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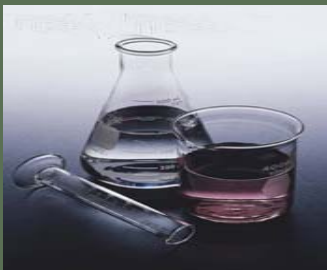


Aggregate Spend 201

Achieving Proactive Aggregate Spend Compliance Management

**National Disclosure Summit
March 3, 2010**

LIFE SCIENCES ADVISORY SERVICES



Achieving Proactive Aggregate Spend Compliance Management

Presentation Summary

- Aside from for state reporting purposes, the aggregate spend data collected by companies may ultimately be used for proactive compliance risk monitoring.
 - Current Aggregate Spend Solutions focus on historical reporting and adherence to the “letter of the law”
 - Leveraging existing aggregate spend reporting data stores, a proactive risk monitoring solution can be implemented to align more closely with the “spirit of the law”
- The following actions are recommend to achieve a Proactive Aggregate Spend Compliance Strategy
 - Identify all data sources with relevant compliance data and establish a data governance strategy for each.
 - Develop a data warehouse which aligns with the data governance strategy and can be used as a single, consolidated source for compliance data.
 - Draw on your company’s compliance expertise to develop an understanding of critical risk areas for compliance monitoring in the area of aggregate spend.
 - Create a compliance dashboard which will present trends and information related to critical risk areas in a format that is easily understood by company management.
 - Memorialize all facets of data collection, reporting, and monitoring in a standard operating procedure.

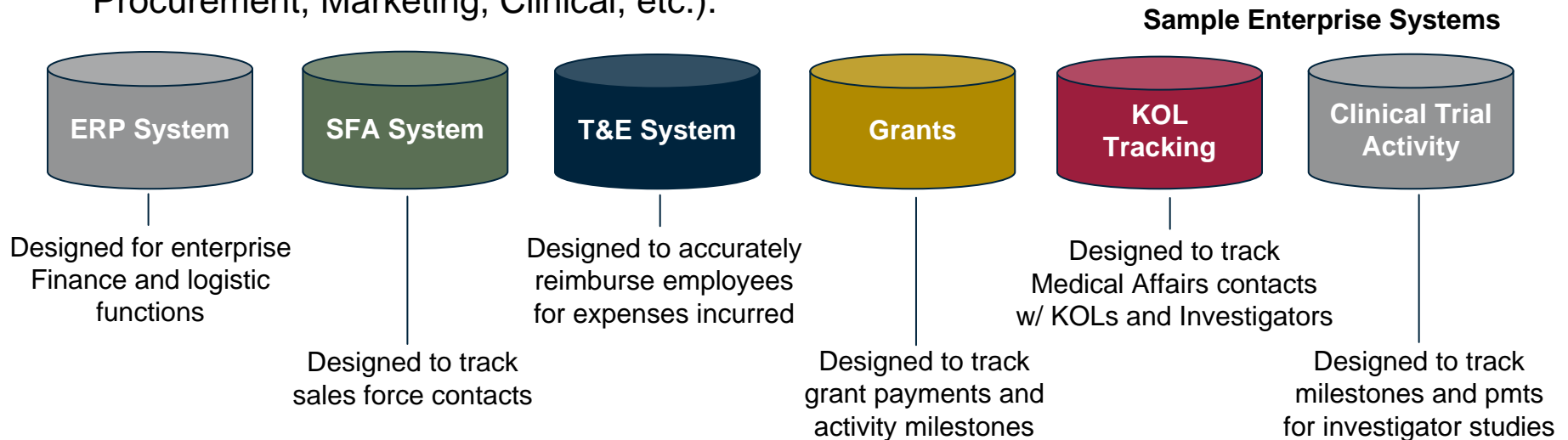
Achieving Proactive Aggregate Spend Compliance Management

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Aggregate Spend 101 Review

Implementation of Quality Standards; Developing a Compliance Framework for Data

- Data can only be as good as the standards under which it was collected.
- Develop a **data governance** strategy for all enterprise systems, third-party systems, and reference data sources that has a focus on regulatory compliance requirements:
 - Availability;
 - Usability;
 - Integrity; and
 - Security.
- Identify the key stakeholders needed to support the initiative (e.g., Compliance, IT, Procurement, Marketing, Clinical, etc.).



