The *state* of drug pricing transparency

In the face of public and media outcry about prescription drug pricing, the Trump administration has indicated that the federal government may be taking more decisive action to lower prices. As progress on the federal level proceeds, state governments have stepped in to address the rising cost of prescription drugs. They are introducing their own measures to require justification of launch prices and annual price increases, and compel transparency of manufacturers' spending on R&D, manufacturing and marketing.

In 2018 alone, state lawmakers filed more than 170 drug cost containment bills and enacted 45.[1] The bills are geared toward instituting wholesale drug importation programs, codifying rules for biosimilar substitutions, regulating PBMs' rebate and copayment practices, eliminating seemingly arbitrary price increases, and, most importantly, increasing pricing transparency.

The laws can be confusing, and some have onerous reporting requirements. It is critical that manufacturers understand the laws as they will likely inform strategic pricing decisions. Tracking new laws and complying with the reporting requirements of those already implemented require new processes and additional resources. Manufacturers cannot risk losing market opportunities, the public's negative reaction, or the noncompliance penalties that may come from failing to meet a state's requirements.

Staying one step ahead: Tips for timely compliance

As states continue to introduce drug pricing transparency legislation, manufacturers may find it increasingly difficult to keep current with and operationalize requirements. To lower the risk of noncompliance, following are some tips to help manufacturers:

Managing compliance risks

- Track proposed developments including bills, rules, regulations, and ballot initiatives
- Establish a governance structure for addressing current and upcoming state and local requirements
- Be mindful of the additional risks triggered by price increases, product launches, and inclusion on state-published lists
- Anticipate the possibility of required reporting to the public (including potentially sensitive information)

Anticipating pricing transparency requirements

- Ensure that data collected for the state fulfills all requirements and can be used to explain price increases and launch price decisions, including, when possible, health economics and outcomes research (HEOR)
- Identify the need for interpretation and reasonable assumptions when collecting information related to pricing transparency requirements, e.g., R&D and marketing costs, profits, rebates
- Quantify drugs' downstream contribution to overall healthcare financial savings or long-term patient benefits
- Ascertain whether relevant states set annual spending targets, which will allow them to negotiate rebates

[1] S. Lanford (2019). As state legislatures convene, lawmakers quickly submit bills to curb prescription prices, National Academy for State Health Policy (NASHP).

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Regulatory overview

The first phase of drug pricing requirements started in 2016, when Vermont passed a law requiring justification of price increases for drugs included on an annual state-created list. Other states, e.g., Nevada, followed with similar list-based reporting requirements, which included such key developments as:

— Reporting to the state is triggered for manufacturers of drugs that appear on a list published by the state (e.g., due to the state spending significant healthcare dollars, or the drug being essential to the treatment of diabetes)

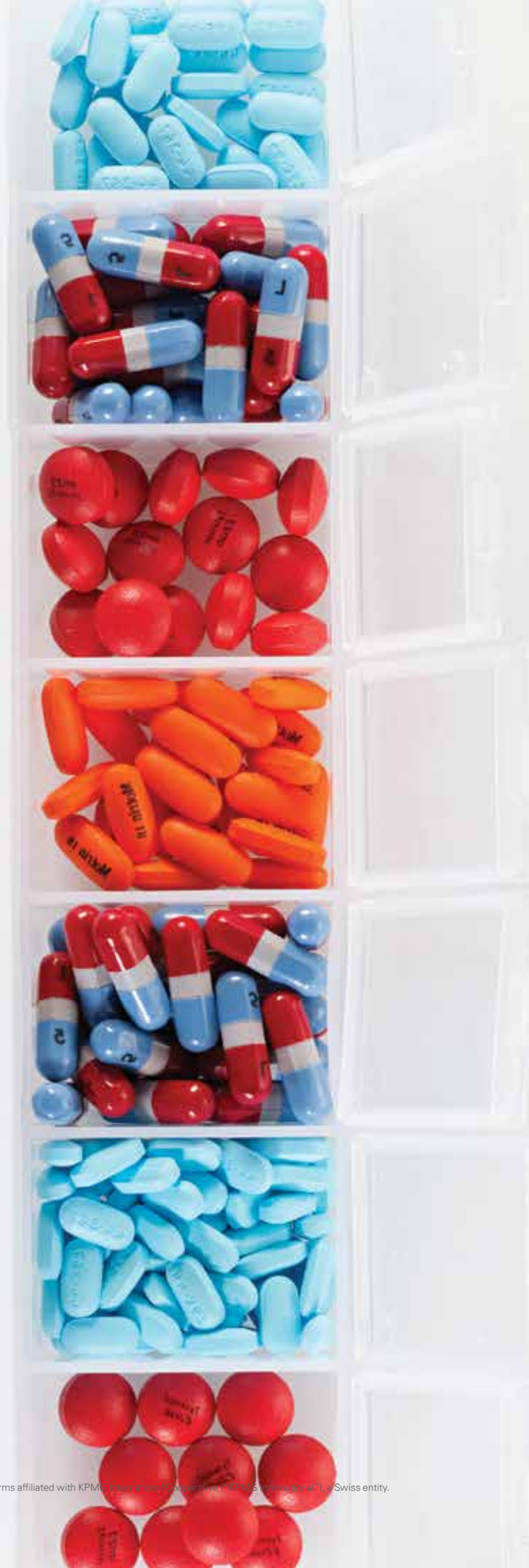
— Requirements include justifying pricing practices (i.e., factors that contribute to price increases)

