



Spread “Sunshine” Throughout Your Organization!

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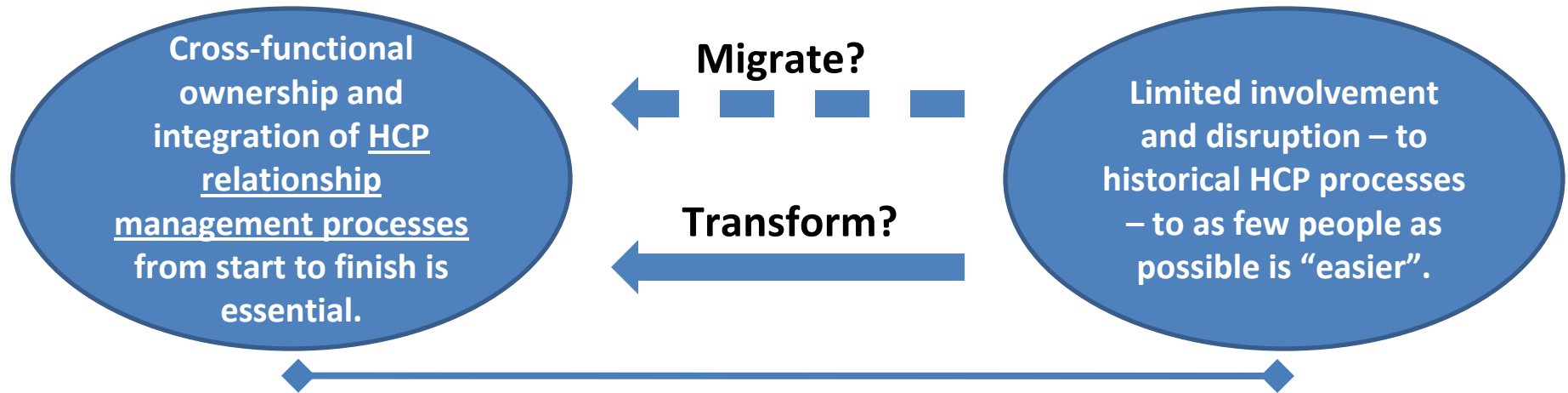
April, 2013 Forecast: Partly Cloudy

- Do you think the submission of reports to the Secretary of the Department of Health and Human Services in March, 2013 will create enough Sunshine?
- Unlikely, given recent history:
 - » Medical Device Deferred Prosecution Agreements (DPA) and Corporate Integrity Agreements (CIA) of 2007: OIG and DOJ
 - » Pharmaceutical CIAs involving HCP Relationships
 - » Foreign Corrupt Practices Act (FCPA) investigations ongoing
 - » CIDs – Civil Investigative demands
 - » False Claims Act focus – Grassley letters
 - » Existing State reporting requirements and others pending
- These reports will create a little bit of sunshine but also lead to more questions...

After the First Reports are Submitted:

- Did you include all required payments – i.e., did you get it all?
- Why did you pay that amount of money to external HCPs?
 - » Fair Market Value?
 - » Justifiable Need?
 - » Credentialed HCPs?
- Can you reconcile this reported data to the general ledger without engaging in a full-blown forensic exercise?
- What special measures, systems or tools are in place to audit and monitor the appropriateness of the activities and accuracy of the data resulting from the activities?

