

When to Look a Gift Horse in the Mouth

The Anti-Kickback Statute and the Open Payments Program

HCCA Webinar

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Objectives

- 1 Understand provisions of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), relating to clinician remuneration.
- 2 Explain the different types of remuneration covered by the Anti-Kickback Statute (AKS) and include relevant examples in orientation for new physicians at your healthcare organization.
- 3 Develop an annual notification process for your group practice or organization's clinicians about how they may review and dispute public reports on the CMS Open Payments website.





Objectives

- ▲ **4** Establish a process to communicate updated compensation limits, which are adjusted annually according to changes in the Consumer Price Index for All Urban Consumers (CPI-U), for limited remuneration to a physician as specified in 42 CFR §411.357(z).

- ▲ **5** Design an effective education program for clinicians regarding the AKS and the Open Payments Program.





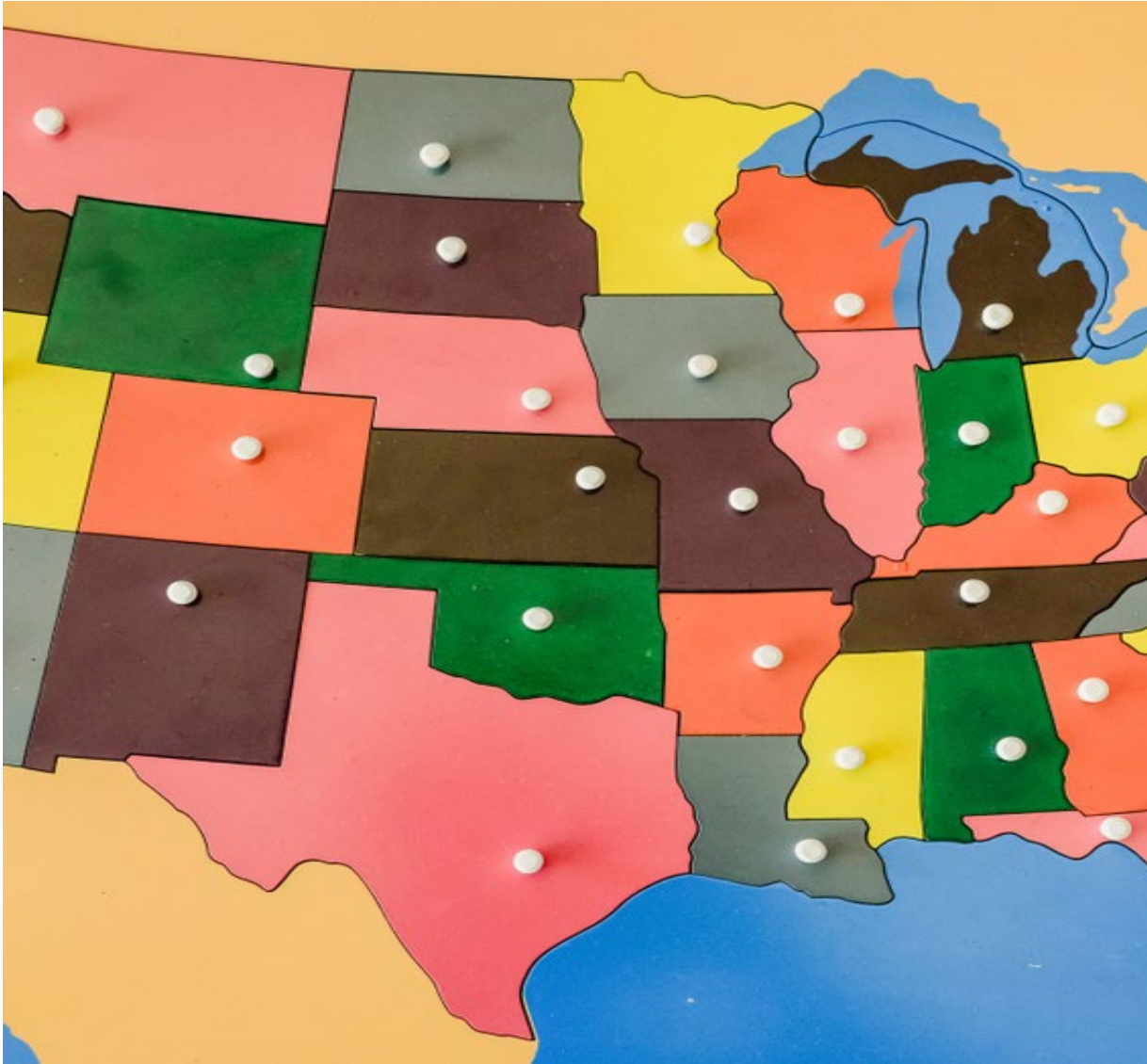
Agenda Overview

- ▲ Anti-Kickback Statute: Provisions and Implications
- ▲ Open Payments Program: Structure and Reporting
- ▲ Indirect Payments and Transfers of Value: Reporting Requirements
- ▲ Open Payments System: Enhancements in OPS 2.0
- ▲ Clinician Education and Compliance Framework
- ▲ Key Legal References and Resources

Polling Question 1



- ▲ Does your healthcare organization or clinical practice have a policy and procedure that addresses accepting gifts?
 - a. I am unsure.
 - b. No.
 - c. Yes.



A Tip for Your Gifts Policy

Don't forget to check state as well as federal statutes!

- ▶ When reviewing your organization's gifts policy, be mindful that your state may ban some or most gifts. Examples are:
 - Vermont: Prescribed Product Gift Ban and Disclosure Law.
 - Maine: Gifts to Practitioners Prohibited

Anti-Kickback Statute: Provisions and Implications



The Stark Law & The Anti-Kickback Statute (AKS)

▲ The Stark Law

- This law is also known as the Physician Self-Referral Law. It prohibits physicians from having a financial interest including ownership, investment, and compensation arrangements, with any provider or entity to which they refer patients covered by Medicare or Medicaid, unless an exemption applies.
- The Stark Law is a “strict liability” statute, which means that proof of intent to violate the law is not required.
- Penalties include fines as well as exclusion from participation in federal health care programs.

▲ The Anti-Kickback Statute

- This law prohibits knowingly taking or providing anything of value to induce patient referrals for items or services reimbursable by a federal health care program.
- Remuneration includes anything of value, whether cash, cash equivalents, an opportunity to earn a fee, items, space, equipment, or services, regardless of the amount or remuneration.
- Violation of the federal AKS constitutes a felony punishable by a maximum fine of \$100,000, imprisonment of up to 10 years, or both. A conviction will also lead to mandatory exclusion from participation in federal health care programs.





Definition and Scope of Remuneration under AKS

Overview of Anti-Kickback Statute

AKS prohibits knowingly paying or receiving remuneration to influence patient referrals or federally funded healthcare business.

Definition of Remuneration

Remuneration includes anything of value such as cash, free rent, meals, travel, or excessive medical compensation.

Evaluating Expensive Meals

Determining when a meal is “too expensive” involves scrutiny by the Office of the Inspector General, using the gift horse analogy.

What Constitutes an Expensive Meal?

