Compliance Strategies & Operational Considerations to Manage Disclosure Regulations

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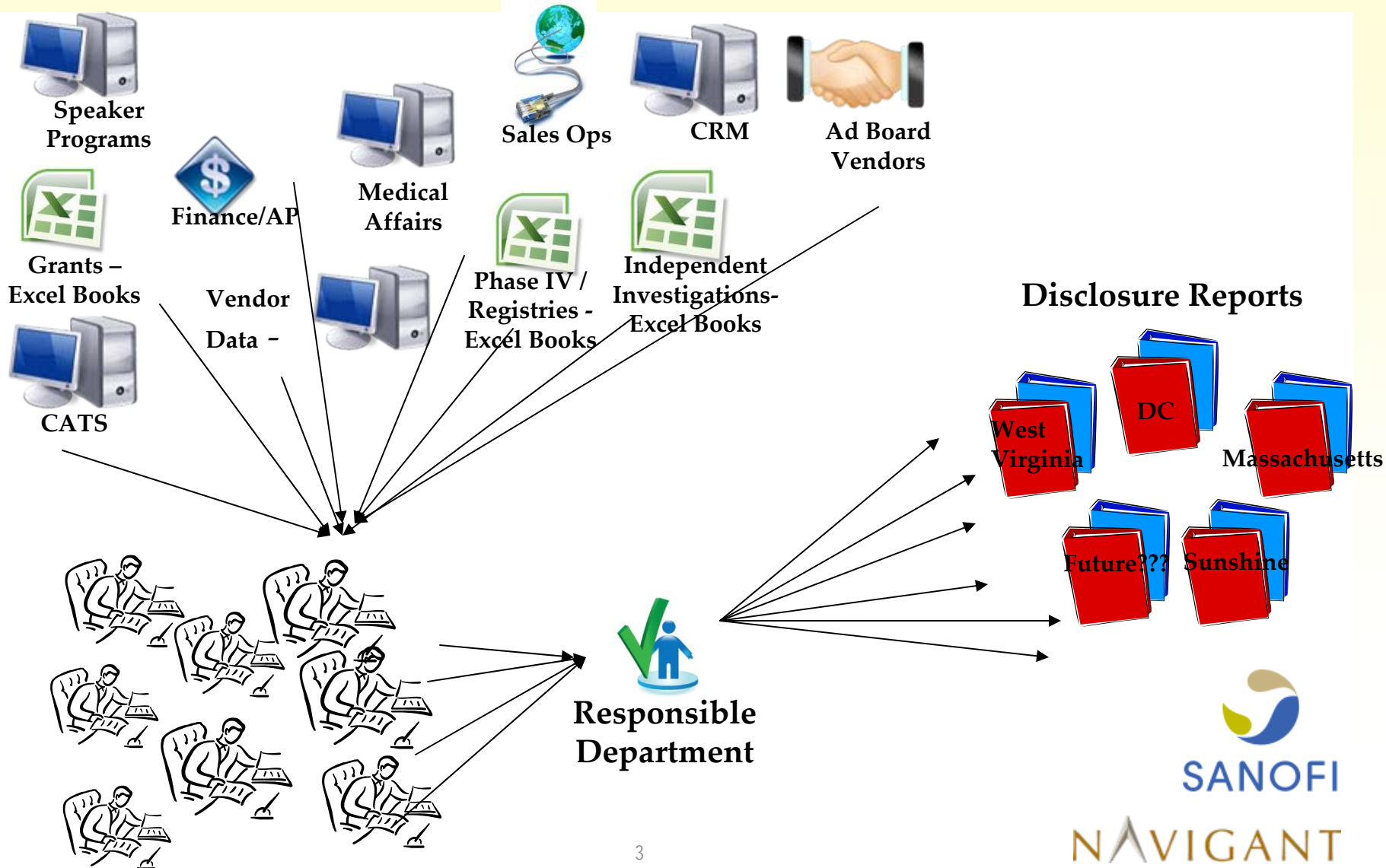
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The Complexity of Transparency

Speaker Programs

Finance/AP

Medical Affairs

Sales Ops

CRM

Ad Board Vendors

Grants – Excel Books

Vendor Data –

Phase IV / Registries - Excel Books

Independent Investigations- Excel Books

CATS

Disclosure Reports

West Virginia

DC

Massachusetts

Future??? Sunshine

Responsible Department

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Paddling Up the Transparency River

