



*The Seventh Annual* —————  
**Pharmaceutical Regulatory and Compliance Congress**  
————— *and Best Practices Forum*

# Are you Ready to Audit your Aggregate Spend Processes and Systems?

## Key Steps You Need to Consider Now

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# Today's Agenda

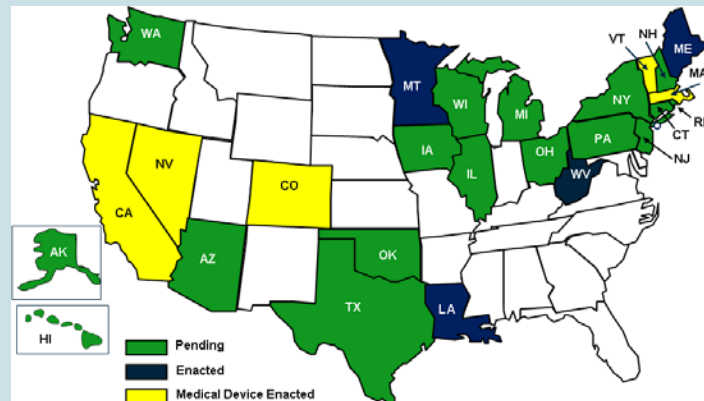
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- I. The Importance of Auditing Aggregate Spend Processes and Systems
- II. Identifying Audit Resources and Responsibilities
- III. Identifying Data Sources and Processes for Collecting Data
- IV. Understanding All Data Sources and Processes for Collecting Data
- V. Areas of Considerations
  - Traditional Challenges
  - Continuing Challenges
  - Emerging Challenges
- VI. Action Items



# Importance of Auditing Your Aggregate Spend Program

- Pharmaceutical manufacturers are responsible for auditing as part of implementing and maintaining an effective compliance program
  - NV and MA require certification that a manufacturer has conducted audits as part of its compliance program
  - New CT and CO laws state that companies must be in compliance with the PhRMA code, which states that companies should periodically monitor speaker programs for compliance with FDA regulatory requirements
  - OIG compliance guidance also encourages auditing and monitoring
- Fines for incorrect reporting exist for DC, ME, MA, VT, and WV
- The Physician Payment Sunshine Act requires national disclosure of spending data from pharmaceutical and medical device companies.
  - The first filing is due in March 2013
  - This data will be public and will be reviewed by healthcare professionals, who may dispute a company's data
  - Incorrect data could lead to repercussions for both Compliance and Business areas



# Identifying Audit Resources and Responsibilities

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- An **internal audit group** may have the infrastructure and relationships to efficiently manage an audit for the Company; however, auditing Aggregate Spend data requires a different level of data review than most traditional internal audits.
  - Audits of aggregate spend data are not subject to the same standards as financial audits; the business unit which owns the aggregate spend program will need to provide subject matter expertise to guide the audit appropriately.
- An **external resource** can provide an independent perspective and will have a good understanding of relevant regulatory and compliance issues.
- A Teaming Approach
  - Consider delegating parts of the audit process to specific individuals in the company who may have more direct knowledge of a specific spend area – for instance, district/division managers could audit expense reports for reported healthcare professional meal attendees



# Identifying Data Sources / Data Collection Processes

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- In order to audit, a company must understand all spending areas and all data that are being collected
  - **All** source systems and **all** processes should be documented
  - Many aggregate spend data collection processes include the addition of supplemental data to original source data; this may require a unique approach for the audit of these items
  - Spend information may be housed both in traditional source systems as well as in the aggregate spend data store (if one exists)
- If manual processes are involved in the collection of data, companies should ensure that these processes are documented in policy or procedure documents.
  - Allows process to be transferable to others in the company and promotes the conduct of an audit

**Note:** The term “audit” as used in this discussion document is used in the terms of a gap or process assessment.

# Identifying Data Sources / Data Collection Processes

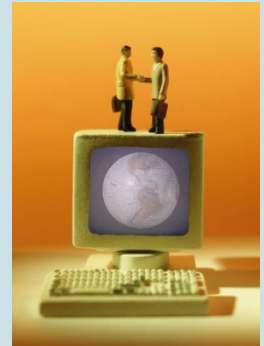
- Relevant spend data may be located within many different areas across your organization

<b><u>Clinical / Research &amp; Development</u></b>	<b><u>Commercial Operations</u></b>	<b><u>Compliance</u></b>
<b>Contracting</b>	<b>Federal/State Government Affairs</b>	<b>Finance/Accounts Payable</b>
<b>Information Technology</b>	<b>Legal</b>	<b>Managed Markets/Value and Access</b>
<b>Market Research</b>	<b>Medical Affairs/ Medical Information</b>	<b>Procurement/ Purchasing</b>
<b>Sales and Marketing</b>	<b>Sales Training</b>	<b>Third Party Vendors</b>

- Spend that you should consider auditing includes meals, payments for consulting, speaker training or programs, advisory boards, or other payments, distribution of reprints or educational items, provision of travel, and many other activities.