Aggregate Spend 101 Review

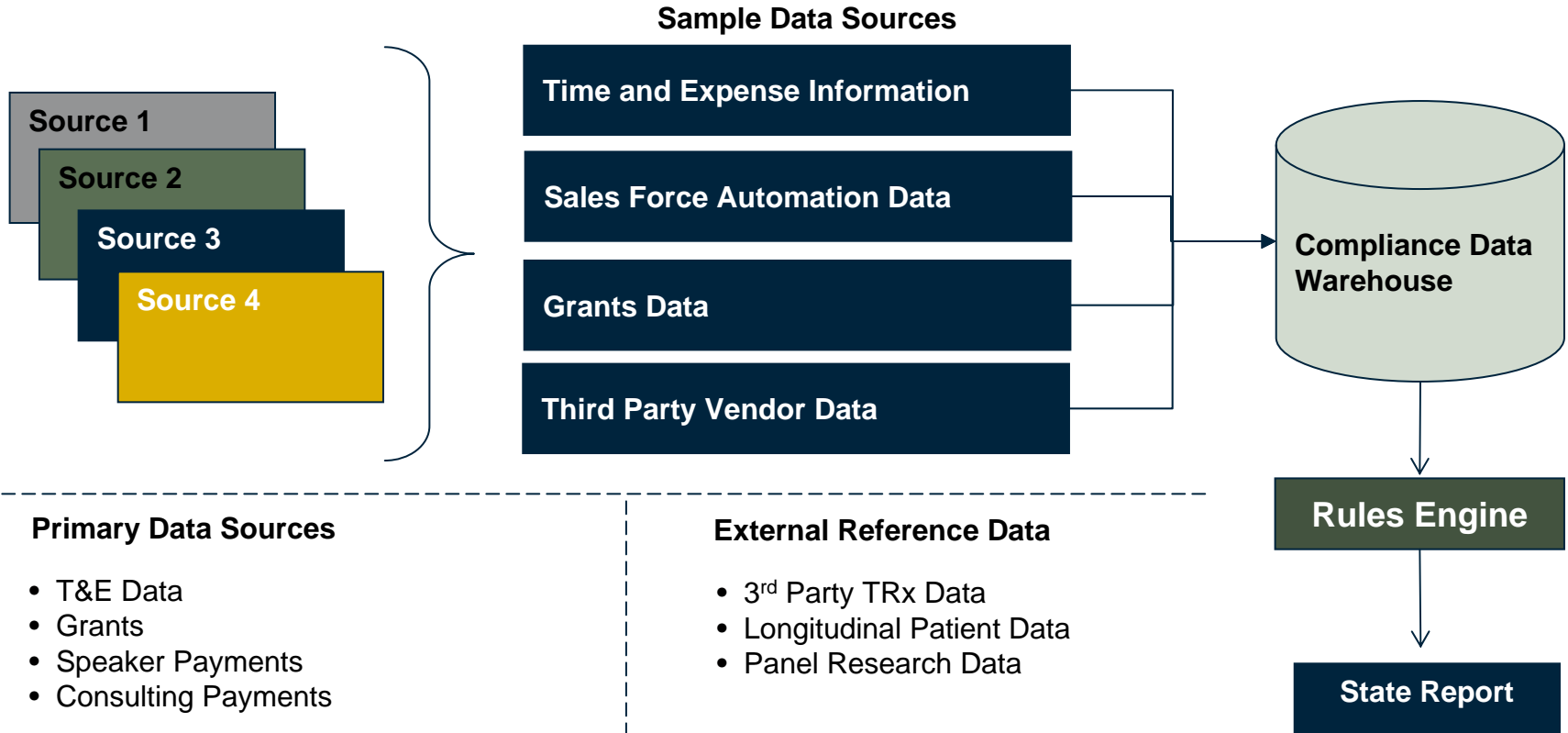
The Data Landscape



- The data governance strategy must be implemented across all enterprise systems, third-party data sources, and reference data sources in the organization.
- The strength of an organization's spend reporting framework is as good as the "weakest link" in the process (internal and external sources)