3. Good Business Practices

2. HCP Communications & Dispute Resolution

1. Data Collection & Reporting

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Data Collection and Reporting

Data Collection and Reporting

» Reportable Information – Covered Recipients

» Reportable Information – Payments or Transfers of Value

» Data and Information Technology

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Reportable Information – Covered Recipients

» Obtain and validate the Covered Recipient's:

  › Full name as listed in NPPES

  › Primary business address

  › National Provide Identifier ("NPI") as listed in NPPES

  › Specialty

  › State professional license number(s) and the State(s) in which the license is held (for at least one State where the physician maintains a license)

» Reconcile with the National Plan & Provider Enumeration System (NPPES)

» Obtain and validate

  › Pharmaceutical/biological Related Covered Product's NDC number or if name has not been selected, the name registered on clinicaltrials.gov

  › Medical device/supply Related Covered Product's marketed name and therapeutic area or product category

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Reportable Information – Payments or Transfers of Value

» Obtain and validate:

> › Transaction date, total value (including tax and shipping), and form (e.g. cash/cash equivalent, in-kind items or services)

> › Name of the covered recipient receiving a research payment or other transfer of value

> › Name and primary business address of a non-covered recipient (i.e. a non-teaching hospital or clinic) receiving a research payment or other transfer of value

> › Name(s) of any related covered drugs, devices, biologicals or medical supplies and the relevant National Drug Code(s) for drugs and biologicals as applicable

> › Information about each physician covered recipient principal investigator as applicable

> › Name of the research study

Reportable Information – Payments or Transfers of Value (cont.)

» Methodology to determine

  › Fair market value

    – In-kind item or service

    – Stock, stock options, or any other ownership interests

    – Dividends, profits or other returns on investment

  › The eligibility for delayed publication of a research payment or transfer of value

  › The total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both

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Data and Information Technology

» Identify:

  › Systems within your organization with spend or transfers of value going through them; and any other information to support reporting

  › Timing of data capture of these systems

  › Internal owners of these various systems

  › If data is duplicated in multiple systems

  › What information needs to be captured from which data sources (i.e., via a data map)

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Data and Information Technology (cont.)

» Process:

› To assign unique identifiers (e.g. a customer master number) to link data

› To aggregate data into a centralized repository

› For testing, reconciliation and/or scrubbing to remove redundancies and ensure the data is accurate and complete

› For validating data integrity from third-party vendors that interact with Covered Recipients on behalf of your organization

› To backup your systems and third-party data sources on a regular basis

› For a secure means for transferring data from the vendor to your organization

» Review your data retention policies to ensure that they are sufficient to support reporting requirements

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Illustration: Aggregate Your Data

Aggregate Spend Reporting Diagram
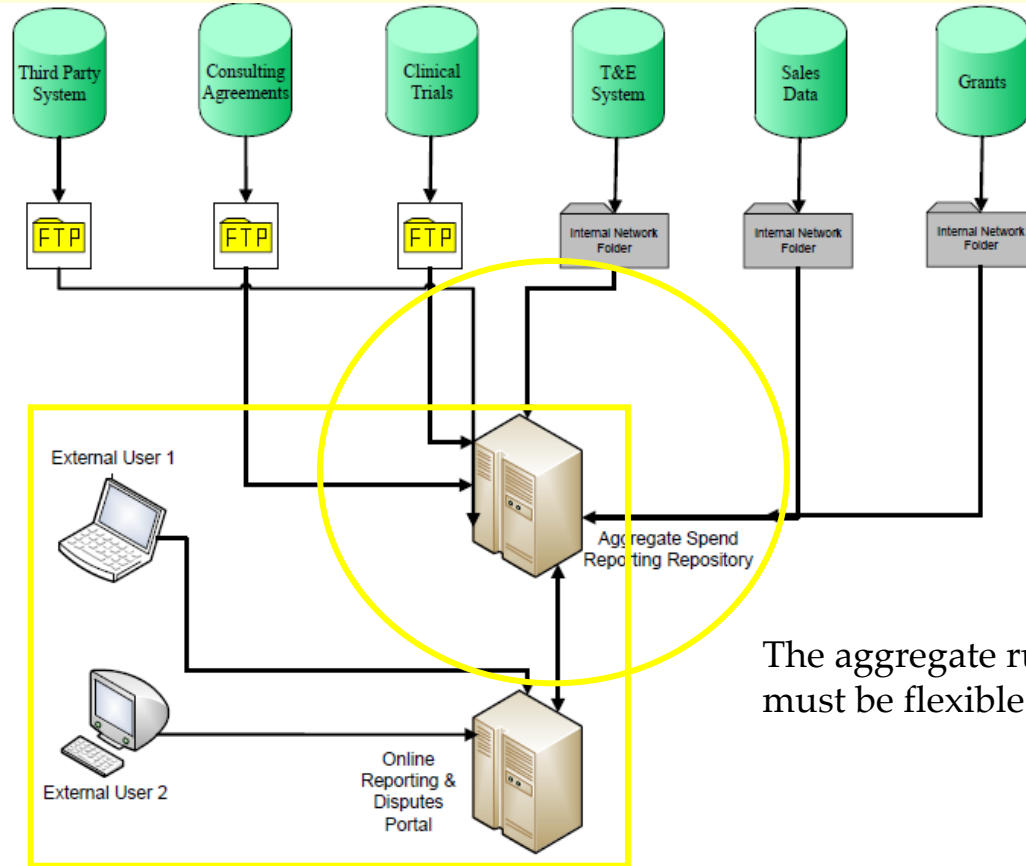
Unique Identifiers within the data are used to map the different types of spend from a HCE/HCP and are a **MUST.**