Continuum: “Sunshine” Ownership



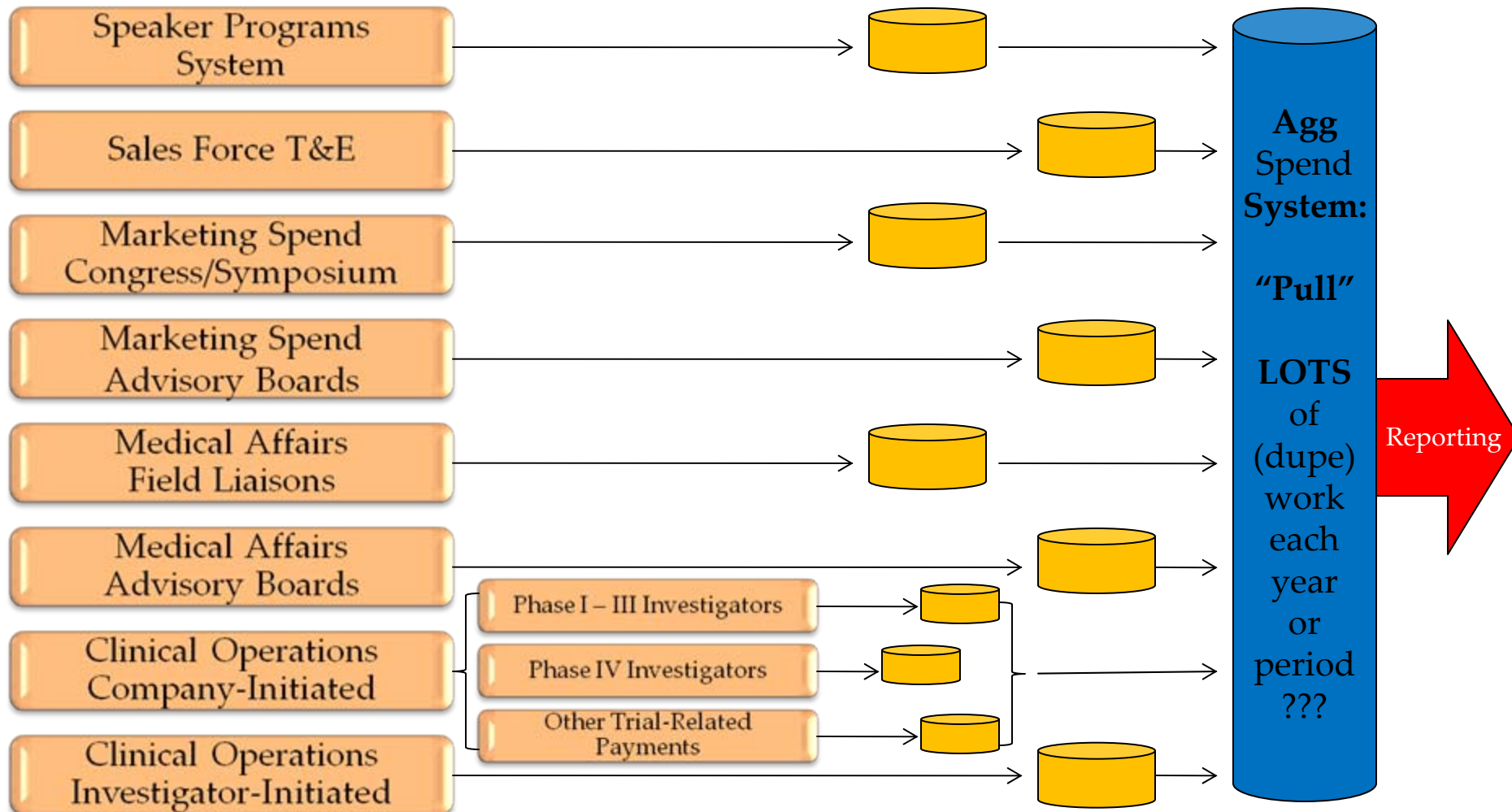
Implications:

- Push data through the business
- Common definitions, formats, etc.
- Efficiency
- High value of resulting data: business and compliance utilization
- Educated stakeholders
- Compliance effectiveness