Aggregate Spend 101 Review

Establish a Compliance Data Warehouse; Leverage for State Reporting



- A flexible rules engine available in most commercial Aggregate Spend solutions today should be considered for reporting

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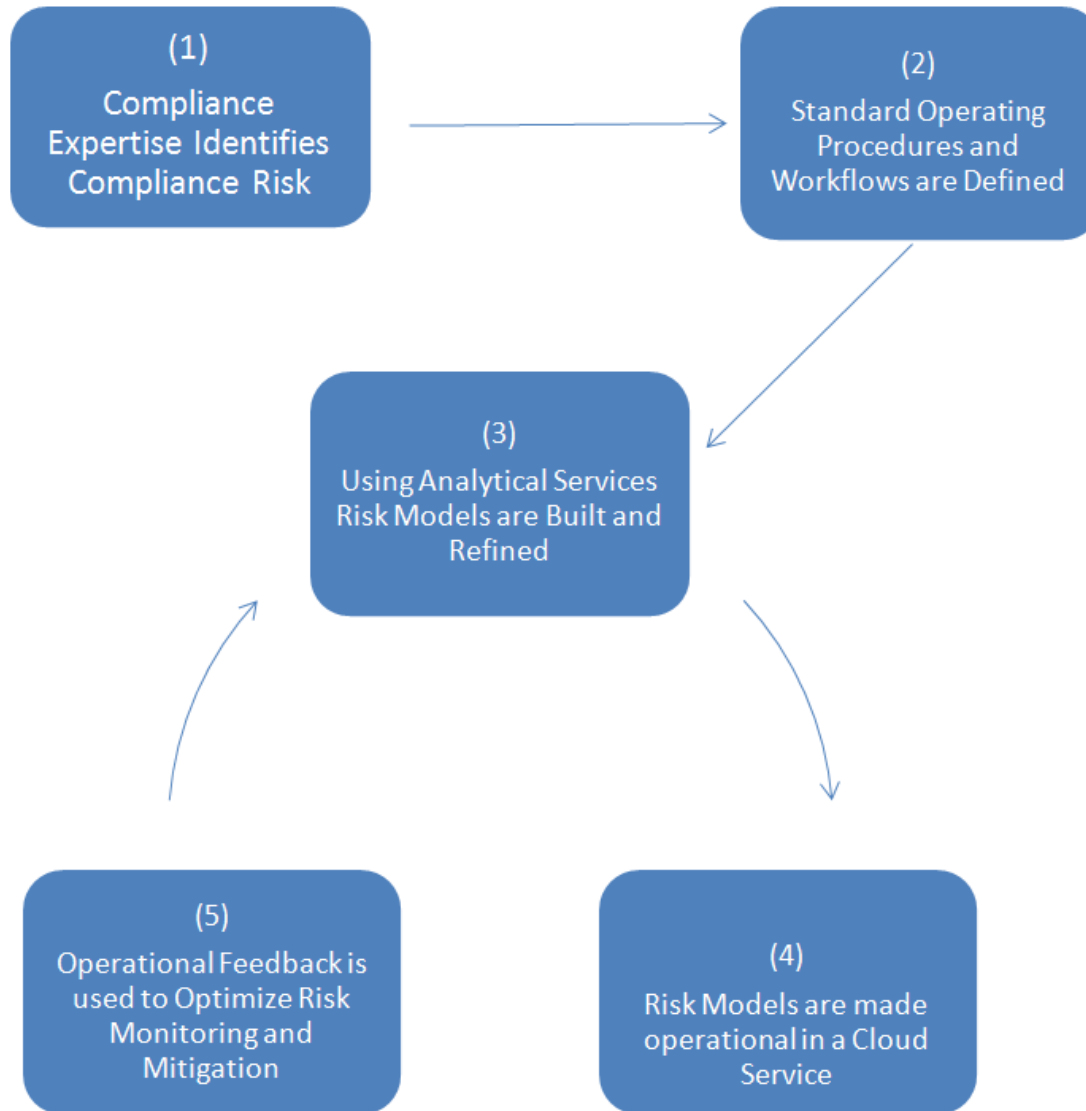
Source Data for Monitoring & Compliance