The aggregation must be able to be scalable

The aggregate rules engine must be flexible

Regardless of how good your system is,
bad data in **always** leads to bad data out

Manual Aggregation vs. Enterprise Integration

|	Manual Data Aggregation	Enterprise Data Aggregation	Enterprise Integration Points
Web-Based	✖	✔	Can be accessed anywhere with an internet connection
Ease of Use	✖	✔	User friendly interface
Security	⇄	✔	All data housed on secured servers
Ease of access to information	✖	✔	Easily access all information in one centralized location
Resource needs	⇄	⇄	Infrastructure and support costs – long run vs. short run
Cost-Efficient	⇄	⇄	Only small amounts of custom coding after development needed

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Dash Boarding and Reporting: Using Data Analytics and Visualization

The dashboard needs to simplistically show the information and trends related to critical areas of Aggregate Spend to effectively monitor compliance and alert on suspicious activity.
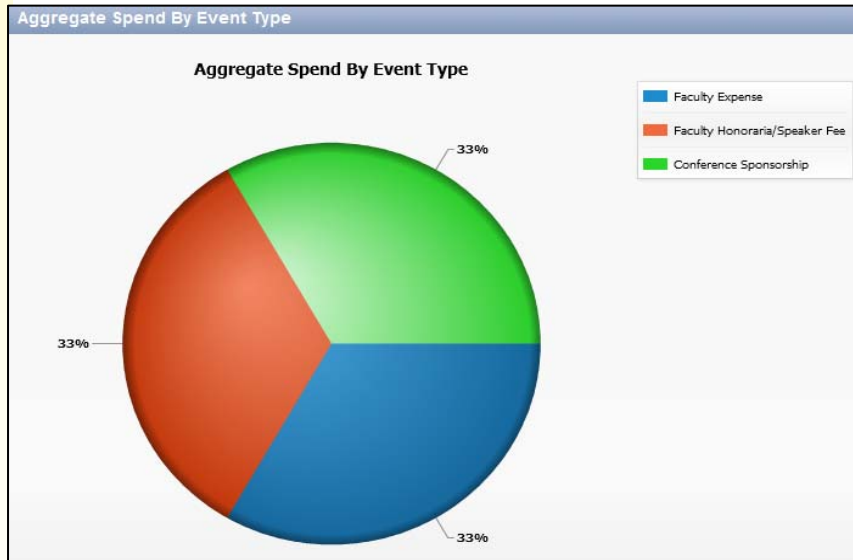
Early data assessment for trend identification and pattern recognition

Integration of disparate systems and public data for event re-creation and analysis