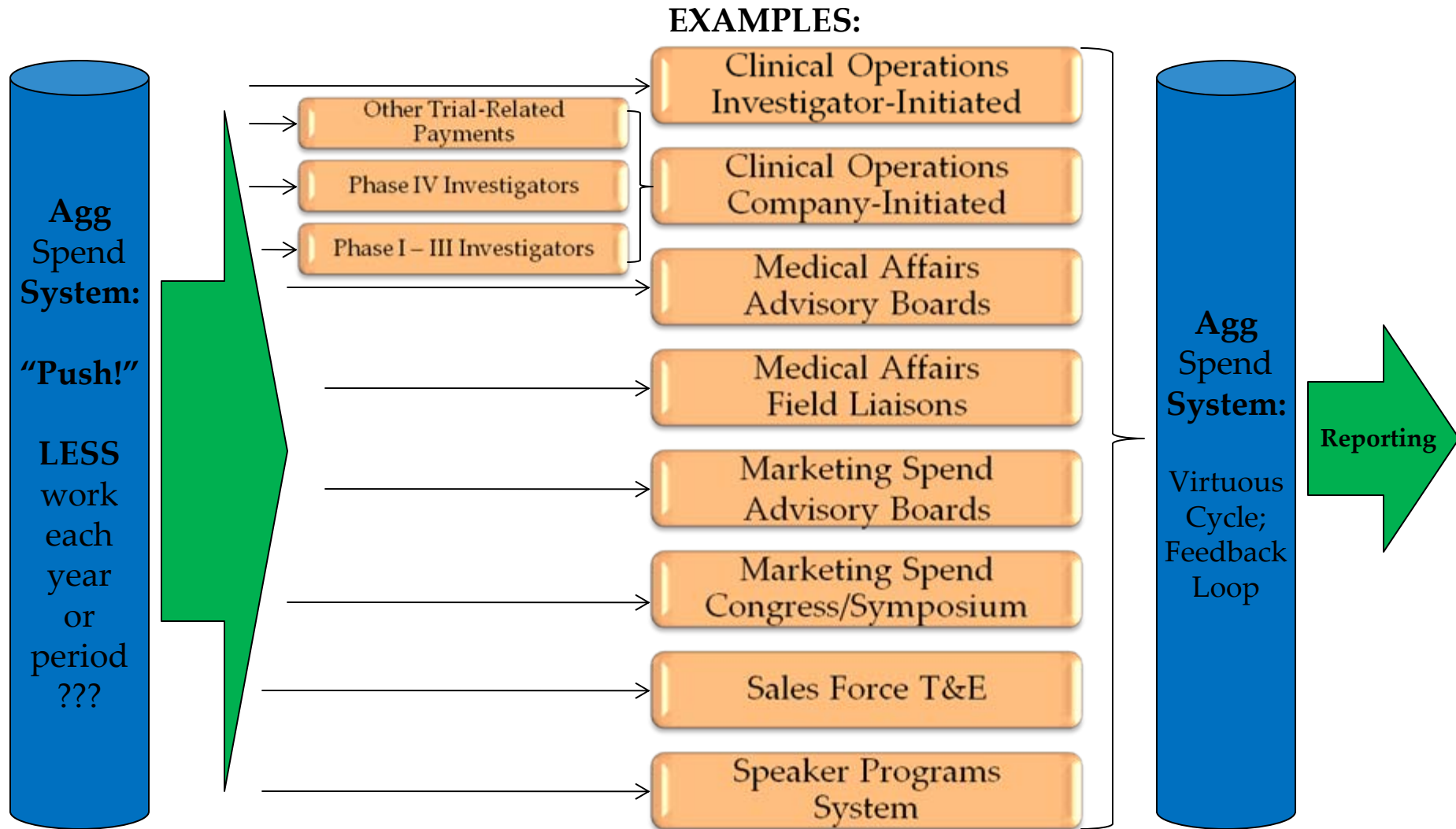
- Pull data from the business
- Multiple definitions, formats, etc.
- Inefficiency
- Low value of resulting data: reporting purposes only
- Uninformed colleagues
- Poor compliance

“Pull” Strategy

EXAMPLES:



“Push” Strategy



HCP Relationship Cycle: Components and Value

HCP Relationship Cycle Stage	Component	Timing	Business Value	Compliance Value
Pre-Contract	HCP Credentialing & “Roster” Management	Annual calibration	Customer Relationship Management (CRM)	HCP services alignment
	Needs Assessment – by activity/event, monthly, quarterly, annually	Options: by activity/event, monthly, quarterly	Resource optimization; good business	Justification of need for external HCPs
	Rate Card – Fair Market Value	Every 1-2 years	Consistent message to HCPs; simplifies processes	Justification of amount paid to external HCPs
	Policies, processes and technology to facilitate entire HCP relationship cycle	Now and never ending!!!	Streamline processes	Guardrails and checkpoints
Contract	Standardization and Templates for Work Plans, Contracts and Addendums	Every 1-2 years	Streamline processes	Controls
Post-Activity	Internal Reporting: Contractual and Non-Contractual Activity (consistent mechanisms across entire organization)	Ongoing	CRM and efficiencies	Real-time tracking and monitoring
	Payments: efficiencies with A/P, financial system and HCP relationship system	Ongoing	Happy HCPs	Real-time tracking and monitoring; improved auditing
Reporting	Automation of various templates for States, Sunshine and other needs	Annual/variable	Feedback loop for future planning	Efficiency and analysis

Thirteen Questions: Compliance Effectiveness – i.e., Spreading Sunshine

OIG Element	Question	Answer	Tested?
Oversight	Can you provide evidence that HCPs have been credentialed through an internal process and are selected for specific services based on their credentials and other justifiable factors, as opposed to insufficient or inappropriate reasons?	Y / N	Y / N
	Can you provide evidence that each service activity that involves a contracted HCP meets a reasonable, unmet business need that couldn't be met by the use of Company-employed HCPs or in some other type of activity?	Y / N	Y / N
	Can you provide evidence that the fees indicated in each arrangement are fair market value based on appropriate criteria and credible analysis and that are applied consistently across the organization?	Y / N	Y / N
	Can you provide evidence that your Company has a Chart of Accounts or equivalent that captures all internal and external HCP touch points and payments (i.e., evidence that you understand the total money flow to HCPs)?	Y / N	Y / N
Written Standards	Are there policies and procedures in place that govern the continuum of HCP relationships and aggregate spend reporting, aligned with the 'Oversight' questions above?	Y / N	Y / N
	Do your systems (be they Pull or Push) efficiently align with and / or support written standards, including document retention policies, and create mechanisms for compliance controls and monitoring?	Y / N	Y / N
Training and Education	Has the compliance department provided appropriate training as it relates to the Sunshine Act, State requirements, aggregate spend reporting and the requirements related to contractual and non-contractual relationship management?	Y / N	Y / N
Open lines of Communication	Has the organization established a well publicized, anonymous hotline or similar mechanism so that employees, and HCPs, may report potential compliance issues?	Y / N	Y / N
Auditing and Monitoring	Is there a risk assessment process that addresses anti-kickback risk and incorporates aggregate spend and related reporting requirements?	Y / N	Y / N
	Does the annual compliance auditing and monitoring program incorporate key approval points such as HCP credentialing, needs assessment, payment authorization, reporting accuracy?	Y / N	Y / N
	Have you built into the formal compliance audits a degree of independence?	Y / N	Y / N
Responding to Detected Deficiencies	Has the organization created a response team, consisting of representatives from compliance, audit and any other relevant functional areas, which may be able to evaluate any detected deficiencies or external inquiries (e.g., subpoena) with the Aggregate Spend and HCP relationship management functions quickly?	Y / N	Y / N
Enforcement of Standards	Are disciplinary standards established which describe disciplinary action (up to and including termination) for compliance-related violations, and are they applied across the continuum of sales representative – C-suite executives?	Y / N	Y / N

Critical Success Factors to Spreading Sunshine

- C-suite education, sponsorship and commitment
- Cross-functional stakeholders with incentive to actively participate and line management endorsement/support
- The right resources at the right time for the right duration
- HHS Secretary Guidance re: Sunshine Act report format
- System flexibility to change and adapt over time with new/updated laws



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Thank You for Your Time