Using Core Transactional Data for Monitoring

Understanding the enterprise systems and the operational transactions across the various functional areas is critical to developing a monitoring strategy.

Functional Dataset	Monitoring Focus
<ul style="list-style-type: none">SFA System	<ul style="list-style-type: none">Product samplingEducational gift item distribution
<ul style="list-style-type: none">Time & Expense System	<ul style="list-style-type: none">Meals
<ul style="list-style-type: none">Internal / External Travel System	<ul style="list-style-type: none">TravelMeeting Card / Purchasing Card payments
<ul style="list-style-type: none">Accounts Payable / ERP System	<ul style="list-style-type: none">Honoraria for fee-for-service activitiesReimbursement for travel or other expensesIndirect payments to HCPs via third party vendors
<ul style="list-style-type: none">Third Party Vendor Systems	<ul style="list-style-type: none">Spending / payments related to speaker programs or other events
<ul style="list-style-type: none">Human Resources	<ul style="list-style-type: none">Sales representative salary and benefits
<ul style="list-style-type: none">Grants System / Portal	<ul style="list-style-type: none">Grants, sponsorships, and corporate memberships
<ul style="list-style-type: none">Clinical Trial Activity System	<ul style="list-style-type: none">Payments related to clinical trials, investigator initiated studies, and other clinical activity

Risk Model Development and Optimization Process



Common Examples of Risk Scoring in Financial Services



The Altman-Z Bankruptcy Risk Score

Characteristics include:

- Working Capital / Total Assets
- Retained Earnings / Total Assets
- Earnings Before Interest and Taxes / Total Assets
- Market Value of Equity / Total Liabilities
- Sales/ Total Assets

Z Score Below 1.8 – Bankruptcy is likely within 2 years

Z Score Above 2.99 – Bankruptcy is unlikely within 2 years

The FICO Credit Risk Score

Characteristics Include:

- Total Credit Capacity
- Length of Credit History
- Payment Delinquency
- Total Credit Utilization

FICO (300 to 850)

FICO Scores are left skewed with a median of 723

A score of 723 or above predicts a low risk of granting the subject credit

Pharmaceutical Compliance Risk Scoring – Aggregate Spend

An Example Compliance Risk Score (CRS)

Characteristics Include:

- Type of Spend
- State
- Allowable Spend Utilization
- Allowable Spend Capacity
- Spend Amount
- Frequency of Transactions

CRS (9 -45)

Low Risk (9-12)

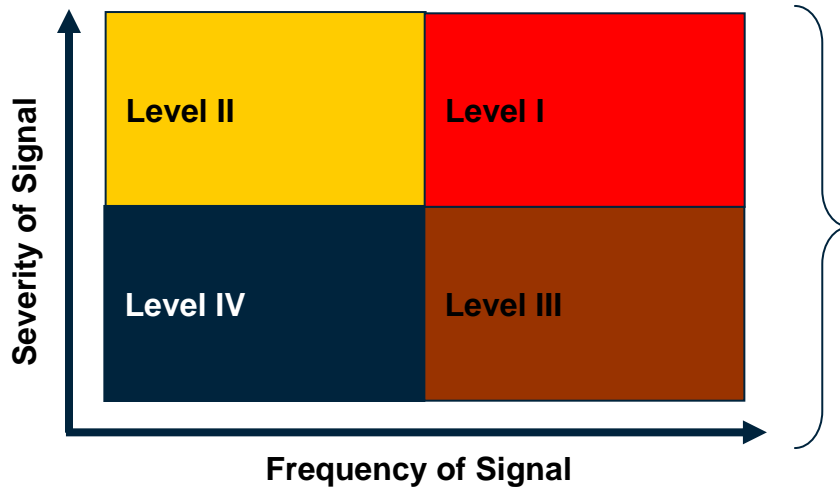
Medium Risk (13-28)