The OIG does not define “expensive” with a specific dollar amount.



- ▲ Factors used by the OIG to evaluate meals:
 - What is the **context** of the meal? It should be incidental to a legitimate educational purpose and not be the main focus.
 - Is the meal **reasonable and of modest value**? Modest value would be judged by local standards.
 - Is the **intent** to influence or reward referral decisions?
 - Who are the **recipients** of the meal? The meal should be for the physician or other health care providers, not for their family, friends, or other guests.
 - Is **alcohol** available? The OIG’s concern is heightened when alcohol is provided free of charge.

Exceptions



- ▲ Certified, accredited CME
- ▲ Buffet meals, snacks, soft drinks available to all participants at a conference
- ▲ Product samples not intended to be sold and intended for patient use
- ▲ Educational materials for direct patient benefit
- ▲ Short term loan of a medical device for a trial period under 90 days
- ▲ Items or services provided under a contractual warranty
- ▲ Transfer of anything of value to physician when the physician is a patient
- ▲ Others (see <http://www.ama-assn.org/go/sunshine>)

Penalties and Recent Violation Cases



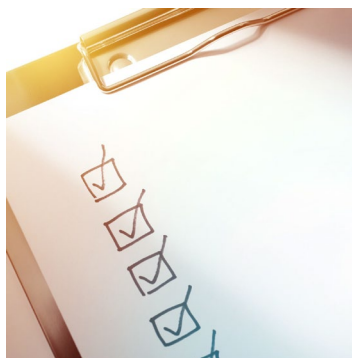
AKS Legal Consequences

Violating the AKS is a felony with penalties including fines up to \$100,000 and imprisonment up to 10 years.



Mandatory Federal Exclusion

Convicted physicians face mandatory exclusion from federal health care programs, impacting their professional practice.



Recent Violation Cases

Recent AKS cases involve physician remuneration schemes, highlighting the importance of compliance.

Shedding Light on the Sunshine Act

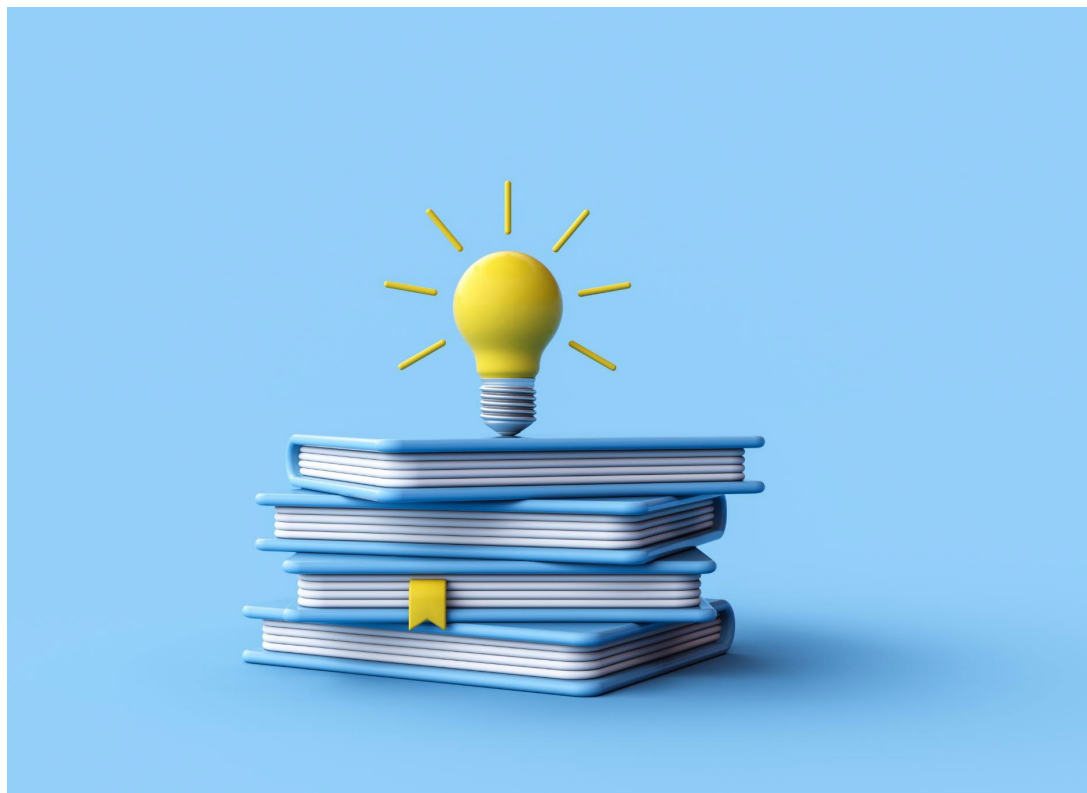


Sunshine Act and Open Payments Program Relationships

- ▲ **AKS:** Law surrounding inducements
- ▲ **Sunshine Act:** Folded underneath AKS with reporting requirements for gifts
- ▲ **Open Payments Program:** Operational system of Sunshine Act; mechanism for disclosure



Reporting and Transparency under the Sunshine Act



Mandatory Reporting Requirements

Requires disclosures of payments and other transfers of value made to healthcare providers participating in federal healthcare programs by manufacturers of drugs, biologicals, medical devices and medical supplies and by group purchasing agents.

Covered Recipients

- Physicians (MD, DO, dentists, podiatrists, chiropractors, optometrists)
- Teaching Hospitals
- Advanced Practice Providers (CRNAs, PAs, midwives, NPs)

Enhancing Transparency

- Enacted as part of the Affordable Care Act.
- Open Payments System (OPS) as national disclosure system and operational arm of the Sunshine Act.
- Intent for Sunshine Act and OPS to promote transparency in financial relationships within healthcare.