Fund flow tracking and heat map review for volume and value analysis

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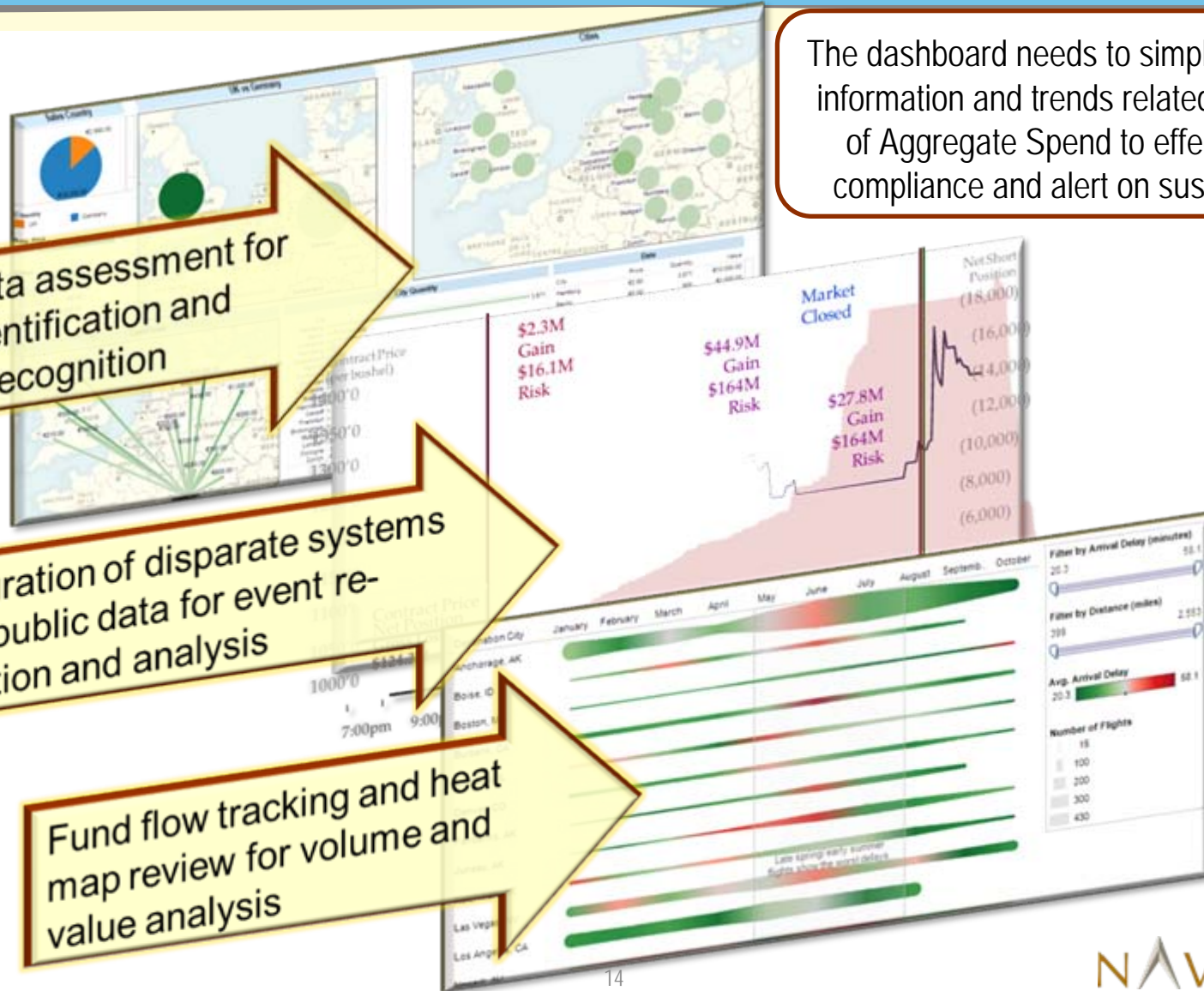
Dash Boarding and Reporting: Internal and External Uses

Aggregate Spend By Event Type

- Faculty Expense — 33%
- Faculty Honoraria/Speaker Fee — 33%
- Conference Sponsorship — 33%

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Aggregate Spend Report

HCP Name: Ology, Radi

Faculty Honoraria/Speaker Fee

Date	Value	Location
11-FEB-12	$1,000.00	AK
Total	$1,000.00	

Faculty Expense

Date	Value	Location
01-FEB-12	$1,000.00	AK
25-FEB-12	$1,000.00	AK
Total	$2,000.00	

Conference Sponsorship

Date	Value	Location
08-FEB-12	$1,000.00	AK
Total	$1,000.00	

| Total Expenditures | $4,000.00 | |

- This feature can be used internally at various corporate levels
- Reports are customizable based on the business need
- It allows for a holistic view of where spend is going by event type

- Used externally for reporting to State and Federal Agencies
- Reporting needs to show the <u>facts</u> within the data
- Reports can be sent to physicians before being reported to government agencies

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HCP Communication & Dispute Resolution

Are HCPs Ready and Informed?

