TIME TO VALIDATE YOUR COMPANY'S OPEN PAYMENT SUBMISSION DATA

Federal regulators are increasing efforts to shine more light onto relationships between physicians and the pharmaceutical and medical device industry. Scrutiny will only get more onerous, and deadlines are being enforced. The Centers for Medicare & Medicaid Services (CMS) requires manufacturers to submit their Open Payments report by March 31 every year. These filings will continue to build on the unprecedented visibility into the financial interactions between manufacturers, physicians and teaching hospitals.

Open Payments submissions are subject to audit and subsequent penalties for inaccuracy. The minimum ne is $1,000 per instance of an inaccurate payment — up to a total fine of $150,000 annually. This means an audit needs to find only 150 inaccurate payments to impose the maximum fine, and such findings may lead to further investigation. If these investigations reveal that inaccurate data was knowingly reported, manufacturers may face fines up to $1 million.

Maintaining an Aggregate Spend repository is complicated and time-consuming. The volume and variation of payments make it difficult to ascertain the accuracy of the data. However, this is not a reason to make no attempt at finding inaccuracies. Industry experts believe that about 10-15 percent of data in Open Payments files is inaccurate. If no efforts are made to validate it, chances are a manufacturer will have payment inaccuracies or omissions. Discovering these inaccuracies now will provide a clear roadmap towards making improvements in systems and processes that capture data.

Why have accurate data?

A large number of manufacturers believe that CMS will increasingly scrutinize filings now that the program is in its third submission year. While this may be true, the First Quarter 2016 provides the perfect opportunity to identify areas for improvement within the systems and processes used to capture reportable payments prior to submission. Manufacturers should not wait until after the submission period, when CMS will be increasingly likely to investigate inaccuracies; some data issues may be severe, could violate policies and should be addressed immediately.

In addition, since an officer of the company for each manufacturer, such as the chief financial officer, will be required to personally attest to the accuracy of a company's data it is important that the compliance and IT staff is able to

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certify that the data is accurate. If the resources responsible for generating the federal and state reports can show that a systematic validation was completed prior to generating the report confidence in the accuracy of the report will increase, financial risk due to inaccuracies will decrease, and a validation audit trail will exist.

Where to begin?

The validity of Aggregate Spend reports is dependent upon the accuracy of the data captured in the source systems. However, when auditing source systems or source data, review teams have often discovered that not all data is captured accurately or loaded correctly into the spend reporting system database. The place to begin when validating spend data is literally "at the beginning" — ensuring that source data is captured and loaded correctly.

Based upon experience in validating spend reporting solution environments, policy and procedures, data, and systems, issues typically fall within the following three areas:

Inaccurate source system data. Data captured in the source systems may be inaccurate or data may not be extracted correctly (from the source system) for loading into the spend-reporting system. For example:

- A physician is miss-classified as a business guest (or vice-versa)

- The number of qualified attendees is underreported resulting in an inflated per person meal amount

- Events that must be reported have not been loaded into the repository

Inaccurate master data. The accuracy of an Open Payment submission is only as good as the master data. Common issues include:

- A covered recipient is misidentified, such as a physician with the same name in another state

- Key identifiers are missing, such as National Provider Identifier, State License Number, Taxpayer Identification Number or Specialty

- The listed specialty does not match the National Plan and Provider Enumeration System (NPPES) taxonomy

- Organizations are incorrectly identified as a teaching hospital vs. non-covered

Open Payments submission templates missing required information. CMS has defined the values required for submission templates. Data commonly missing from generated reports includes:

- The travel destination for travel-related payments

- Research related information including names of principal investigators

These areas for "accuracy risk" may seem obvious, but result from multiple audits performed by Huron Life Sciences confirm that source data issues continue to exist.

How can a company identify common data accuracy issues? And what can a company do to anticipate problems and mitigate risk?

Validation Methodology

Even before CMS implemented the two-phase reporting requirement, many manufacturers were beginning to validate the detailed data and determine if they could generate accurate reports. Working with these manufacturers, Huron Life Sciences scrutinized data capture procedures, the accuracy of the data captured, and the ability to generate required reports, in order to identify operational improvements that will help maintain a sustainable process.