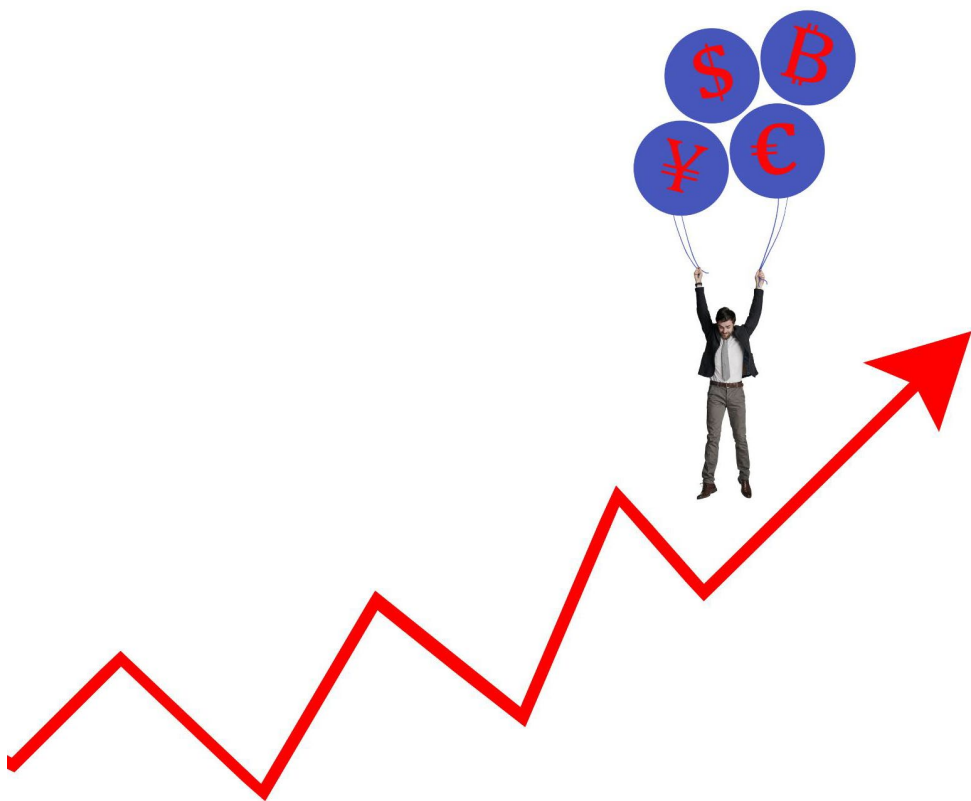
Key Elements

- ▲ Annual manufacturer submitted reports to CMS
- ▲ Information available to public on a searchable website
 - <https://openpayments.system.cms.gov/>
 - Released June 30
- ▲ Right for physicians to review reports and challenge if false, misleading, or inaccurate



Open Payments Program: Structure and Reporting





Payment Categories and Classification

Payment Categories Overview

- **General**
- **Research** - made in connection to formal research agreement.
- **Ownership and Investment Interests**-information about physicians or immediate family have with reporting entities.

Classification of Payments

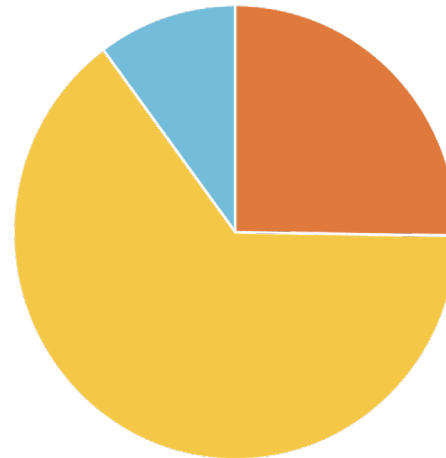
- **Direct** - Paid directly to covered recipients.
- **Indirect** - Paid indirectly to covered recipients via an intermediary.
- **Third Party** - Designated by covered recipients to be paid to another party.

Open Payments Program Year 2024 Update



\$13.18 BILLION

Total Value of Records Published in 2024



Payment Amount by Type



\$3.33 Billion
General Payments



\$8.52 Billion
Research Payments



\$1.34 Billion
Ownership/Investment
Interest*



Adapted From [Open Payments Data Overview | CMS](#)

**Ownership or Investment Interest includes those held by physicians or their immediate family members. This category is not applicable to non-physician practitioner covered recipients or teaching hospital covered recipients.*

Reporting Stats 2025

16.1 MILLION Total Records Published in 2025



651,977

total physicians
with payment
records



338,340

total non-
physician
practitioners with
payment records



1,288

teaching hospitals
with payment
records



1,798

companies
making
payments

Annual Reporting Cycle and Data Review Process



Data Review Period

Entities review data collected from the previous calendar year to ensure accuracy and completeness before reporting.

Dispute and Feedback Period

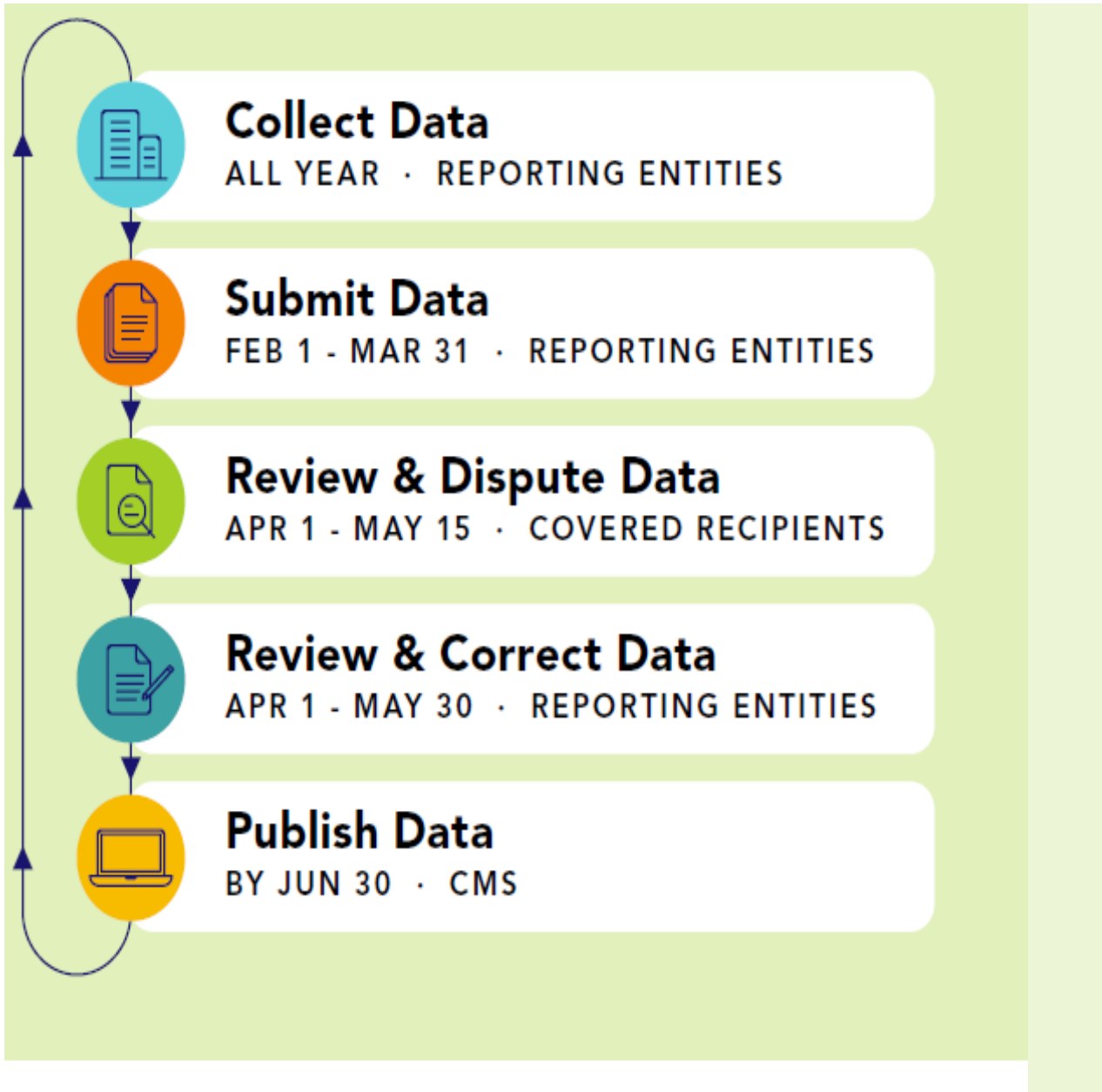
Covered recipients have a designated period to examine and dispute reported data for corrections and updates.

