of value to a physician when the physician is a patient and not acting in his or her professional capacity as a physician
- Discounts (including rebates)
- In-kind items used for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund

1. CME is "independent" under the law when a manufacturer does not require, instruct, direct or otherwise influence how payments are disbursed.

* For a full list of exemptions, visit ama-assn.org/go/sunshine.