OMNITEK CONSULTING

Closing the Open Payments Gap

WHITE PAPER

Why Accurate Federal Transparency Reporting Is Getting Harder to Fake Your Way Through

Abstract

CMS's Open Payments program captured $13.18 billion in publishable payments across 16.16 million records in the most recent program year, spanning more than 650,000 physicians and 1,288 teaching hospitals. Enforcement against inaccurate reporting has historically been light, but that is changing. CMS requested an increased budget specifically to expand Open Payments oversight, moved to a combination of risk-based and random audit selection that flags unusual reporting patterns and data irregularities, and can impose civil monetary penalties of up to $1.5 million per reporting entity per year. Manufacturers that have treated Open Payments as an annual data dump, reconciled loosely and submitted under deadline pressure, are running out of room to keep doing that. This white paper applies established data governance and audit-readiness best practices to closing the specific gaps, spend categorization errors, source system fragmentation, and late dispute resolution, that turn an annual reporting exercise into an audit liability.

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An Annual Deadline That Used to Be Forgiving

For most of Open Payments' history, the program worked like an annual filing deadline that rewarded getting something submitted over getting everything right. Compliance teams pulled data from expense systems, CRM platforms, and speaker program vendors, reconciled what they could in the weeks before the March deadline, and accepted that some records would carry categorization errors or missing detail. Enforcement was rare enough that the practical cost of an imperfect submission was low, and the incentive to invest in a genuinely accurate reconciliation process was correspondingly weak.

That calculation is shifting. CMS's most recent report to Congress shows the program capturing $13.18 billion in publishable payments and ownership interests across 16.16 million records, split across $3.33 billion in general payments, $8.52 billion in research payments, and $1.34 billion in ownership and investment interests.[i] The number of reporting entities actually declined, from 1,911 to 1,798 year over year, but the volume and scrutiny applied to what remains has not shrunk with it.[i]

CMS's compliance outreach corrected or updated 2,170 records in the most recent program year, evidence that the agency is not simply collecting data passively but actively identifying and chasing down inaccuracies.[i] That is a meaningfully different posture than the program's early years, and it is the leading edge of a shift toward genuine enforcement.

The Enforcement Shift Compliance Teams Are Underestimating

Historical enforcement activity under Open Payments has been genuinely light. Legal analysis of CMS enforcement data counted nine enforcement events in fiscal year 2022, three in 2021, and seven in 2020, numbers small enough that many compliance functions reasonably deprioritized Open Payments accuracy relative to higher-visibility risk areas.[ii] That is the pattern most current compliance programs were built around, and it is exactly the pattern CMS's recent moves are designed to break.

CMS requested an increased budget specifically to support expanded Open Payments operations and enforcement, and shifted its audit selection methodology to combine risk-based targeting with random selection.[ii] The risk factors that trigger a targeted audit are specific and identifiable: credible tips, unusual or inconsistent reporting patterns, data irregularities, and a documented history of noncompliance.[ii] A manufacturer with categorization inconsistencies across business units, payment records that do not reconcile cleanly against underlying expense data, or a pattern of late corrections is describing itself directly into that risk profile, whether or not anyone intended it that way.

The financial exposure behind that risk is not trivial. Civil monetary penalties under Open Payments can reach $1.5 million per reporting entity per year, adjusted annually, and CMS's own report to Congress confirms the agency issued nine pre-demand warning letters and completed four audits in its most recent fiscal year, a small number in absolute terms but a clear signal of active, ongoing audit activity rather than a dormant enforcement program.[i]

Applying Best Practices: Closing the Gaps Audits Actually Find

A foundational best practice in data governance is building one reporting engine that absorbs new transparency obligations across jurisdictions instead of rebuilding for each one. Applied specifically to Open Payments, that discipline extends into a targeted practice for closing the four gap types that most commonly turn a routine submission into an audit finding.

1. **Source System Reconciliation Before Submission, Not After a Dispute.** Payment, travel, and speaker program data typically live in separate systems that were never designed to reconcile against each other automatically. Building a standing reconciliation process that runs quarterly, rather than a scramble in the weeks before the annual deadline, catches mismatches while there is still time to investigate them properly.
2. **Consistent Spend Categorization Across Business Units.** The same type of payment, a speaker honorarium or a consulting fee, needs to be categorized the same way regardless of which business unit or brand team generated it. Categorization drift across units is exactly the kind of inconsistent reporting pattern that CMS's risk-based audit selection is designed to catch.
3. **A Documented Data Lineage for Every Reported Record.** Every payment record should be traceable back to its originating transaction, with a clear chain from source system to submitted report. This is not just good hygiene. It is the specific evidence a manufacturer needs to produce quickly and credibly if CMS opens an audit.
4. **Dispute and Correction Resolution Inside the Program Window.** CMS's pre-publication review, dispute, and correction period exists precisely so covered recipients can flag errors before data goes public. Manufacturers that treat this window as a formality rather than a genuine quality checkpoint miss the chance to fix problems before they become permanent public record.

None of these four practices require new software procurement. They require treating Open Payments reconciliation as a standing operational discipline rather than an annual project, the same shift best practice applies to state transparency obligations more broadly.

