



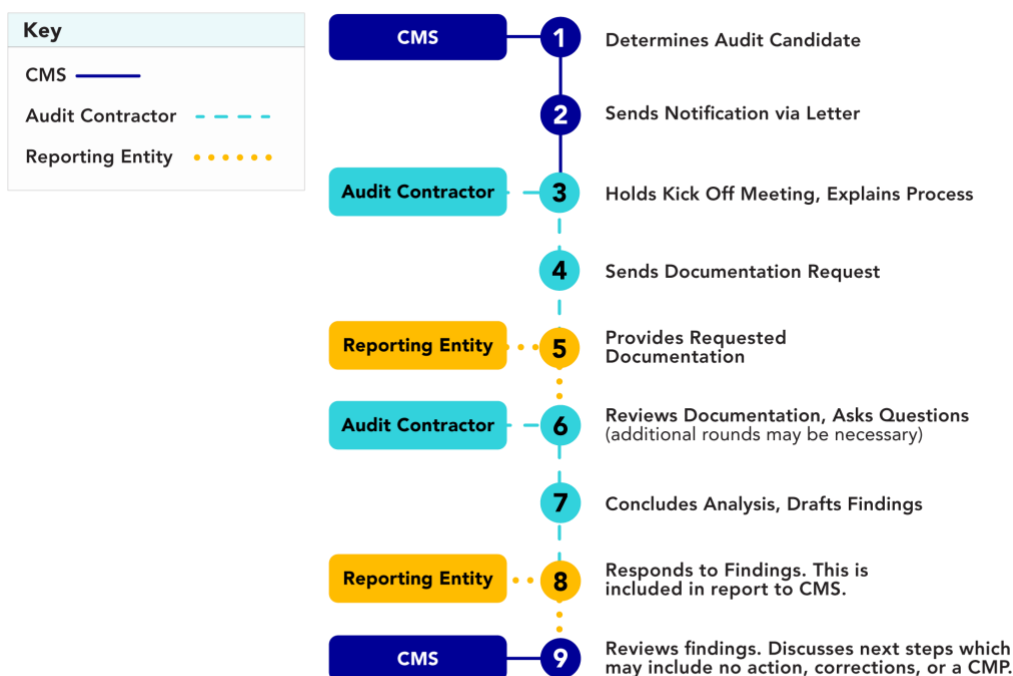
**Open Payments**

# Audit Resource

## Overview

The Centers for Medicare & Medicaid Services (CMS) Open Payments program has the authority to conduct reviews of the documentation of reporting entities,<sup>1</sup> in the form of an audit, for the purposes of verifying reporting to the Open Payments program.<sup>2</sup> Confidence in the data is key to the value of transparency, and these audits assist CMS in ensuring that Open Payments data is reported accurately, completely, and timely. The reporting entities required to submit records to the Open Payments system must maintain the underlying documentation for at least five years from the date it is published. The purpose of this document is to provide additional information and suggestions regarding the audit process since a well-designed audit program decreases the burden of an audit.

CMS recognizes that audits can result in some burden. This document's purpose is to answer questions, with the aim of facilitating an orderly audit. Review [the Final Rule](#) at 42 CFR 403.912(e)(2) for reporting requirements and CMS's audit authority.



<sup>1</sup> Applicable manufacturers and applicable group purchasing organizations, see 42 CFR 403.902.

<sup>2</sup> 42 CFR § 403.912(e)

## Documents Subject to Audits

At the outset of an audit, CMS or its contracted auditor will clearly communicate and walk through the information that a reporting entity must provide. Any pieces of documentation that are relevant to your organization's reporting requirements are subject to an audit, such as, but not limited to, checks, receipts, and standard operating procedures.

Open Payments records may include financial documents, therefore audits may require a general ledger review, though CMS will not be conducting a financial audit. While the list of possible audited document types may be broad, CMS can tailor its requests based on the reporting entity's structure or the purpose of the audit (if issue-based) and will ask for documents related to specific records as needed. These types of reviews are essential to confirm program compliance and/or to identify unreported or incomplete records. Table 1 provides a non-exhaustive list of these examples.