Data Updates by Entities

Reporting entities update the information based on recipient feedback to maintain data accuracy and integrity.

CMS Data Release Deadline

CMS releases the revised data by June 30th for the prior year, finalizing the annual reporting cycle.



The Open Payments Cycle

- Key takeaway-window to review and dispute (April 1- May 15)



Polling Question 2



- ▲ For Program Year 2025 (Jan. 1, 2025–Dec. 31, 2025), what is the small payment or other transfer of value threshold that must be reported based on the requirements under Open Payments?
 - a. \$10.46
 - b. \$11.46
 - c. \$12.46
 - d. \$13.46

Indirect Payments and Transfers of Value: Reporting Requirements



Definition and Criteria for Indirect Payments by Manufacturers and GPOs



Definition of Indirect Payment

Indirect payments occur when manufacturers or Group Purchasing Organizations (GPOs) requires, instructs, directs, or otherwise causes third parties to transfer value to covered recipients or physicians.

Reporting Requirements

Applicable manufacturers and GPOs must report indirect payments to physicians under Open Payments regulations.

Criteria for Reportability

Payments are reportable if the manufacturer or GPO directs or causes the transfer of value to a covered recipient via third parties.



Third Party Payments



Definition

Payments at the request of a covered recipient, even if routed through non-covered individuals or entities.

Reporting Requirements

Must be reported if the covered recipient (MD) requests or directs a payment be made to another individual or entity and the payment is for the benefit of the covered recipient.

Knowledge Standard

Reporting required if the vendor knows or should reasonably know payment is for the benefit of the covered recipient.



Third Party Payment Examples



- A physician asks a manufacturer to pay a consulting fee to a colleague or assistant.
- A teaching hospital directs a grant to be paid to a specific department or researcher.
- A physician requests travel expenses be paid to a third party who will accompany them to a conference.

Examples and Exclusions in Indirect Payment Reporting



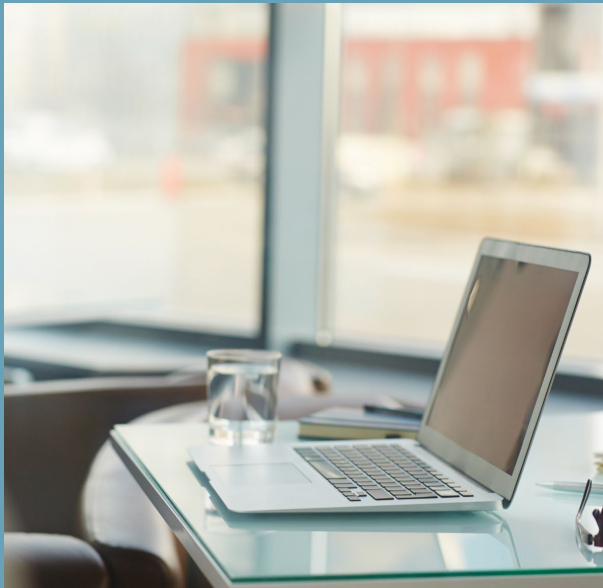
Third Party Non-Reportable Indirect Payments

Payments to continuing education providers used at their discretion are not reportable as indirect payments.

Non-Covered Recipient Employees

Payments to non-covered employees of hospitals or physician practices generally do not require reporting under Open Payments, unless payment ultimately benefits a covered recipient (Third Party Payment).

Polling Question 3



- ▲ If the amount transferred to, requested by, or designated on behalf of a covered recipient exceeds an aggregate total amount for the calendar year, must all payments or other transfers of value (including small payments) be reported?
 - a. No.
 - b. Yes.

Attribution and Division of Indirect Payments



Attributing Payments to Recipients

Payments should be attributed to each individual physician who requested or benefits from the payment or transfer of value.

Division of Payments

Payments do not need to be reported in the name of all members; division should fairly represent the situation.

Methods of Division

Payments may be divided evenly or based on who requested or benefited from the payment or transfer of value.



Knowledge and Responsibility in Indirect Payment Reporting



Definition of Indirect Payment

An indirect payment involves transfers of value made via a third party as instructed by an applicable manufacturer or group purchasing organization.

Reporting Requirements

Open Payments mandates reporting of both direct and indirect payments made to covered recipients to maintain transparency.

Knowledge and Responsibility

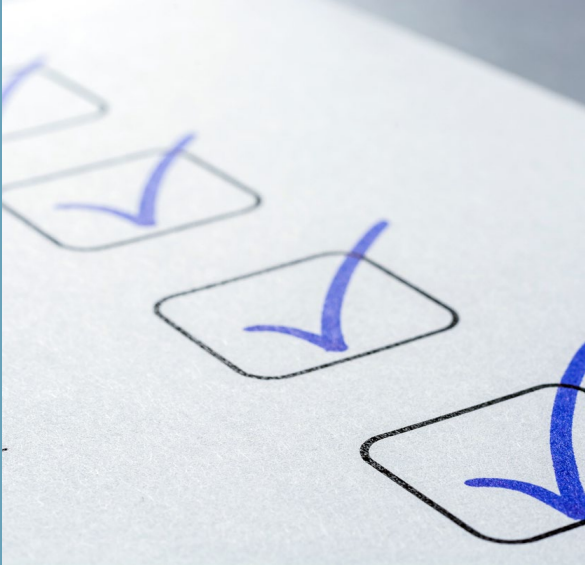
Manufacturers must report indirect payments if they know the recipient's identity or act with deliberate ignorance regarding it.

Exceptions in Reporting

If manufacturers are unaware of the recipient's identity, reporting is not required under specific regulatory conditions.



Polling Question 4



- ▲ Based on 42 CFR Section 403.912 (e), for how many years must applicable manufacturers and applicable group purchasing organizations maintain documentation of payments or other transfers of value, or ownership or investment interest?
 - a. At least three years
 - b. At least five years
 - c. At least seven years
 - d. At least ten years

Open Payments System Enhancements in OPS 2.0: Reviewing Data



Login and Registration

Login Enhancements

All users can access OPS 2.0 at [Open Payments](#).