In the second phase, additional states, e.g., California and Oregon, passed drug pricing transparency legislation focused on all manufacturers—not only those included on lists published by the states—which included such key developments as:

— Manufacturers may trigger reporting by making drug price increases that exceed a statutory threshold, or by launching a new product at an introductory price that exceeds a statutory threshold

— For all scenarios, requirements go beyond historical government reporting obligations to include previously unaddressed and potentially sensitive data sources, including:

  – Cost accounting (e.g., research, development, and manufacturing costs)
  – Profit
  – Patient assistance programs
  – Marketing and pricing plans
  – Price justification factors that require consistency and cross-functional input and agreement



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Industry-leading practices: Set up the organization for success

1. **Assign a lead to oversee and coordinate efforts**, which may include individuals from legal, compliance, transparency reporting, or government pricing departments.
2. **Establish clear objectives**, and prioritize them based on potential impact to the business.
3. **Define the scope of the initiative**, ensuring that drug pricing and cost transparency; prohibitions on advertising and gifts; marketing, sales and clinical trial disclosures; and samples/coupons/copay cards are addressed.
4. **Assign roles/responsibilities to individuals** who will provide input, make decisions or take action.
5. **Identify stakeholders who may be impacted** from functions such as compliance, finance, healthcare professional (HCP) engagement, market access, public affairs, R&D, sales/marketing, and strategic pricing.
6. **Remember that anticipating compliance requirements can be critical to making informed business decisions**, including whether or not to proceed with planned price increases.

How KPMG Can Help

No matter how far your organization has progressed in its efforts to meet state requirements, we can help:

— **Navigate the state transparency landscape:** We help clients understand and inventory the various bills, triggering events, and reporting requirements.

— **Process development and enhancement:** Our team can assist in clarifying roles and responsibilities to help ensure that reporting is handled efficiently and effectively. Further, we can help identify the systems and data necessary to meet reporting obligations.

— **Pricing strategy:** We help clients work through strategic considerations related to raising prices.

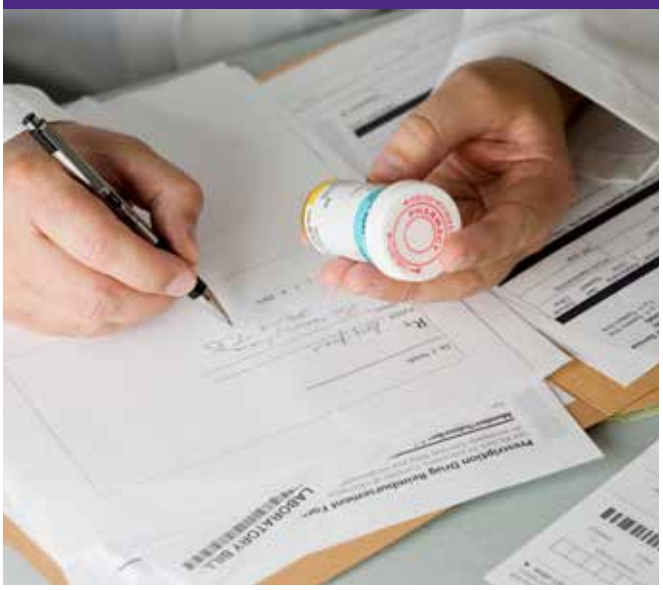
— **Facilitate data gathering and reporting:** We help clients understand reporting requirements, develop clear request lists, and utilize various systems to compile the necessary information.

Why KPMG

Industry knowledge and experience: KPMG is a recognized leader in the healthcare industry with broad and extensive experience in compliance management, and in related service areas such as government pricing and spend transparency reporting. Our work with clients encompasses large and complex dataset analysis to extract useful data, as well as the specialized cost accounting experience necessary to meet compliance requirements.

Highly efficient service provider: KPMG brings to compliance engagements an extensive suite of proprietary ideas, tools, and techniques. These include frameworks for addressing complex issues, which we customize as necessary to meet client needs.

Big Four firm: KPMG brings accountability and a reputation built from accomplishments within the government reporting community, including thought leadership, expert testimony, and work on landmark settlements and other significant matters with various government bodies (e.g., U.S. Attorney General, CMS policy personnel, etc.)



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