» **<u>50% of HCPs Unprepared for Sunshine</u>**

› Survey of 1,000 Physicians, half of the respondents did not know that the law required reporting of expenditures annually

› Approximately 20% of respondents said they would **<u>sever</u>** their relationship with Manufacturers who reported inaccurate information to the public

Source: According to MMIS' 3rd annual survey of doctors.
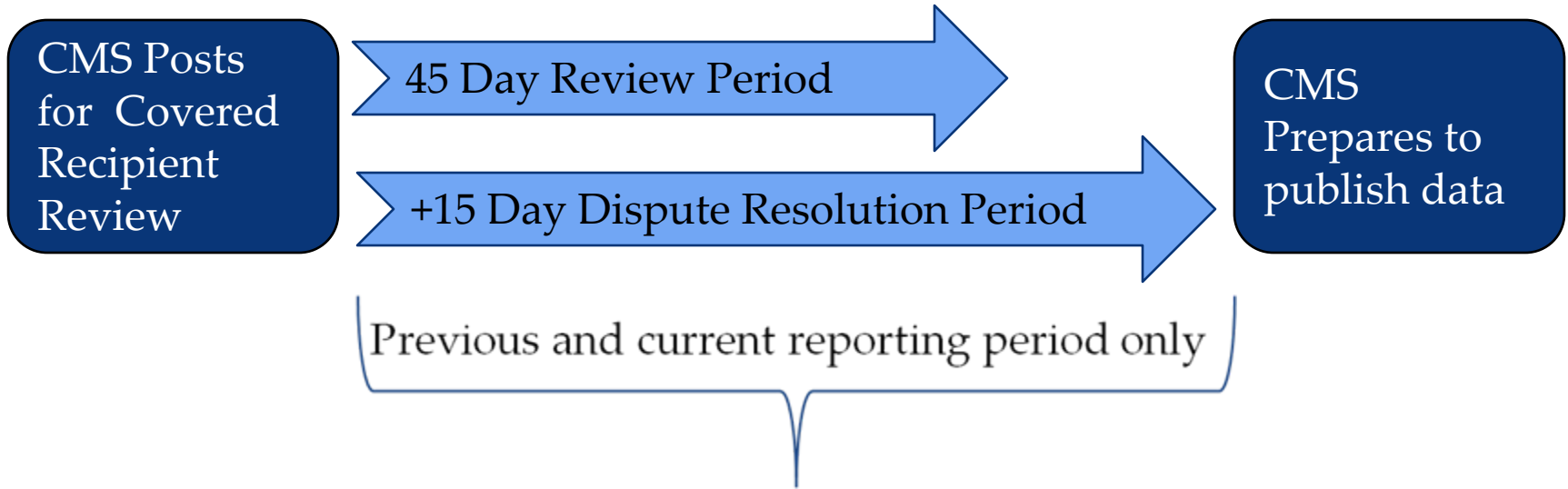
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Are HCPs Ready and Informed? (cont.)

» **<u>Other concerns from HCPs</u>**

› HCPs concerned that reputation could be damaged by inaccurate reporting

› Dispute Resolution (covered in the next section)

› Who is going to be using this publicly available data. Some lessons learned on the CIA experience with public postings:

- Affiliated medical facility
- Estranged spouse
- IRS
- Physician threatens legal action for incorrect posting

How Can a Covered Recipient Dispute a Value?

CMS Posts for Covered Recipient Review

45 Day Review Period

+15 Day Dispute Resolution Period

CMS Prepares to publish data

Previous and current reporting period only

Is this enough time to research and potentially correct a dispute?

