

Sunshine Act:

Physician financial transparency reports

Beginning Aug. 1, 2013, the Physician Payments Sunshine Act (Sunshine Act), which is part of the Affordable Care 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 on an annual basis. In addition, manufacturers and group purchasing organizations must report certain ownership interests held by physicians and their immediate family members.

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 may 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.

How to challenge false, inaccurate or misleading reports

Physicians will have at least 45 days once Centers for Medicare & Medicaid Services (CMS) provides access to individual physicians' consolidated industry reports via an online portal to challenge reports. Access will not occur until after the calendar year has come to a close. The portal will allow physicians to contact the manufacturer(s)/group purchasing organizations (GPOs) that submitted inaccurate, misleading or false information in order to resolve disputed submissions.

- If a physician and manufacturer(s)/GPO(s) cannot resolve the dispute, they are provided an additional 15 days before the report is made public to try to achieve resolution.
- If resolution is still not reached, the disputed information will be flagged, but the report will be posted on the public Web page CMS develops for such reports.
- Physicians are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.
- Once CMS establishes the online portal, physicians will be urged to sign-up in order to receive direct notice when the reports are made public.
- You should check with any manufacturer from which you have received payment or any item of value to see what information they are tracking and intend to report.
- If you hold any ownership interests in a manufacturer or GPO, you should also check to ascertain what ownership interest(s) they intend to report. (Ownership or investment interests in publicly traded security and mutual funds are excluded from reporting.)

RESOURCES

On April 24, 2013, the AMA presented the free webinar **"Physicians preparing for the Sunshine Act: What you need to know and how to prepare."** The archived broadcast for this webinar is available. This webinar will help you: initiate and complete key steps to prepare for reporting that will begin on Aug. 1, 2013, and identify and utilize resources that are available to ensure that reportable financial interactions between a physician and industry and ownership interests are accurately and fairly reported.



What you can do now to prepare for the Sunshine Act

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 before Aug. 1. We will provide regular updates that can help you prepare for reporting.

KEY DATES

Aug. 1 through Dec. 31, 2013:

Manufacturers are required to begin collecting and tracking payment, transfer and ownership information. Thereafter, they are required to report for each full calendar year.

Jan. 1, 2014: We anticipate that CMS will launch the physician portal that allows physicians to sign-up to receive notice when their individual consolidated report is available for review. This portal will also allow physicians to contact manufacturers/GPOs if they want to dispute the accuracy of a report.

March 31, 2014: Manufacturers/GPOs will report the data for 2013 to CMS.

April–August 2014: We anticipate that CMS will provide physicians access to their individualized consolidated version of all manufacturers/GPO reports for the prior calendar year at some point in 2014 between April and August. Physicians may access the consolidated reports via an online website portal maintained by CMS by contacting the manufacturer/GPO through the portal.

Sept. 30, 2014: CMS will release most of the data on a public website.



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.

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.

Third party. There are certain transfers **not** made directly to physicians that are subject to reporting (called indirect transfers). Transfers or payments that the physician specifies should be given or paid to another person or entity would be reportable, so too would any transfer or payments that another person indicates are being made on behalf of the physician. CMS **requires** reporting even though a physician does not receive the payment or transfer.

Indirect. Another reportable indirect transfer includes when manufacturers make a payment to a third party, such as physician organization, and then **requires, instructs, or directs** the payment or transfer of value to be provided to a specific physician or intended for 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 public reports

The majority of the information contained in the transparency reports will be available on a public, searchable website. By statute, physicians are provided, at a minimum, 45 days to review their own consolidated transparency report and make corrections before the report is made public. Physicians have additional time, cumulatively two years, to dispute reports even after the reports are made public. If a physician makes use of the dispute process, the public data will be marked as disputed in the public database.

What is exempt from reporting?

- Certified and accredited CME
- Buffet meals, snacks, soft drinks, or coffee generally available to all participants of large-scale conference or similar large-scale events
- 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
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan
- In the case of a physician who is a licensed non-medical professional, a transfer of anything of value to the physician if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional (For example, payments to a physician who is licensed to practice law and who is retained by a manufacturer to provide legal advice would not be subject to reporting.)
- In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the physician with respect to a civil or criminal action or an administrative proceedings
- A transfer of anything the value of which is less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the manufacturer during the calendar year exceeds \$100, subject to increase each year using the consumer price index