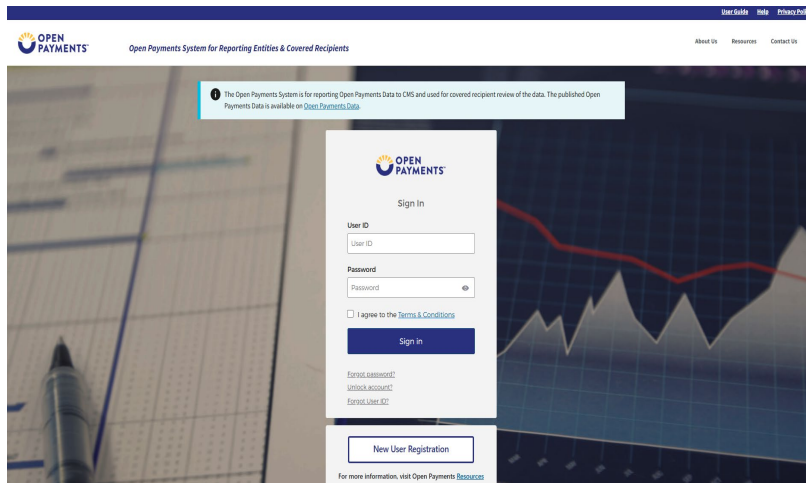
New User Registration Process

New users must register through a two-part process involving CMS Portal Identity Management and Open Payments profile creation.

Identity Verification Requirement

Some users must complete identity verification based on their role before accessing the Open Payments system.

An authorized representative may be nominated to act on the physician's behalf.



<https://openpayments.system.cms.gov/login>

[User Guide](#) [Help](#) [Privacy Policy](#)

OPEN PAYMENTS™ *Open Payments System for Reporting Entities & Covered Recipients* [About Us](#) [Resources](#) [Contact Us](#)

i The Open Payments System is for reporting Open Payments Data to CMS and used for covered recipient review of the data. The published Open Payments Data is available on [Open Payments Data](#).

OPEN PAYMENTS™

Sign In

User ID

Password

I agree to the [Terms & Conditions](#)

Sign in

[Forgot password?](#)
[Unlock account?](#)
[Forgot User ID?](#)

New User Registration

For more information, visit Open Payments [Resources](#)



User Account and Profile Management Features



The screenshot displays the 'OPEN PAYMENTS' user interface. On the left, a vertical navigation menu is titled 'My Profile' and includes links for 'My Open Payments Profile', 'Overview', 'Profile Details', 'My Links & Notifications', and 'My Profile'. The main content area is titled 'View My IDM Portal Profile' and contains a form with the following fields: 'First Name', 'Middle Name', 'Last Name', 'Date of Birth', 'Email Address', 'Phone Number', 'Home Address Line 1', 'Home Address Line 2', 'City', 'State', 'Zip Code', and 'Zip+4 Code'. A yellow 'Note' box at the bottom of the form states: 'Warning to change your profile will take you to the IDM Portal website.' A 'Change Profile' button is located at the bottom right of the form.

Profile Update Workflow

Users update IDM profiles via OPS 2.0 menu with seamless redirection to IDM Enterprise Portal, maintaining login status.

Organized Data Entry Sections

OPS 2.0 organizes data entry into workflows with collapsible help text and sections for personal and recipient information.

Navigation and Pop-ups

Vertical navigation panel shows section progress; pop-up modals enable fast edits retaining user position after closing.

Immediate Error Feedback

Error messages appear instantly when users exit fields, improving form accuracy and user experience.



How to Review and Dispute Reported Data

- ▲ Request Access to Open Payments via CMS Enterprise Portal (<https://portal.cms.gov/portal>).
 - Log in.
 - Click Request Access Now, Request New System Access.
 - Choose role as physician.
 - Enter personal information (NPI, DEA #, license information).
- ▲ Log in/Register to the Open Payments System (<https://openpayments.system.cms.gov/>).
- ▲ Access the "Review and Dispute" tab.
- ▲ Select name and program year.
- ▲ Click "Show Records".
- ▲ April 1-May 15.
- ▲ Data gets published publicly reported June 30.



CMS Enterprise Portal <https://portal.cms.gov/portal>

CMS.gov | Enterprise Portal

Applications Help About

CMS.gov | Enterprise Portal

User ID

Password

I agree to the [Terms & Conditions](#)

Login

Forgot your [User ID](#) or your [Password](#)?
Need to [unlock](#) your account?

New User Registration

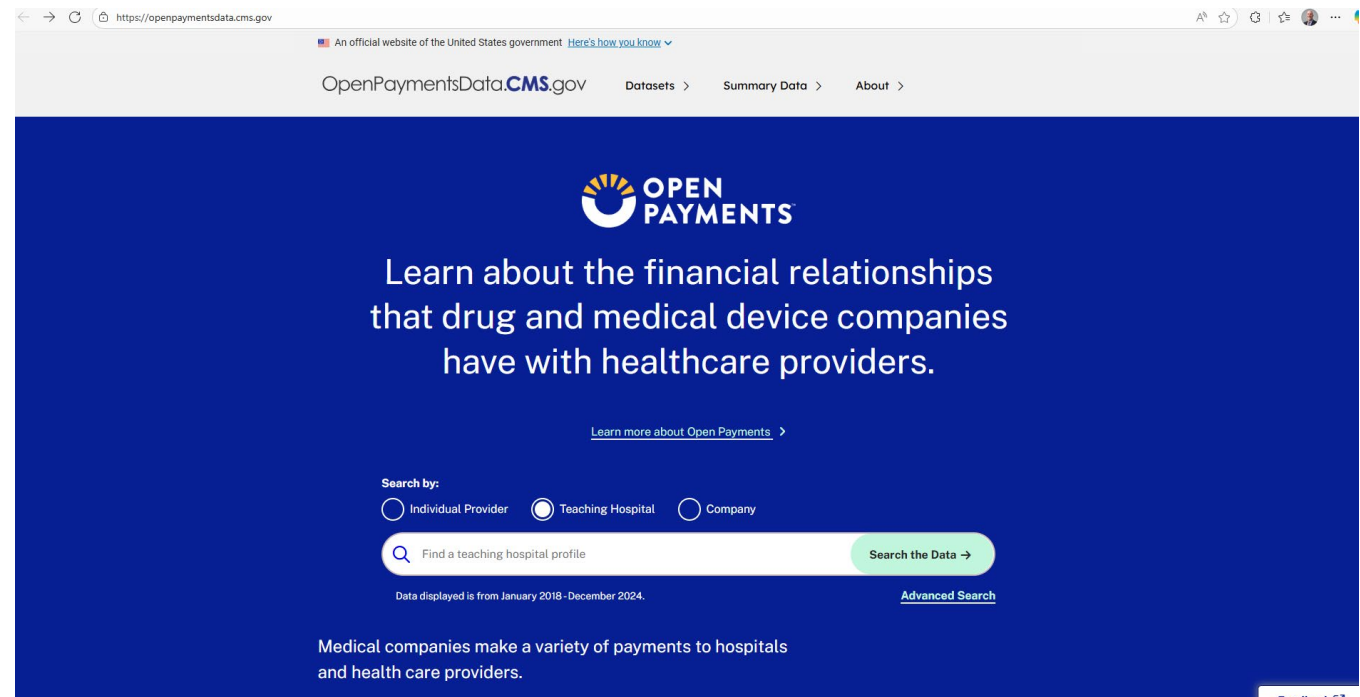
How can I help you?



Publicly Available Information

<https://openpaymentsdata.cms.gov/>

- Tools to search by provider, hospital, or company.
- Over 88 million records published, totaling \$76.99 billion in payments 2013-2024.
- CA requires MDs, since 2023, to notify patients about the Open Payment database.