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Covered Recipients Education and Communication

» Plan:

  › For communicating data reporting requirements to the Covered Recipients with whom your organization interacts

  › To ask Covered Recipients to verify their personal information required for reporting (name, address, specialty, state license and NPI numbers)

  › To document situations when a Covered Recipient declines a payment or other transfer of value

  › To document requests from Covered Recipients to make payments on their behalf to another individual or entity

  › To address disputed information

» Also, will you provide Covered Recipients an opportunity to review the information that will be reported prior to submission?

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Employee Education and Communication

» Do you have a plan to educate employees and third party agencies who interact with covered recipients regarding the new or updated policies and procedures?

» Do you have resources available and dedicated to answering questions employees might have about the various interactions, and associated policies and procedures, with covered recipients?
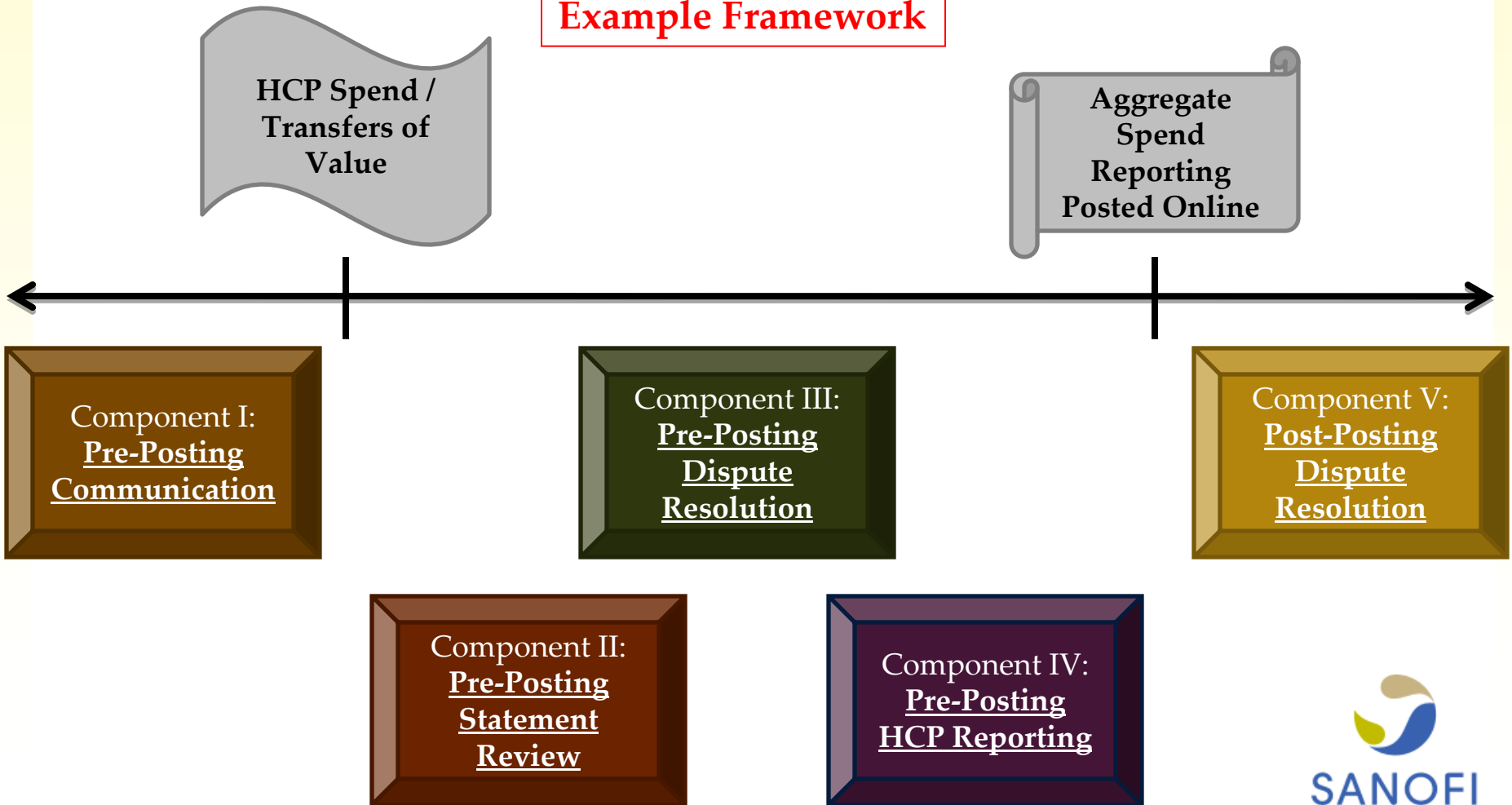
HCP Inquiry & Dispute Resolution Process: Potential Components