***Using a third-party data submission contractor does not constitute an exemption to document retention.*** In other words, if your company outsources recordkeeping, Open Payments reporting, or any other function implicated in complying with CMS reporting or audit requirements, your company is still responsible for producing the requested documentation. You may wish to incorporate the possibility of audits into the contracts you hold with your distributors and agents and outline the responsibility for documenting and producing required documents. On a similar note, regarding mergers & acquisitions, the acquiring entity should consider the risks associated with the acquired company's compliance program.

## Sample List of Potential Audit Documents (Non-Exhaustive)

Documents are subject to audit authority from five years from the date of publication.

Document Type	Document Request
Policies and procedures used for Open Payments reporting.	A copy of company policies and procedures for Open Payments reporting, if they exist. It has proven highly beneficial to have such documents in writing and up to date as they can help the auditor understand your data and documentation tracking and reporting setup quickly and streamline the audit process. Examples include a directory of reporting roles, a previously conducted internal audit or compliance risk identification and mitigation exercise, and comprehensive policies and procedures for collecting, submitting, and safeguarding the data.

Document Type	Document Request
Copies of documentation related to General Payment records.	Supporting documentation for an auditor-generated sample of records submitted and attested by the reporting entity. Examples are copies of receipts, contracts, sign-in sheets, or checks.
Copies of documentation related to Research Payment records.	Supporting documentation for an auditor-generated sample of records submitted and attested by the reporting entity. Examples are copies of research controls or protocol, orders for supplies, or checks.
Copies of documentation related to physician ownership and investment interest.	<p>Supporting documentation for ownership and investment interest may include:</p> <ul style="list-style-type: none"> <li>-Articles of incorporation and bylaws for the organization.</li> <li>-Entity ownership, including the name of each owner and ownership percentage and indication of whether each individual is a covered recipient or the immediate family member of a covered recipient.</li> <li>-Copies of stock subscription and stock option agreements.</li> <li>-A list of common ownership entities and their relationship to the entity.</li> <li>-Copies of financial reports.</li> <li>-Copies of valuation studies.</li> </ul>
Copies of agreements for any services provided by Open Payments covered recipients.	Supporting documentation for an auditor-generated sample of records submitted and attested by the reporting entity for the past five years. These include consulting fees, speaker or educational fees, or any other compensation.
Copies of loans, leases, and material contracts with Open Payments covered recipients.	Documentation of any loans, leases or material contracts that may exist for an auditor-generated sample of physicians who received transfers of value from the reporting entity in the past five years.
General ledger details of expenses associated with Open Payments categories.	Provision of general ledger detail for company expenses in the General Payment categories applicable to Open Payments reporting. The general ledger is used to conduct exclusion testing to confirm that the appropriate records were reported.

## FAQs

These are the most common audit questions asked of CMS by reporting entities. These FAQs can also be found in [the FAQ document](#) on the [cms.gov/OpenPayments](https://www.cms.gov/OpenPayments) Resources Page.

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### Who does CMS audit?

CMS has the authority to audit any applicable manufacturer or applicable group purchasing organization, and these reporting entities are responsible for ensuring that their documentation is maintained for at least five years from the time the record is published. CMS will choose an auditee in one of two ways:

- **Issue-Based:** CMS has identified potential or confirmed noncompliance and is requesting documentation around these records to gather further details. There are a variety of factors and sources of information that CMS will use when identifying compliance issues, but entities should keep in mind that CMS is looking for records that do not meet the requirement for complete, accurate, and timely reporting. This could include inaccuracies in record details like amount or an incorrectly reported covered recipient, or records that should have been reported but were not. CMS will also consider the size of an entity when looking at metrics for potential reporting issues, such as the relative number of disputes and percentage of payments disputed.
- **Randomly Selected:** CMS may randomly select an auditee.

The number and percentage of entities selected randomly versus using issue or risk-based methods may vary based on specific caseload and other factors each year.

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### How can my organization prepare for an audit?

To ensure an audit can be completed smoothly and expeditiously, the most important thing your organization can do is have your documentation readily available. CMS suggests making sure all the appropriate employees, executives, or vendors, including third parties, are aware of how they can support your organization's compliance with Open Payments requirements so that responding to an audit request is not a surprise. This may entail setting up a formal plan or including a documentation requirements clause in a vendor contract.