High Risk (29-45)



Developing a Framework of Predictive Analytics

Integrating Core Transactional Datasets to Develop Risk-Based Scores



Developing a Risk Based Scoring Mechanism

By developing a risk-based weighting to various types of transactional signals, a broad predictive model can be developed to identify specific brands, sales teams, districts, or individuals responsible for transactions that have caused a threshold alert to be created. Based on the level of the alert, a secondary review could be initiated based on the level of the transaction.

$$\text{Threshold Score} = W_1(A) + W_2(B) + W_3(C) + W_4(D)$$

- Companies could use their experience with compliance monitoring and investigations to develop risk based scores that are good indicators of predictive risk for issues in sales and marketing expenditures
- The models could score individual employee transactions and physician behaviors based on pre-assigned values weighted for the individual's activity.
- The transactions would typically be aggregated and analyzed through a predictive model. The model would then create a risk alert based on the severity of the score.

Development of Monitoring Models

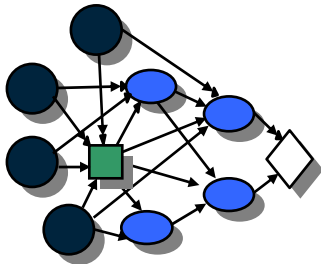
An Iterative Approach to Development and Implementation

Develop HCP Level Decision Models at the Channel Level

Create Risk Curves Based on Specific Tolerance Thresholds

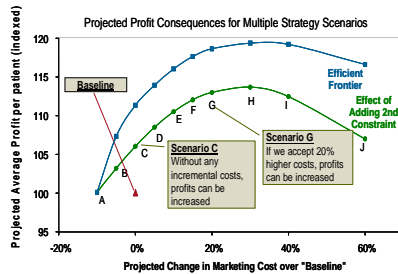
Roll-up Channel Models Into Strategic Risk Management Model & Optimize for Alerts

Providing Predictive Analytics to Address Key Monitoring Objectives



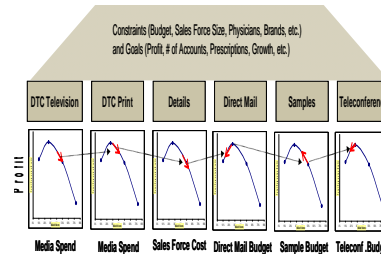
Determines risk sensitivity to channel tactics

Captures the action-reaction dynamic of activities that may influence HCP behavior



Map field and home office actions to identify potential risk thresholds

Allows for the application of multiple factors on a weighted basis

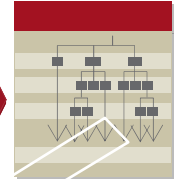


Captures interaction effects of channel tactics

Addresses carryover effect from various channels

Derives strategic - level activity reports

	Relationship SM	Base Case SM	Incremental SM
Net Sales Forecast	\$ 47,500,000	\$ 50,000,000	\$ 58,000,000
Sales and Promotional Expense			
DTC TV	\$ 3,000,000	\$ 4,000,000	\$ 4,000,000
DTC Print	\$ 8,000,000	\$ 10,000,000	\$ 10,000,000
Field Force (PE)	\$ 6,000,000	\$ 6,000,000	\$ 6,000,000
Samples	\$ 2,000,000	\$ 3,000,000	\$ 3,000,000
Direct Mail	\$ 5,000,000	\$ 2,000,000	\$ 2,000,000
Events	\$ 2,000,000	\$ 5,000,000	\$ 6,000,000
KOL/Physicians/O.E.	\$ 1,000,000	\$ 3,000,000	\$ 3,000,000
Total	\$42,500,000	\$53,000,000	\$58,000,000



