

Aggregate Spend Management & Disclosure

Complicating Factors and Leading Practices

Since 2002, more than 20 states have introduced legislation requiring pharmaceutical and medical device manufacturers to disclose payments or exchanges of financial value to physicians and other health care professionals (HCPs). To date, 7 states (CA, MA, ME, MN, NV, VT, WV) and Washington D.C. have passed such legislation (see Figure 1), with most imposing financial penalties for non-compliance.

While states increasingly pass new and expanded legislation, the federal government is proposing to increase the scale of disclosure substantially. The federal legislation, known as the Physician Payments Sunshine Act (S.301, H.R. 3138), proposes disclosure of spend on HCPs across all states and will likely impact most pharmaceutical and medical device companies operating in the U.S.

In addition, the Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed) have both recently updated their codes on interacting with HCPs. Though both the updated PhRMA code and updated AdvaMed code are voluntary, over 30 pharma/biotechs and over 60 medical device companies have already adopted their respective codes, whose guidelines are applicable to all 50 states.

Complicating Factors

Complying with the PhRMA/ AdvaMed codes as well as upcoming state and federal legislation is complicated by the following factors:

1. With current state requirements often handled manually, the effort to collect, aggregate and report is not scalable.

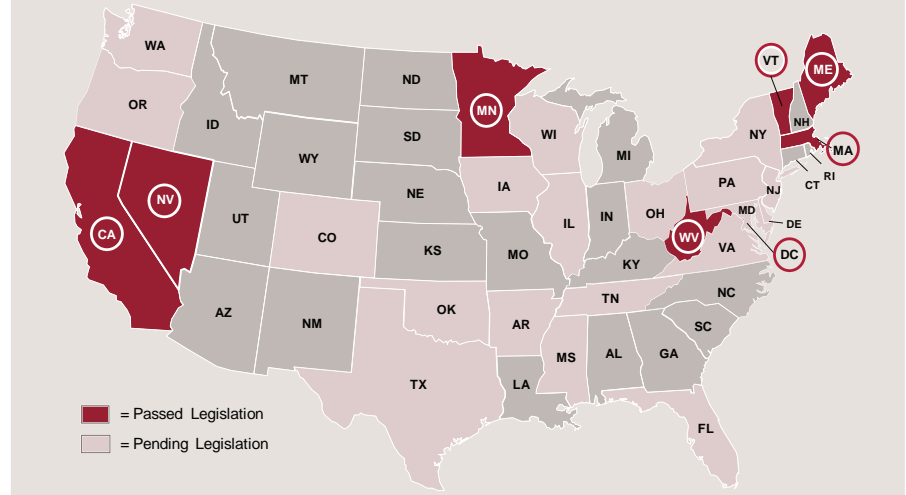
Currently, most companies only collect information required for state reporting, but are starting to plan for the federal bill. The practices of manual spend aggregation and reporting are not scalable and may require increasing time or support as requirements expand. Additionally, this manual process increases risk of error and data inaccuracy.



Leading Practices— Aggregate Spend Tracking

- Instituting a cross-functional executive team to support the aggregate spend initiative
- Instituting a cross-functional team to support legislation interpretation and business rule decisions
- Enterprise-wide mapping of value exchanges (such as payments, honoraria, gifts) with HCPs across all business functions
- Establishing a unique identifier across the enterprise for each HCP and designing and implementing robust business processes for management of HCP master data (e.g., address changes, de-duplicating)
- Designing flexible and scalable data collection and warehousing to support current state reporting requirements and PhRMA/AdvaMed codes as well as future federal and state reporting requirements
- Developing communications and training for employees, HCPs and third-party suppliers to ensure understanding of the purpose of the initiative, and rules and requirements for individuals affected by the legislation
- Generating automated compliance monitoring methods and corrective action to evaluate organizational compliance with rules and regulations

Figure 1: States with Existing Compliance and Disclosure Laws and Pending Legislation



2. There are disparate data requirements for reporting for each state, PhRMA/AdvaMed and the federal bill.

Current disclosure standards vary widely across states. For example, states differ on definitions of who is a reportable HCP, submission standards, and value exchange thresholds (see Figure 2).

3. Limited organizational awareness and training exists today.

Because HCP spend occurs by employees in many different functions and departments, initiatives to develop an aggregate spend solution warrant greater cross-functional participation and change management. Ongoing employee education becomes critical for enterprise-wide compliance.

4. Value exchange data exists in numerous systems and intersects with multiple business processes.

Within a single company, an HCP or health care organization (HCO) may interact with (and be tracked by) multiple departments, business processes and IT systems. Expenses and spend information tied to these events will need to be standardized to meet aggregate spend requirements,

requiring business process and technology changes which balance compliance needs, burden to the business, development costs and time to implement.

5. HCPs may be identified and tracked differently in various systems, resulting in duplicate or inconsistent HCP records.

Accurate identification of HCPs is critical for accurate data aggregation and reporting. Duplicate HCP records can occur when an HCP is called on by different parts of the business and the interactions are stored in different systems. These duplicates will need to be reconciled to accurately report the total spend.

6. Legislation and industry codes are often vague and ambiguous, requiring interpretation by companies.

To operationalize an aggregate spend solution, companies will need to interpret legislation and business rules around the requirements. Lawmakers have emphasized that companies should be transparent and consistent with their interpretations, stating them in their transmittal letters to states.