The screenshot shows the homepage of the Open Payments website. The browser address bar displays <https://openpaymentsdata.cms.gov>. The page header includes the text "OpenPaymentsData.CMS.gov" and navigation links for "Datasets", "Summary Data", and "About". The main content area features the "OPEN PAYMENTS" logo, a blue background with white text stating "Learn about the financial relationships that drug and medical device companies have with healthcare providers.", and a link to "Learn more about Open Payments". Below this is a search section with the label "Search by:" and three radio button options: "Individual Provider", "Teaching Hospital" (which is selected), and "Company". A search input field contains the text "Find a teaching hospital profile" and a green "Search the Data" button. At the bottom of the search section, it notes "Data displayed is from January 2018 - December 2024." and provides a link for "Advanced Search". The footer contains the text "Medical companies make a variety of payments to hospitals and health care providers." and a "Feedback" link.



Clinician Education and Compliance Framework



Polling Question 5



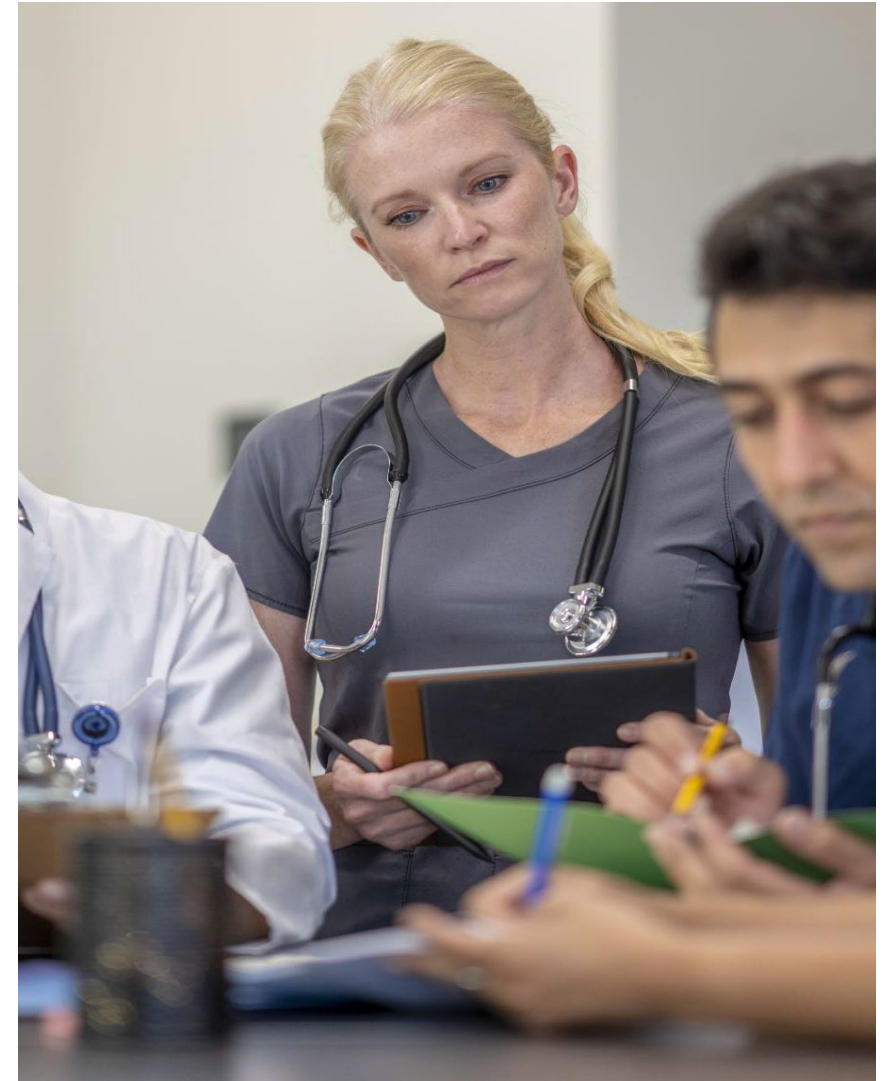
- ▲ Do you incorporate information on AKS, the Sunshine Act, physician gifting and the Open Payments System in your organization's compliance education?
 - a. I am unsure.
 - b. No.
 - c. Yes.

Components of Education and Training

Organization Policies/Guidelines/Code of Ethics

Onboarding and Orientation

Annual Updates



Engage and Include the Clinicians!



Code of Ethics/Organization Policies

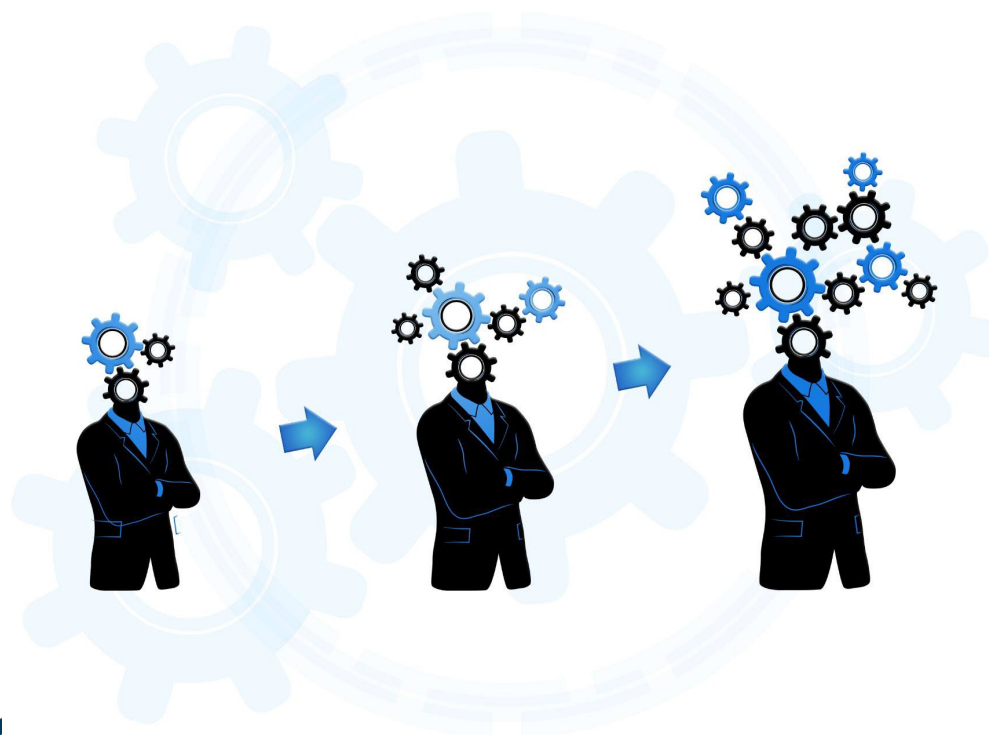
AMA Code of Ethics

- ▲ Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.
- ▲ To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:
 - (a) Decline cash gifts in any amount from an entity that has a direct interest in physicians' treatment recommendations.
 - (b) Decline any gifts for which reciprocity is expected or implied.
 - (c) Accept an in-kind gift for the physician's practice only when the gift:
 - (i) will directly benefit patients, including patient education; and
 - (ii) is of minimal value

Modify/adopt AMA Language

Internal Policies Regarding Accessing Open Payments System

Policies surrounding sponsored lunches, etc.