Strategic to tactical linkage enables guidance and optimization of Risk alerts

Creates optimized monitoring reports by objective

Dashboards Created for Compliance Monitoring

Creation of Various Dashboard Views Based on Technical Requirements

After creating models utilizing internal and external data sets, dashboards can be created to effectively monitor compliance and alert on suspicious activity.

Strategic View



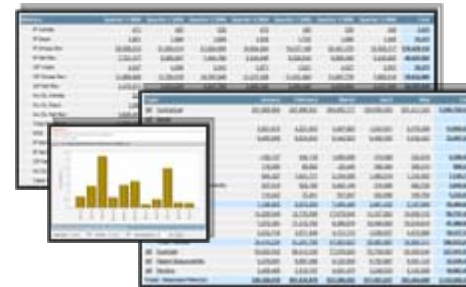
Executive Scorecards

Manager View



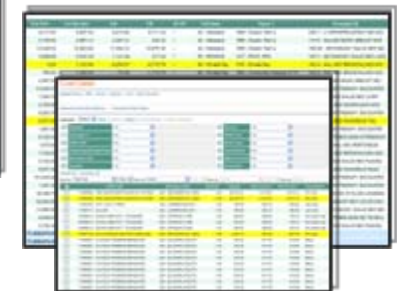
Personal Dashboards

Operational View



Root-Cause Analysis

Work List View



Transaction Detail

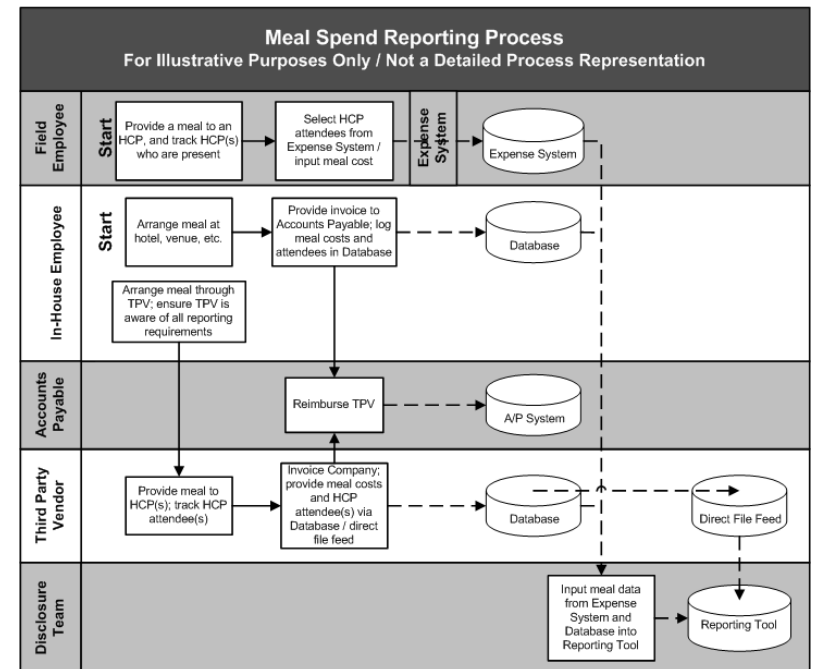
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Aggregate Spend Data Collection and Reporting SOPs

Promoting Consistent and Meaningful Data Capture and Report Creation

- Unless aggregate spend data has been collected in a consistent and thorough manner, a company's data store, spend reports, and compliance dashboard will not be reliable.
- Companies should consider developing spend reporting Standard Operating Procedures (SOPs) to promote thorough and consistent data capture and define how data will be used in the company's compliance monitoring program.
- Robust SOPs will indicate:
 - the specific stakeholders that are involved in spend reporting.
 - for each potential type of spend, the actions that must be taken to report that spending.
 - the specific factors which will be monitored in the company's compliance dashboard.