Figure 2: Disclosure Requirements by State

Type of Report	States							
	CA	DC	MA	ME	MN	NV	VT	WV
Disclosure Requirements								
Itemized reporting of each payment		X		X	X		X	
Summarized reporting of payments			X					X
Marketing Code of Conduct program required	X	X	X			X		
Dollar caps on individual HCPs	X				X			
Public Access to Disclosed Information								
Disclosure of reports accessible to public			X		X		X	
Agency (e.g., HHS) provides reports of aggregate spend	X				X	X		
Enforcement Mechanisms								
Fines for non-disclosure of payment	X	X	X	X	X	X	X	
Minimum Payments								
Minimum payments for reporting	Not specified	\$25.01	\$50	\$25.01	\$100	N/A	\$0	

Source: State laws as of January 1, 2010

3. Organize HCPs.

Establish company-wide customer master data management (MDM) for HCPs and HCOs to appropriately allocate the spend information. Medical practices need to be assigned multiple identifiers to track activity among the principal practitioners and HCPs must be assigned company-wide unique identifiers. MDM can help enable overlap identification and allocation of new disclosure categories, while maintaining access barriers between various employees. Furthermore, designating a single HCP identifier across the company will help maintain compliance with spend thresholds.

4. Align impacted groups.

Through cross-functional governance, identify and make executive decisions to balance corporate risk tolerance against business disruptions, resource limitations and audit requirements. Create a working team (representing at a minimum legal, compliance, marketing and sales, IT, R&D and finance) to understand the

Preparing Now for the Future

Companies can prepare for 50-state aggregate spend reporting by automating data capture, aggregation and reporting. Capgemini has found that companies can successfully tackle aggregate spend solutions in the following four ways:

1. Prepare for flexibility and scalability.

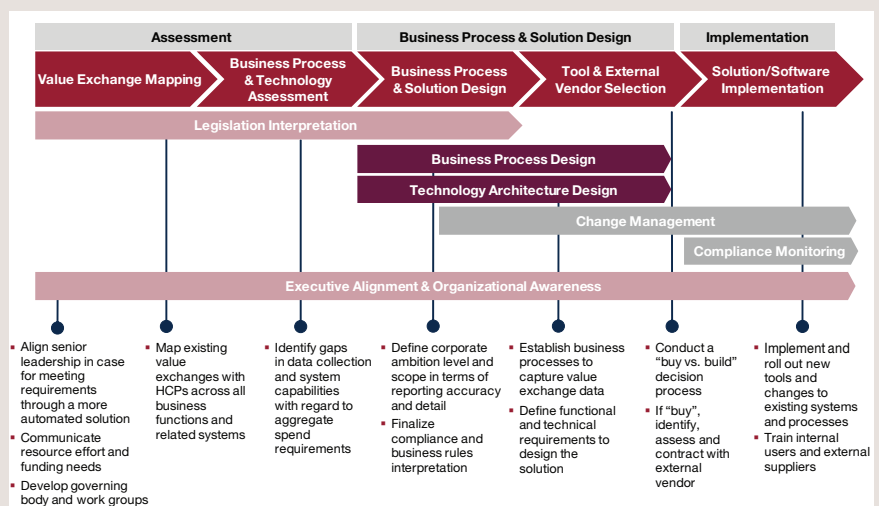
Prepare for potential increased scale and scope of requirements by aggregating the spend data only for reporting while capturing and retaining data granularity at the lowest possible level. This helps to maintain flexibility as changes to disclosure standards and requirements occur. With granular data and flexible design, aggregate spend solutions can be developed and implemented once, minimizing future training and system changes.

2. Establish a clear definition of “HealthCare Professional.”

Many states indicate which HCPs are included in their scope of reporting

requirements, whereas PhRMA and AdvaMed codes and the federal bill are more vague. Companies should clearly establish which HCPs they are collecting spend data on, and how their definition of an HCP affects business burden to collect the data.

Figure 3: Essential Aggregate Spend Dimensions and Key Activities



specific challenges of fulfilling the requirements, standardizing data definitions and establishing company-wide data capture processes. Execute on a communication and training plan for all stakeholders in the company, including third-party suppliers. Investigate whether supplier contracts need to be re-negotiated to provide for more detailed spend reporting.

Benefits of a Systematic Approach

Given the scale of automation required, a well-designed aggregate spend solution provides increased efficiency and time-savings from automating tracking and reporting, risk mitigation through more robust data-driven reporting and audit readiness. It also has many potential benefits to the rest of the business:

- Better customer insight, customer segmentation, business analytic and targeting through transparent view of enterprise-wide HCP activity
- Greater clarity of spending enables control of activities
- Identification of non-value adding activities leading to increased focus on priority promotional activities

A Call to Action

Some organizations view the complications of aggregate spend and the constantly changing environment as reasons to avoid starting to address regulations. Given the long lead time and changes required, companies avoid this at their own risk. There is much work to do to be ready for future requirements. Flexible long-term plans should also include short-term actions (see Figure 3).

A first step is to assess the impact of disclosure requirements on the business. This assessment can help identify:

- Business processes that include interactions with HCPs
- The type and volume of HCP interactions initiated by third-party agents on behalf of the company
- Mechanisms by which value exchanges are captured within various systems

Assessing the impact now allows for an earlier understanding of further effort required to address gaps, more orderly planning for budget and head count needs, more orderly integration into the business and IT long-term plans and preparation of impacted individuals.

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