A successful and accurate system requires a four-stage approach:

Validate Historical Data → Identify Root Causes → Operationalize Improvements → Educate Employees

STEP 1: VALIDATE HISTORICAL DATA

The objective of this step is to analyze the data captured in the source systems to validate that it is "complete and correct." Specifically, during this step the following data elements should be reviewed:

- Expense data

- Contract payments made to Healthcare Professionals (HCPs)

- Indirect payments

- Data files extracted from source systems

- Data files extracted from the aggregate spend application

Tasks and Considerations for this step include

- Collect data from source systems

- Collect raw data extracts from aggregate spend reporting application

- Combine data from the data capture systems, customer master, Aggregate Spend repository, and Open Payments submission templates and review for:

    a. Inaccurate source system data

    b. Inaccurate master data

    c. Open Payments submission templates missing required information

STEP 2: IDENTIFY ROOT CAUSES

Determine why the identified issues are occurring and build approaches for addressing and correcting them. Common root causes that result in data or reporting issues are listed in the previous section, but typically include:

- HCPs are misclassified in travel and expenses (T&E) systems

- Not all attendees at an event are captured

- HCP master data contains errors

- All required events are not loaded into the spend reporting application's database

Tasks and Considerations for this step include:

- Inspect the related systems and processes to

identify the root causes of the issues.

    a. Are data errors related to business practice, business processes or system issues?

    b. Are all data sets being extracted from source systems correct and complete?

    c. Is all data being properly uploaded into the Aggregate Spend System?

- Identify changes to systems and processes that will lower or eliminate issues going forward.

STEP 3: OPERATIONALIZE IMPROVEMENTS

The effort to clean data—addressing issues that resulted in inaccuracies—should not be thought of as simply a "one time" remediation effort. The lessons learned should be documented to form the basis for developing stronger data collection procedures across the business to ultimately reduce reporting risk.

Tasks and Considerations for this step include:

- Improve validation within the systems that capture data including:

  - Managers review expenses prior to expense report approval. Consider training the Accounts Payable department on how to validate expense reports prior to approval. This will decrease the need for future remediation efforts at the end of the process, will shift accountability of data accuracy to the point of data entry when the users submit their expense reports, and will ensure that ultimate accountability is reinforced by direct supervisors.

  - Increase field-level validation. Investigate options within the data capture systems to enforce completeness and accuracy of data. For example, an alert could be activated when a user underreports the number of attendees, evidenced by inflated per-person meal amounts.

  - **Include system owners when addressing business processes if specific process and system changes are required.** Create new process diagrams and technical specifications that are applicable to each system.

- Review and remediate data prior to loading into the repository.

  - **Review payments submitted by third parties.** Third parties are notoriously inaccurate with their submitted data. Review data prior to it being loaded to be assured of its completeness, as well as scan for outliers. In addition, seek ways to shift accountability of this data's accuracy to internal business contract owners.

- Use data warehouse and business intelligence tools to identify issues automatically.

  - **Programmatically look for issues.** Loading all of a company's data into its business intelligence tool unlocks the power to inspect all the data quickly and easily. This can be particularly useful in identifying batches of payments that failed to load into the company's repository.

STEP 4: EDUCATE EMPLOYEES

At a foundational level, all employees play a critical role in mitigating the level of risk to the organization. From a tactical perspective, different roles within the organization should have specific responsibilities to ensure data accuracy. The most successful organizations have implemented a customized training curriculum versus a one size fits all approach. Huron has developed training at the employee level across the commercial and clinical enterprise to ensure that employees understand from a tactical and practical standpoint what is expected of them to ensure compliance.

Tasks and Considerations for this step include:

- Delineate between systemic issues versus one time occurrences

- Assess whether data entry issues are a result of pure non-compliance or ineffective training and communication

- Leverage training and communications to address systemic issues

- For pure non-compliance issues, consider working with senior leadership and Human Resources to implement a disciplinary action model

- Incorporate lessons learned from root cause analysis into training materials and retrain as necessary.

CONCLUSION

Regulatory scrutiny of financial relationships between the pharmaceutical and medical device industry and physicians and teaching hospitals will only increase in the years ahead. Companies will be building new complexities and requirements into existing systems to be sure that they are capturing information correctly and reporting it accurately. However, it is vital that companies take the steps necessary to ensure that existing data is complete and accurate, or they will compound mistakes—and risk larger fines—by adding onto databases that are incorrect.

It is not clear when regulators will begin fining companies for reporting inaccuracies. However, companies should use Q1 2016 to test existing data for completeness and accuracy in order to be ready for increased scrutiny that is assuredly just around the corner.

To learn how Huron can be your guide, please contact:

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