Orientation and Training on AKS and Open Payments

Clinician Orientation Framework

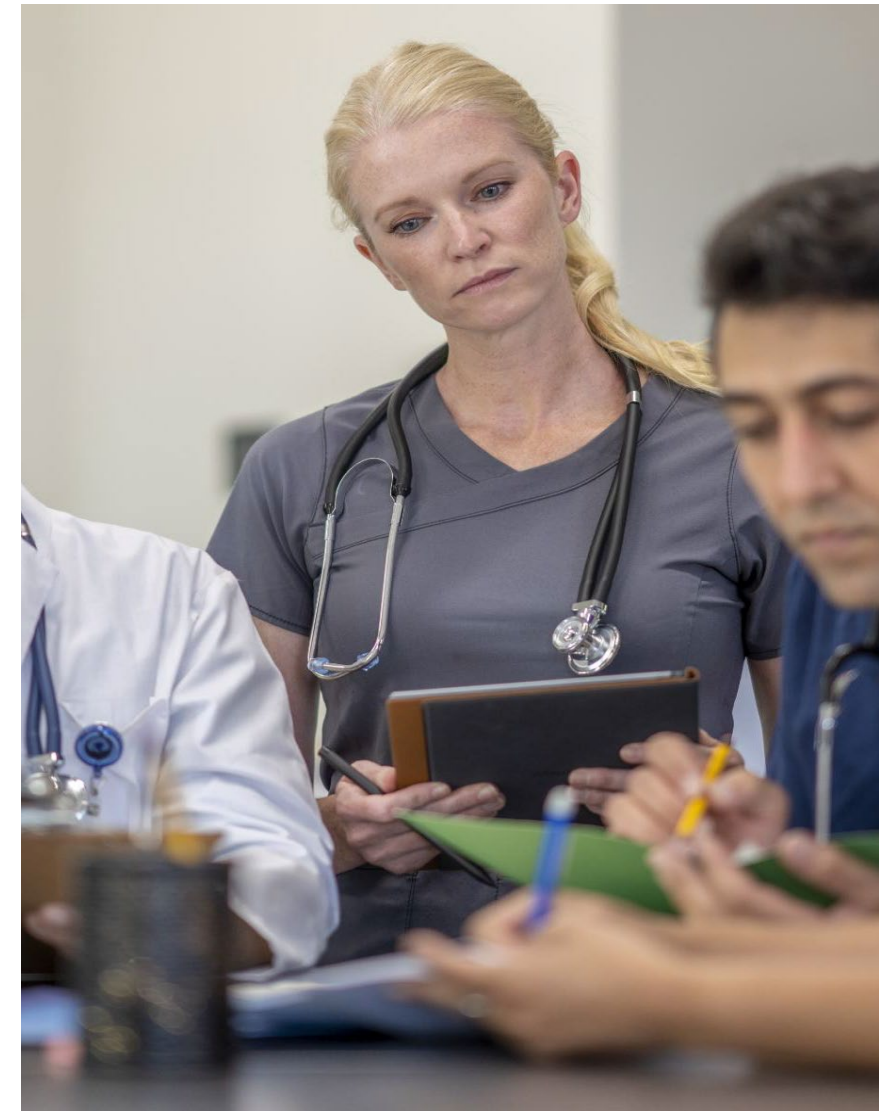
The orientation framework guides clinicians in understanding organizational policies and compliance standards.

AKS Compliance Training

Training covers Anti-Kickback Statute requirements, emphasizing legal and ethical healthcare practices.

Open Payments Program Education

Clinicians learn what is being reported about them and how to review and dispute Open Payments data to ensure accuracy and transparency.



Orientation

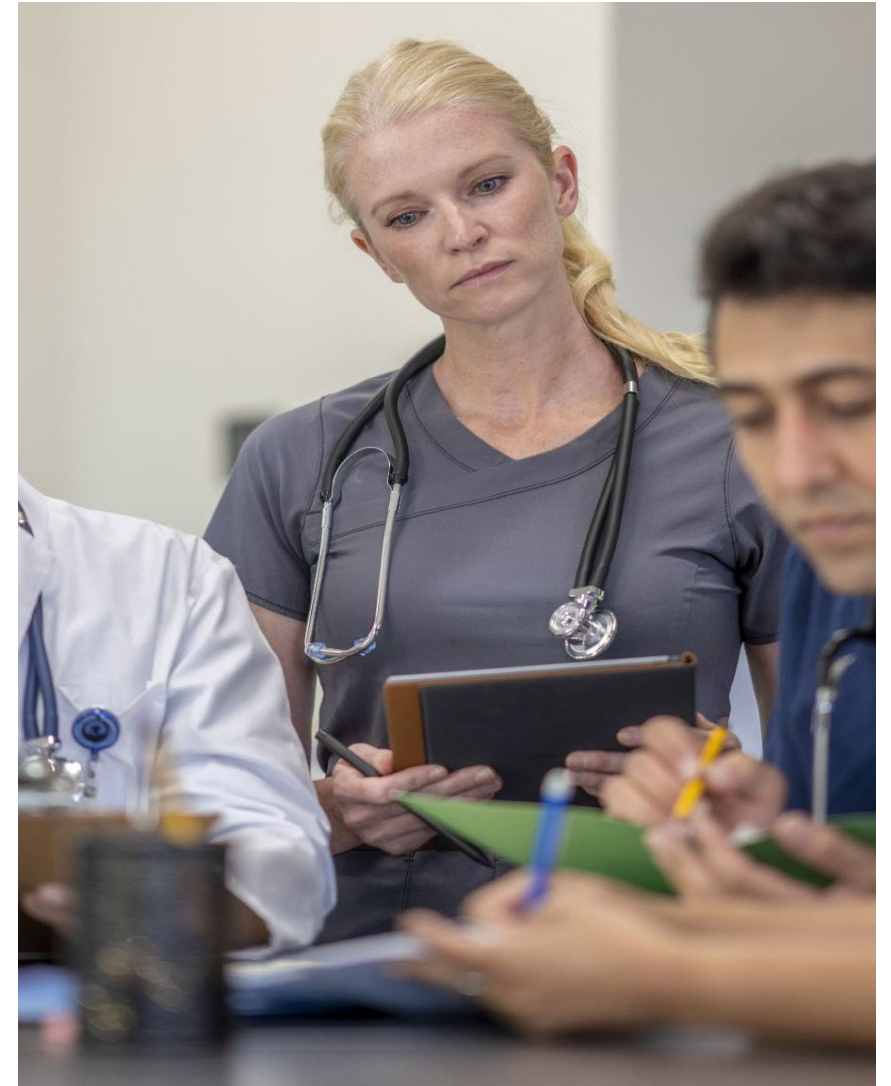
AKS as applied to Physician Gifts and Remuneration

