

Preparing for an Open Payments Audit

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Today's Agenda



Overview of the Open Payments (Sunshine Act) Program

CMS Open Payments Audit Authority

Audit Process and Phases

Audit Considerations

Audit Readiness



Disclaimer



The opinions expressed are those of the presenters and do not necessarily reflect the views of their employers or clients

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Overview of Open Payments

The Open Payments Program (also typically referred to as the “Sunshine Act”) is a national disclosure program designed to promote a more transparent and accountable health care system

- It creates a publicly accessible database of payments and transfers of value that reporting entities, including drug and medical device manufacturers, make to covered recipients, including physicians, advance practice registered nurses, physicians’ assistants, and teaching hospitals

The Open Payments Program was enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act

- Tracking payments and transfers of value was first required beginning August 1, 2013
- We are more than 10 years into implementation!

Audit Authority

The Open Payments Program is administered by the Centers for Medicare & Medicaid Services (“CMS”)

CMS’s authority to conduct audits under the Open Payments Program is codified at 42 C.F.R. 403.912(e)(2)

(e) *Record retention and audits.*

(1) *Maintenance of records.*

- (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer’s or applicable group purchasing organization’s compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.
- (ii) The items described in [paragraph \(e\)\(1\)\(i\)](#) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) **Audit.** HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.



Open Payments Audit Process

The company first receives a letter from CMS

- Notifies the company of selection for an Open Payments audit
- Identifies CMS's subcontracted auditor
- Notifies that the company will be contacted by the auditor

Auditor contacts the company

- Kick-off call with auditor to introduce the team
- Discuss the scope, objectives, and criteria of the audit
- Provide an overview of the audit process



Open Payments Audit Process (cont'd)

Audit criteria/standards considered:

- CMS's Open Payments auditing power under 42 C.F.R. 403.912
- CMS's Open Payments requirements (statute and regulations)
- Generally Accepted Government Auditing Standards ("GAGAS")
- Standards issued by the American Institute of Certified Public Accountants ("AICPA"), as needed

Time period:

- Time period under audit is typically 3-5 years

Audit proceeds in two phases: (1) planning phase; and (2) fieldwork phase



Audit Phase 1: Planning

During the “planning” phase, the auditors seek to understand:

- The company’s structure
- The types of payments and transfers of value made by the organization that are subject to disclosure under Open Payments
- The systems used to track and report payments and transfers of value
- The controls in place to help ensure compliance
- Overall organizational commitment to Open Payments compliance

Companies are asked to complete questionnaires and provide documents to inform these areas



Audit Phase 2: Fieldwork

During the “fieldwork” phase, the auditors engage in transaction testing, where they seek to reconcile the Open Payments reports that the company submitted to CMS with the underlying data recorded in the company’s systems

Specific records are identified for testing

Company asked to provide documents, records, etc. that corroborate and confirm the data reported



Audit Conclusion

When the audit phases are complete, the auditors conduct an exit conference with the company

The auditors will then issue a performance audit report presenting findings, conclusions, and recommendations to CMS



Audit Process Considerations

Keep in mind that auditors are not lawyers or compliance professionals

If needed, vigorously defend your good faith interpretations and approaches

Complications associated with attempting to identify whether there were omissions in data reported to CMS (this is not transaction testing, but testing to determine if there were omissions of payments that should have been reported)

Be mindful that confidential business information might be requested during the audit and take steps to protect the information (e.g., non-disclosure agreements)

Be thoughtful about how you produce documents



Audit Process Considerations (cont'd)

Be thoughtful about communications with the auditors

Be wary of scope creep (e.g., this is not a fraud and abuse audit)

Ensure that you have the appropriate stakeholders managing the company's response, including the narrative responses to questionnaires

- Response teams should include a combination of Legal, Compliance, and Finance, and possibly others
- Think about who internally needs to be updated on the audit and how (e.g., Board, C-suite, Communications, senior leadership)
- Consider whether and how to involve outside counsel



Preparing for an Audit

Review and update, as needed, Open Payments-related policies, SOPs, trainings and other control documents

- Ask: Do our policies, procedures, and other control documents accurately reflect and demonstrate our commitment to Open Payments compliance?

Where there is discretion, consider which control documents the company will provide to the auditor (e.g., will you provide the internal assumptions document?)

Identify where your source materials are located (e.g., receipts, invoices) and determine whether they can be readily pulled, if requested



Preparing for an Audit (cont'd)

Consider how the company might manage the complications around “record omission” testing (i.e., probing into whether something was reportable, but not reported)

Consider convening an internal audit prep team comprised of Finance, Legal, Compliance, and possibly others

Determine how audit considerations might impact reporting determinations you are making now

- Ask: If we take this approach, can we explain it easily to an auditor?

Thank You

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