Although it is not a requirement, audits may proceed more expeditiously when your organization actively documents its processes for reporting. This may be captured in a list of roles & responsibilities, relevant systems, methodologies and assumptions, or other operating procedures. In other words, gathering all the information that is used for reporting into an audit plan. Record retention is required for at least 5 years per 42 CFR § 403.912(e)(1)(i), and audits likewise may proceed more expeditiously when your organization has appropriate documentation for each payment or transfer of value (such as checks or invoices). The documentation should be readily available to be gathered and produced.

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## **What if a third party maintains my organization's documentation?**

The use of a third-party vendor for any or all Open Payments recordkeeping does not excuse any lack of documentation because it falls under the definition of an indirect payment (see 42 CFR § 403.902).

In other words, each applicable manufacturer or group purchasing organization is responsible for providing any relevant documentation and information that is needed to conduct an audit, regardless of whether that information comes from a third-party. It is your responsibility as a reporting entity to ensure that the third party you work with properly maintains and provides you with Open Payments record documentation.

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## **Are there different types of audits?**

In general, CMS or its contracted auditor conducts either a desk audit or a Generally Accepted Government Auditing Standards (GAGAS) audit.

The type of audit that CMS refers to as “desk” audits are less rigorous than GAGAS audits. The desk audit may be conducted by CMS itself or by a contractor and may even be a relatively simple request for documentation of a few records. A desk audit may be requested randomly or because of potential noncompliance. Depending on the nature of any assessed noncompliance risk, the number of records or documents subject to the desk audit may vary.

GAGAS audits are more rigorous and lengthier than desk audits, and an entity’s selection may be random or made by risk-based selection. These audits are conducted by a contractor specializing in this type of audit. For more information on GAGAS audits, refer to the Government Accountability Office’s standards at [gao.gov/yellowbook](https://www.gao.gov/yellowbook).

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## **If CMS finds noncompliance as the result of an audit, will my company be issued a civil monetary penalty (CMP)?**

The issuance of a CMP will depend entirely on individual circumstances. Though noncompliance may be uncovered during an audit, CMS has discretion on whether to issue a CMP. The amount of any potential CMP also depends on mitigating and aggravating factors.

CMS’s priority is data integrity. CMS has the statutory authority to issue a CMP with respect to any records which are reported untimely, inaccurately, or incompletely or not reported at all. For more information about CMPs, review the regulations at 42 CFR § 403.912.

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## How will CMS communicate that our organization is being audited?

CMS will initiate audit proceedings via letter, through the Open Payments System (OPS) Compliance Portal. CMS may also initiate audit proceedings via email. It is important that your contact information in the OPS is as current as possible, since CMS will use that information to communicate about the audit. CMS may not communicate why your organization was selected for an audit. Further instructions and scope will follow and may depend on consultations with the reporting entity. Depending on the type of audit (e.g., desk or GAGAS), your organization may receive these communications from CMS's contractor, which acts as CMS's agent for the purposes of the audit. CMS is available to answer questions if there are any issues. You may reach out to the Compliance Team at [opcompliance@cms.hhs.gov](mailto:opcompliance@cms.hhs.gov) to provide any concerns or feedback.

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## What are the audit participation instructions?

CMS or its audit contractor will provide all required instructions after the audit is initiated. If the audit is more complex, it will involve a kickoff meeting as well as instructions on how to provide the documents that have been identified for review. Depending on their size or sensitivity, documents may be uploaded to the Compliance Portal in the Open Payments System or a secure portal maintained by CMS's contractor or emailed to [opcompliance@cms.hhs.gov](mailto:opcompliance@cms.hhs.gov). The types of documents that must be uploaded will depend on the circumstances that prompted the audit (note that those specific prompting circumstances may not be disclosed to the reporting entity), the type and scope of the audit, which specific records will be reviewed, and the organizational and operating structure of the reporting entity including whether or not the reporting entity outsources any of its physician payments, records management, Open Payments reporting or other significant processes to third parties. Depending on the findings of the document review or conversations with the reporting entity, there may be more than one round of document requests. CMS or the audit contractor will maintain open communications with the reporting entity and provide appropriate timelines, if necessary.

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## How long will the audit take?

Audit duration will vary. Therefore, CMS cannot provide an estimate of how long an audit will take from start to finish. In general, the preparedness of the reporting entity and the complexity of the audit are the most influential factors in the length of time an audit takes. You may wish to ensure that your organization's documents are complete and centralized so you are as prepared as possible when an audit is initiated.

