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26 March 2018

Who is Driving Your Drug Price Transparency Compliance Strategy—the Legislature or Your C-Suite?

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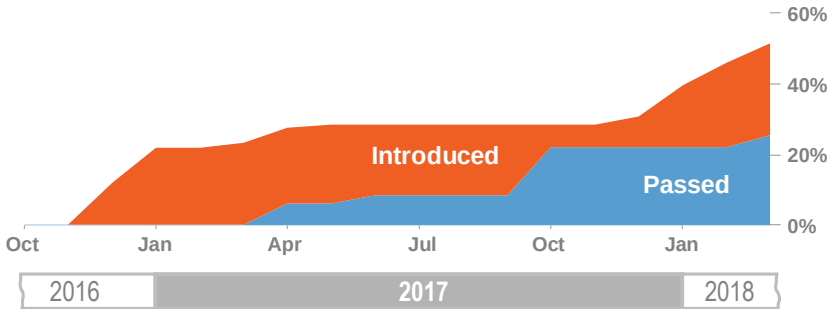
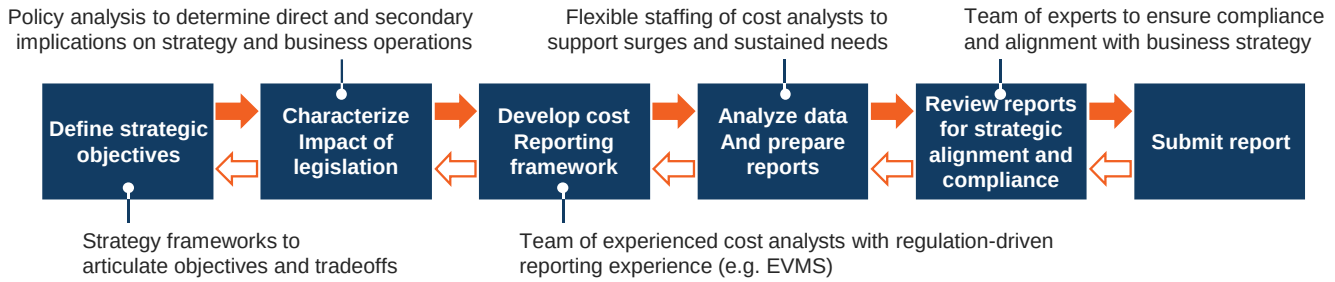
A wave of state and local legislation has the potential to change the profitability and business models of the pharmaceutical industry. California's SB 17 law from October 2017 is a tipping point, catalyzing similar legislation across the country as states seek various approaches to managing prescription drug costs. While there are many dimensions to these laws, one focus is drug price transparency.



As of early 2018, only a handful of states have passed such legislation. However, these cover more than 25% of the US population, and the impacts are spreading across the country. Indeed, after SB 17 was signed into law there was a sharp uptick in new legislation introduced, bringing the combined passed and introduced legislation to cover more than 52% of the US population. Beyond the US impact, with the information required by different pieces of legislation, there is the additional potential to affect global competition. For example, public disclosure of production costs for a particular product could be used by competitors to alter their pricing strategy in overseas markets.

Cost transparency and reporting is a relatively new concept to the pharmaceutical sector, but it is an inherent part of the US Federal Government contracting industry. The Federal Acquisition Regulations (FAR) and its Cost Accounting Standards (CAS) lay out very detailed requirements for cost reporting and disclosure statements. Similarly, Earned Value Management Systems (EVMS) are required to give insights into actual work done. The structure is created so that the government customer has visibility and can assure itself that contractors are not extracting outsized profits. However, this is not a one-sided endeavor. In response to regulations, companies, such as major defense contractors, have developed very sophisticated strategy-driven approaches to capturing, accounting and reporting expenses to maximize "reimbursable" costs associated with government contract work.

SMA is immersed in cost reporting with a team of management consultants, cost analysts and EVMS experts that routinely help government contractors navigate these regulations. Our work is driven by the principle that the business strategy drives the approach to regulatory compliance. Through decades of experience we have honed the art of structuring cost analysis and reporting to balance the business needs of maximizing revenues while ensuring competitiveness.



As regulations proliferate affecting the pharmaceutical industry, we are applying our experience and skills from the defense sector to help drug companies protect their strategic interests. As illustrated above, we begin with the strategic objectives of the business, and use this lens to characterize how particular pieces of legislation can affect the business. This drives the approach to cost reporting and other elements of compliance. Another critical step is a review process for reports prior to their submittal. We model this review on "Red Team" events where Subject Matter Experts and industry veterans assume roles of regulators, competitors, and business functions to assess how the report would be read and used, and provide feedback and guidance for revisions prior to formal filing of the reports.

The whole healthcare industry is undergoing dramatic transformations in the quest to produce better outcomes at lower cost. Recent activity ranging from price transparency and price control legislation to critique of coupons and adoption of co-pay accumulators are targeting the cost of prescription drugs. Our recommended approach to navigating the new regulation is a parallel effort to ongoing advocacy and legal actions on multiple fronts.

With the high degree of uncertainty and the stakes involved, it is important to ensure that compliance activities are not blindly following dicta from populist legislatures, but are driven by corporate strategy and business objectives.

Our strategy-led approach combined with our decades of work in the healthcare/pharmaceutical industry and deep experience in regulation-driven cost reporting is the right combination to support your team in planning, structuring, and executing compliance activities.

[1] ***Dr. Alan Berman*** *is Vice President for Research and Strategic Initiatives at SMA. He specializes in market analysis, strategy development, and new business creation. At SMA, Alan leads and advises some of the more complex consulting engagements, and focuses on growing the SMA business through new intellectual property as well as systems and processes to enable rapid scaling in core and adjacent markets.*