# Understanding Data Sources / Data Collection Processes

- Some information that needs to be understood includes:
  - How is this data entered?
  - Are audits on this data already being conducted for existing Financial or Compliance purposes?
  - Is this data collected from a validated system?
  - Is additional information added manually to existing data? If so, how is it collected?
  - What data resides with third party vendors or in external systems?
  - Is there double entry of this data – for instance, once for aggregate spend purposes and again for payment/reimbursement purposes?
- When considering an audit, companies may find it helpful to document the system and process flow of all relevant data.



# Areas for Audit Consideration

## Data/Processes for Aggregate Spend Auditing

- Reviewing three different types of processes and source systems challenges related to aggregate spend auditing:
  - **Traditional Audit Areas:** are those which have been addressed by certain manufacturers since spend reporting requirements began. In general, many of these audit processes may already be in place.
  - **Continuing Audit Areas:** In many cases, how to audit data in these areas has not been fully resolved or may become cumbersome and/or difficult.
  - **Emerging Audit Areas:** relate to new reporting requirements, including those related to federal reporting. The audit process for these have generally not yet been resolved by manufacturers.



**Traditional Challenges**



**Continuing Challenges**



**Emerging Challenges**

# Traditional Audit Areas



## Initial Steps toward Auditing Aggregate Spend Data

- **Employee Expenses:** In terms of quantity, these expenses generally represent the majority of transactions for many manufacturers.
  - Consider how to build an aggregate spend audit into the existing expense reimbursement audit process; the aggregate spend audit may compare:
    - Documented attendees at a speaker program meal vs. the meal sign-in list
    - Meal attendees in the “comments” field vs. documented HCP meal attendees
    - Documented HCP meal attendees vs. HCPs on a sales rep’s target list
  - In the case of a double-entry method, consider comparing entries between the two systems, specifically those related to travel, meals, and educational items.
- **Third Party Vendor Spend:**
  - Capitalize on existing processes of auditing invoices
  - Push to applicable business owner who would be most familiar with expense details; where appropriate, compare reported attendees against sign-in sheets.

# Traditional Audit Areas



## Initial Steps toward Auditing Aggregate Spend Data

### ▪ Direct HCP Payments:

- Periodically conduct review of direct Accounts Payable transactions
  - Review spend for HCP and HCO names
    - Verify entries related to those names were captured for your aggregate spend purposes
  - Consider prioritizing your review to those G/L codes which are most likely to have relevant spend

# Continuing Audit Areas



## Challenging Items and Audit Considerations

### ■ Educational Items:

- Review the list of items approved by Legal/Compliance/Other Review Committee to ensure all required items are being tracked; compare this to actual tracked items
- Run analytics to compare the quantity of items recorded as distributed vs. the quantity ordered (if available)

### ■ International Spend:

- Foreign affiliates should generally assume the responsibility for auditing their own systems; for instance, affiliates may review accounts payable data for payments issued to HCPs located within the United States

### ■ Indirect HCP Payments: payments issued to HCOs or other organizations on behalf of HCPs; payments are particularly challenging as the level of detail necessary for reporting has not generally been captured in a manufacturer's AP systems

- Review these types of transactions in AP and compare them to those that have been tracked

# Emerging Audit Areas



## Challenging Items and Audit Considerations

- **Clinical Trial Spending:** data required for Vermont 2010 data and for federal 2012 data; these payments are challenging since many are transacted via third parties (CROs, research consortiums, etc.), and many transfers are non-cash transfers of value
  - Clinical Research Organizations should be treated like other TPVs and audited by the appropriate individuals to ensure that the necessary level of detail is being reported
- **Samples, Co-Pay Cards, Vouchers:**
  - As part of existing sample audits, review the reported distribution of samples, co-pay cards, and vouchers against the quantity of each ordered by individual sales reps

# Emerging Audit Areas



## Challenging Items and Audit Considerations

- **Manual Processes and Double Entry of Data:** Some manufacturers resolve “Traditional Challenges” by relying on manual processes, however, these processes may not be validated against actual spend and may leave open areas for inaccurate or missing data
  - Examine all processes which are currently manual and consider how they could be audited against actual expense/payment transactions
  - For all areas that have double entry, where the expense is reimbursed in a different tracking mechanism than the aggregate spend information, companies should consider auditing this data by comparing the two transactions sets

# Considerations for Next Steps

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## Action Items

### ■ Existing Audit Processes

- Confer with the group responsible for your existing audit processes to determine where overlap with aggregate spend data audits may exist

### ■ Determine a Starting Point

- Documenting the systems and processes through which aggregate spend data is captured is an efficient way to begin an audit process as it will clarify where data resides
- Consider auditing those data sources which are most prone to error; this may include:
  - Systems in which data is subject to double entry
  - Systems which rely on manual processes to attribute spending to HCPs

### ■ Discuss Resource Availability

- After identifying a plan for auditing your data, determine which areas can share in audit responsibilities; this may include:
  - Internal business units which are most familiar with spend data
  - Third party vendors

# Questions?

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