CMS Open Payments Review Period – Managing Disputes and Late Submissions

Each year, the CMS Open Payments review and dispute period, April 1st through May 15th, places pressure on pharmaceutical manufacturers to validate data accuracy, resolve disputes, and submit corrections under tight deadlines. Late submissions, corrections or unresolved disputes can increase compliance risk, invite regulatory scrutiny, and damage stakeholder trust, particularly as expectations around aggregate spend and transparency reporting continue to rise.

Managing these challenges requires more than spreadsheets and reactive fixes. Compliance leaders need integrated technology, clear governance, and defensible processes.

During the Open Payments review period, manufacturers may encounter recipient or teaching hospital disputes related to:

- Incorrect payment attribution
- Inaccurate spend amounts
- Misclassified nature of payment
- Missing contextual or ownership details

A common example would involve the incorrect attribution of a reported transfer of value to an individual with a shared name. For example, attributing a payment to Dr. John Doe, a cardiologist practicing in Philadelphia, Pennsylvania, when the payment should have been reported for a physician with the same name practicing in Princeton, New Jersey.

A scalable, well-documented process is essential, especially as transparency programs grow in complexity. Best practices for managing corrections and disputes include:

- Having a centralized dispute management system to ensure consistent tracking, documentation, and decision-making
- Maintaining audit-ready documentation, including HCP communications and resolution rationale
- Validating data continuously to identify issues before the review period
- Establishing clear governance and escalation paths to prevent delays

Late submissions

Late submissions to CMS Open Payments typically occur when reportable data is identified after the annual submission deadline. For example, this may occur when a third-party vendor provides reportable data after the applicable CMS reporting deadline, requiring corrective action by the manufacturer.

When late data is identified, manufacturers should follow a controlled, well-documented process to establish transparency, accuracy, and regulatory defensibility:

- **Validate and Document the Issue**
  Confirm the accuracy and completeness of the late-identified data and document the root cause, including the timing and source of the delay (e.g., third-party vendor submissions).

- **Maintain Supporting Records**
  Retain all relevant documentation, including vendor communications, internal reviews, and corrective actions, to demonstrate good-faith compliance efforts in the event of regulatory inquiry or audit.

- **Submit Corrections Through the CMS Open Payments System**
  Late data is generally submitted as a correction through the Open Payments system, rather than as a new on-time filing. Corrections should be clearly attributable, accurately categorized, and fully reconciled with previously submitted data.

- **Update Assumptions and Methodology Documentation**
  Manufacturers should ensure their assumptions document reflects the nature of the late submission, including any limitations or timing considerations impacting the original report.

- **Assess Compliance and Enforcement Risk**
  Late submissions may carry enforcement or penalty considerations. Compliance teams should assess potential risk, escalate internally as appropriate, and align with legal counsel when warranted.

Establishing clear internal controls, third-party data governance, and ongoing monitoring reduces the likelihood of late submissions and supports a defensible Open Payments program.

Late Open Payments submissions, disputes, or corrections don't have to be disruptive. With the right technology and governance, manufacturers can resolve disputes efficiently, maintain defensible submissions, and reduce compliance risk.

About the Author

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Tania Tardif is a Compliance Manager with more than 15 years of experience across pharmaceutical, healthcare, and clinical environments. She currently serves as a Transparency Compliance Manager at QPharma, where she leads client-facing Spend Transparency initiatives, overseeing data stewardship, regulatory reporting, dispute resolution, and regulatory assurance for federal and state transparency requirements.

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