Aggregate Spend Data Collection and Reporting SOPs

Promoting Consistent and Meaningful Data Capture and Report Creation

DRAFT	AGGREGATE SPEND REPORTING SOP Version 2.1	CONFIDENTIAL
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Section I - Meals

1. Accounts Payable

A. Accounts Payable is responsible for reimbursing TPVs which have provided meals for HCPs. This reimbursement is executed through the Accounts Payable system and is subject to all applicable Company guidelines/procedures.

2. Disclosure Team

The Disclosure team must import HCP meal expense data into the Reporting Tool after it has been provided by TPVs or Company employees.

- A. In-office or limited out-of-office meal data which occurred in the state(s) in which reporting is being compiled must be extracted from the Expense System and imported into the Reporting System.
- B. Other meal expenses are provided by TPVs or in-house employees via databases; the Disclosure Team must then manually enter these spend details into the Reporting Tool and associate all spend with the relevant HCPs.
- C. In the case of those TPVs which have file feed capabilities, meal expenses would be directly input into the Reporting Tool via a dedicated file feed; the Disclosure team would not be responsible for entering these expenses directly, but is responsible for monitoring to ensure that data provision occurs in a timely manner.

3. Field and In-House Employees

If Field or In-House employees provide a meal directly to an HCP either in-office or, in a limited number of circumstances, out-of-office:

- A. At the time of the meal, employees must track all HCP(s) who are present based on Company's definition of HCP.
- B. After the meal, the meal expense must be submitted through the Expense System. Employees must indicate all HCP(s) who were present at the meal by selecting the HCP(s) in attendance from the customer master drop down list. Note that HCP(s) must be entered in as HCPs, and not as business guests.

If Field or In-House employees directly arrange a meal at a hotel, venue, or other location which is paid through Accounts Payable:

- A. At the time of the meal, employees must track all HCP(s) who are present based on Company's definition of HCP.
- B. After the event, the employee must submit the invoice for the event to Accounts Payable.
- C. The employee must then track, via database, a list of the HCP(s) in attendance and the meal cost.
- D. This spreadsheet would then be forwarded to the Disclosure Team.

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■ Complete SOPs should:

- Contain the specific systems which employees must use to enter HCP/HCO spending, and to report on this spending
- The exact data parameters which are required for both data entry and report generation
- Data review and approval responsibilities

■ Other Critical Considerations:

- What type of training will accompany the rollout of these SOPs?
- Who will be responsible for maintaining these SOPs, and how often will they be updated?
- Who will be responsible for approving these SOPs?

Aggregate Spend Data Collection and Reporting SOPs

Potential Issues

- Considering that aggregate spend regulations are continually changing and developing, should the SOP capture:
 - the Company's "as is" state at the risk of becoming obsolete
 - the Company's proposed "to be" state which has not yet been instituted
- Consider the potential audience of the SOP:
 - an SOP which will be reviewed / maintained by Internal Audit should address each risk in the process and the controls being taken to address those risks
 - an SOP which will be broadly utilized by company employees as a work instructions document should contain the necessary level of tactical detail

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Presentation Conclusion: Lessons Learned

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Contact Information

Manny Tzavlakis
Director
Huron Consulting Group
Office: 646-520-0247
Cellular: 312-532-1504
mtzavlakis@huronconsultinggroup.com

John Poulin
Solution Architect
Huron Consulting Group

Cellular: 312.730.0305
jpoulin@huronconsultinggroup.com

Joseph Morrell
Associate
Huron Consulting Group
Office: 202-585-6825
Cellular: 312-731-7469
jmorrell@huronconsultinggroup.com