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## How long are Open Payments records subject to an audit?

Documentation is subject to an audit from five years from the date of publication (42 CFR §403.912(e)(1)(ii)). CMS will likely audit multiple years' worth of records, although this will depend on the specific circumstances of the audit.

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## Is the documentation provided during the audit secure and confidential?

CMS has established policies and procedures to reasonably and appropriately protect the security, integrity, and confidentiality of the information, including electronic or paper media, that CMS creates, receives, maintains, uses, or transmits. All who audit on behalf of CMS operate pursuant to these policies and procedures to safeguard against unauthorized use and access to the sensitive information entrusted to them. If your organization has any concerns about the type of documentation that is requested, CMS can produce relevant security information about its portals and storage.

CMS recognizes the utmost importance of security and confidentiality of records and documents subject to audit and takes comprehensive measures to ensure that information stays secure and is accessed on a strict need-to-know basis. All electronic systems used to transmit and store audit related information, (including CMS and/or contractor systems), undergo robust security testing to demonstrate compliance with applicable Federal Information Security Modernization Act (FISMA) standards to protect data and systems from unauthorized access, use, disclosure, disruption, modification, or destruction.

CMS uses and discloses information only in a manner consistent with Federal law as required by the following Acts:

- FISMA – Federal Information Security Modernization Act of 2014 (<https://www.congress.gov/bill/113th-congress/house-bill/1163>)
- FIPS 199 – Standards for Security Categorization of Federal Information (<https://csrc.nist.gov/publications/detail/fips/199/final>)
- NIST SP 800-53 Rev. 5 – Security and Privacy Controls for Information Systems (<https://csrc.nist.gov/publications/detail/sp/800-53/rev-5/final>)
- CMS ARS (<https://security.cms.gov/policy-guidance/cms-acceptable-risk-safeguards-ars>)

As further protection for particularly sensitive information, documents/files are clearly marked to alert any reviewer that this information should be treated as confidential.

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## What is the assumptions document and how does it relate to an audit?

The assumptions document is a free-form text explanation of methods, assumptions, and any special circumstances or considerations of relevance to the accuracy, completeness or timeliness of reported data that an applicable manufacturer or group purchasing

organization can fill out during their attestation in the Open Payments system. Completing the assumptions document is not required, but CMS highly encourages the assumptions document to be utilized in circumstances that are unusual or may raise a “red flag” during the compliance team’s review of the data. Though filling out a thorough assumptions document does not guarantee your organization will not be audited, it may be helpful to provide context to CMS when the Compliance Team considers possible reporting issues.

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## **Will my organization be able to respond to any findings of Open Payments noncompliance?**

Throughout the audit, you will have communication with the auditor and/or CMS and be able to provide any explanations or clarifications that you see fit. If a contractor conducts the audit, your organization will be able to formally review the audit report and provide your own response before it is submitted to CMS. Your review and response can be as detailed as your organization chooses and will be included as part of the final report. CMS will consider your organization’s response before determining any formal compliance actions for any non-compliance identified during an audit.

## Legal Authority

CMS's audit authority for Open Payments is found at 42 CFR § 403.912(e) and reads:

(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 manufacturers 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.

## Contact Us

Do you have additional questions about audits, or want to share feedback? Contact the Open Payments Compliance Team at [opcompliance@cms.hhs.gov](mailto:opcompliance@cms.hhs.gov).

If you would like technical help with reporting, submit an email to the Help Desk at [openpayments@cms.hhs.gov](mailto:openpayments@cms.hhs.gov). For live assistance, call the Open Payments Help Desk Support at 1-855-326-8366 (TTY Line: 1-844-649-2766). The Help Desk is available 9:00 a.m. – 5:00 p.m. (ET) Monday through Friday excluding federal holidays. For more reporting resources, visit [cms.gov/OpenPayments](https://cms.gov/OpenPayments).

## Disclaimer

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

**Activities/persons addressed by this document:** Open Payments applicable manufacturers and group purchasing organizations (GPOs)

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**Citation to statutory provision / regulation applicable to this document:**

- Statute citation: Social Security Act SEC. 1128G. [42 U.S.C. 1320a-7h]
- Rule citation: 42 C.F.R. §403.900-14