What Closing the Gap Buys, and Where It Gets Hard

Advantages

- **Materially lower audit risk:** consistent categorization and clean data lineage directly address the risk factors CMS has stated it uses for audit selection, reducing the likelihood of being flagged in the first place.
- **Faster, more credible audit response:** a manufacturer that can trace any payment record back to its source system in minutes responds to an audit request from a position of confidence rather than a scramble.
- **Fewer public corrections:** catching errors during the dispute and correction window, rather than after publication, protects the manufacturer's public transparency record from repeated visible amendments.
- **Reusable infrastructure for state reporting:** the reconciliation discipline built for Open Payments accuracy directly strengthens the broader reporting engine used for state transparency obligations.

Risks and Barriers

- **Cross-functional ownership gaps:** payment data often originates in finance, medical affairs, and commercial systems that report to different leaders, and reconciliation stalls without a single accountable owner for data quality.
- **Legacy categorization inconsistency:** correcting years of accumulated categorization drift across business units takes real effort and may surface historical reporting issues that need their own remediation plan.

- **Vendor data quality:** speaker program and travel vendors vary widely in how cleanly they can provide reconcilable data, and contractual leverage to demand better data quality is not always available mid-contract.
- **Resourcing a quarterly discipline:** moving from an annual push to standing quarterly reconciliation requires ongoing capacity that competes with other compliance priorities for budget.

Case in Point: The Categorization Pattern That Triggered a Look

A mid-size medical device manufacturer's Open Payments submissions had, for several years, categorized the same type of proctoring payment differently depending on which regional sales team originated it, a legacy of decentralized data entry that nobody had ever consolidated. The inconsistency was not intentional and did not change the total dollar amount reported. It simply meant the same payment type appeared under different categories across the company's own submissions.

CMS's risk-based audit selection flagged the pattern as an inconsistency worth reviewing. The resulting inquiry required the compliance team to reconstruct several years of categorization history, document the legitimate business reason for the variation, and implement a corrected, standardized categorization scheme going forward, a process that consumed several months of compliance staff time that a standing reconciliation discipline would have prevented from ever becoming an issue. No penalty was ultimately assessed, but the audit response itself represented a meaningful, avoidable cost.

Recommendations for Compliance and Legal Leaders

1. **Move reconciliation from annual to quarterly.** build a standing process that catches source system mismatches with enough runway to investigate and fix them properly.
2. **Standardize spend categorization across every business unit.** before an audit forces the standardization retroactively and under time pressure.
3. **Document data lineage for every reportable payment type.** so an audit response can trace any record back to its source in minutes rather than weeks.
4. **Treat the dispute and correction window as a real quality checkpoint.** not a formality, and staff it accordingly during the review period each year.
5. **Assign single accountable ownership for Open Payments data quality.** spanning finance, medical affairs, and commercial data sources rather than leaving reconciliation to whoever happens to notice a discrepancy.
6. **Build vendor data quality requirements into contract renewals.** for speaker program and travel vendors whose data feeds directly into reportable payments.

Measuring Success: KPIs for Open Payments Accuracy

- **Pre-submission reconciliation coverage:** the percentage of reportable payment records reconciled against source systems before the annual submission deadline.

- **Categorization consistency rate:** the percentage of same-type payments categorized identically across business units, tracked toward full consistency.
- **Dispute window resolution rate:** the percentage of flagged discrepancies resolved within the CMS pre-publication review period rather than carried into a post-publication correction.
- **Data lineage traceability:** the percentage of reportable payment types with documented, auditable lineage from source transaction to submitted record.

Conclusion

Open Payments spent its first decade as a program that rewarded submission over accuracy, and a compliance function built around that reality is now exposed to a program CMS is actively reshaping into one that audits, questions, and penalizes. The dollar figures make the stakes concrete: $13.18 billion in reported payments, civil penalties reaching $1.5 million per entity, and an agency that has explicitly requested more budget to look harder.

Applying disciplined best practices to a standing Open Payments reconciliation practice does not require new technology or a larger compliance team. It requires treating data quality as an ongoing operational responsibility rather than an annual scramble, closing the specific gaps, categorization drift, fragmented source systems, unresolved disputes, that CMS's own audit criteria are built to find. Manufacturers that make that shift now are choosing to close the gap on their own terms, before an audit closes it for them.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

For compliance and legal teams managing Open Payments accuracy, OmniTek applies proven best practices to build a practical reconciliation discipline: standing quarterly reviews, consistent categorization across business units, documented data lineage, and genuine use of the dispute and correction window. Whether you are strengthening your process ahead of increased CMS scrutiny or responding to an audit that already found a gap, OmniTek can help you build a reporting function that holds up under review.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.

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Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.

Endnotes

[i] Centers for Medicare & Medicaid Services, "Open Payments Fiscal Year 2025 Report to Congress", available at https://www.cms.gov/files/document/open-payments-fy-2025-report-congress.pdf

[ii] Gardner Law, "CMS Audits on the Horizon: Prepare for Increased CMS Audits Under the Sunshine Act", available at https://gardner.law/news/prepare-for-increased-cms-audits-under-the-sunshine-act