Legal and Ethical considerations

Organizational Policies

OPP-what is reported, how and when to review and dispute data

Resources



Periodic Education

Weave into Scheduled education

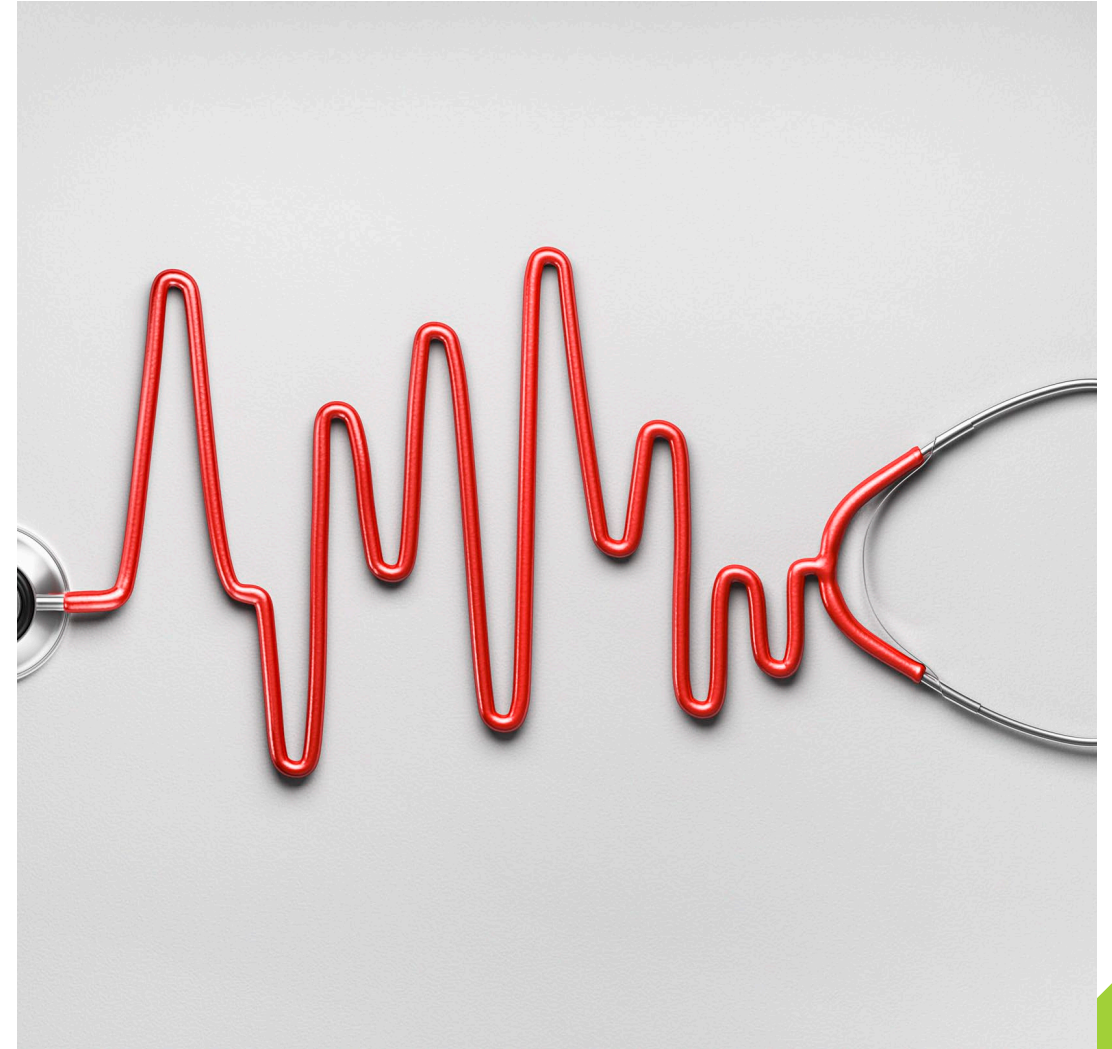
Updates/limits

Organizational Policies

Reminders to Review Data April 1-May 15

Instructions on Reviewing and Disputing Data

Resources/links



Key Legal References and Resources



References

1. [42 C.F.R § 403.902 \(Definitions\)](#)
2. [42 C.F.R § 904 \(Reports of payments or other transfers of value to covered recipients\)](#)
3. [42 C.F.R § 906 \(Reports of physician ownership and investments interests\)](#)
4. [42 C.F.R § 908 \(Procedures for electronic submission of reports\)](#)
5. [42 C.F.R. § 912 \(Penalties for failure to report\)](#)
6. [42 U.S.C. § 1320a-7b \(Criminal penalties for acts involving Federal health care programs\)](#)
7. [Physician financial transparency reports \(Sunshine Act\) | American Medical Association](#)
8. [Vermont Office of the Attorney General, “Guide to Vermont’s Prescribed Products Gift Ban and Disclosure Law for Disclosures of 2025 - Due April 1, 2026” <https://ago.vermont.gov/disclosures-manufacturers-prescription-drugs-biological-products-medical-devices>](#)
9. [What is Open Payments? | CMS <https://www.ama-assn.org/about/ethics>](#)
10. [U.S. Department of Health and Human Services, Office of Inspector General, “Special Fraud Alert: Speaker Programs”, November 16, 2020](#)



Additional Resources:

1. CMS Medical Learning Booklet “Medicare Fraud and Abuse: Prevent, Detect and Protect, Report
<https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/fraud-abuse-mln4649244.pdf>
2. OIG website with guidance on compliance education for new physicians
[A Roadmap for New Physicians | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services](https://oig.hhs.gov/compliance/physician-education) (<https://oig.hhs.gov/compliance/physician-education>)
3. OIG website with guidance on overall compliance education for physicians
[Compliance Programs for Physicians | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services](https://oig.hhs.gov/compliance/physician-education/compliance-programs-for-physicians) (<https://oig.hhs.gov/compliance/physician-education/compliance-programs-for-physicians>)



Additional Resources:

4. General Open Payments Information

[What is Open Payments? | CMS \(https://www.cms.gov/priorities/key-initiatives/open-payments\)](https://www.cms.gov/priorities/key-initiatives/open-payments)

5. Review Your Data: Quick Start Guide for Health Care Providers

<https://www.cms.gov/files/document/op-review-your-data-quickstart-guide.pdf>

6. OPS Log in and Registration Site

[Open Payments \(https://openpayments.system.cms.gov/login\)](https://openpayments.system.cms.gov/login)

7. Publicly Accessible Site to Search Open Payments Data

[Open Payments \(https://openpaymentsdata.cms.gov\)](https://openpaymentsdata.cms.gov)



Conclusion

Regulatory Compliance Importance

Understanding key statutes is vital for healthcare stakeholders to maintain legal and ethical compliance.

Promoting Transparency

Transparency in healthcare interactions builds trust and supports ethical standards in the industry.

Continuous Education

Staying informed about reporting and system updates ensures ongoing adherence to regulations.





Thank you for joining us today. Any questions? We value your feedback.

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