Example Framework

HCP Spend / Transfers of Value

Aggregate Spend Reporting Posted Online

Component I: **Pre-Posting Communication**

Component III: **Pre-Posting Dispute Resolution**

Component V: **Post-Posting Dispute Resolution**

Component II: **Pre-Posting Statement Review**

Component IV: **Pre-Posting HCP Reporting**

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Do you have the upstream compliance controls in place....

to manage your downstream reporting?

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Implications & Challenges

» <u>Greater Transparency = Greater Scrutiny</u>

» Widespread public disclosure of Industry interactions with HCPs will shape how these relationships are viewed by the enforcement authorities, regulators, legislators, and the public.

» Trust will become an increasingly important element of the relationships between Industry companies and HCPs

» Anticipate new standards for "effective compliance" with emphasis on greater visibility and prompt response to impropriety

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Organizational Structure: Resources, Roles and Responsibilities

» **Executive sponsors** and other **key contributors** in your organization to ensure successful collection and reporting of your data

» **Designation of who/which department is accountable** for understanding your organization's policy and procedure matrix and ensuring that appropriate updates/revisions have been made

» **Business resources and existing controls** that will be used to ensure that all relevant data is initially captured as completely and accurately as possible

» **Designation of ownership of the relevant Vendor relationships** to ensure they are as informed/ involved as possible at all times

» **Responsible for testing and monitoring** – at Headquarters and in the Field – to identify potential gaps in policies or processes and understand the "story" told by the data?

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Written Standards

» Does your organization have **policies** in place that **govern the continuum of its relationships with Covered Recipients** (physicians and teaching hospitals)?

   » Food and Beverage?
   » Entertainment?
   » Gifts?
   » Speakers?
   » Consultants?
   » Fee for Service/Fair Market Value?
   » Preceptorships?
   » Travel and Expense Reimbursement?
   » Education (Accredited and Non-Accredited)?
   » Grants?
   » Charitable Donations?
   » Market Research?
   » Research?
   » Clinical Investigations?
   » Use of third-party vendors who interact with Covered Recipients on behalf of your organization?
   » Royalties and Licensing?

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Written Standards (cont.)

» **Procedures**, including detailed review and approval processes related to services provided by, and/or grants and charitable donations provided to, Covered Recipients and to maintain documentation:

  » Of **legitimate and unmet business need**

  » That **service providers are selected based on their credentials** and other justifiable factors

  » That **service fees represent fair market value** for the service provided, and FMV based on appropriate criteria and are applied consistently across the organization

  » Of **whether the education is non-accredited or accredited**; and, whether your organization was involved with selecting the speaker or provided an identifiable set of individuals to be considered as speakers for the continuing education program

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Written Standards (cont.)

» **Procedures**, allowing for **consistent designation** regarding the nature **of payments** made to Covered Recipients (e.g., General Ledger codes)

» **Procedures**, including an **established means for allocating the value of a meal/snack/beverage** across multiple Covered Recipients, clearly documenting:

>> Whether the Covered Recipient accepted or declined the meal/snack/beverage;

>> The total number of people who accepted the meal/snack/beverage;

>> The total value of the meal/snack/beverage including tax and tip; and

>> Identifying a standard process for managing and documenting policy exceptions

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Auditing and Monitoring

» To assess whether activities conducted align with policies and procedures

» To test your data to determine if there are any gaps in your policies, procedures or training

» To allow time to resolve any deficiencies prior to the start of data collection on August 1, 2013

» Plus maintain focus on other risk areas within your overall A&M plan

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Critical Success Factors: Avoiding Sunburn Traveling on the *Delta Queen Disclosure*

Sufficient resources; clear roles and responsibilities
Consistency / Standardization in Policies and Processes
Documentation / Memorializing Decisions at Milestones

Education and Communication – Internal and External

Data sources and data warehouse organization
Aggregate data with flexible rules engine and Unique Identifiers.
Auditing and Monitoring
Maintaining Flexibility

Diagnostic: https://technologysolutions.navigant.com/pls/apex/f?p=133