



State price transparency
Operational considerations for 2020

Current environment

In recent years, an increasing number of US states have passed—or are in the process of passing—new regulations designed to increase transparency.

Many states have determined that it's in their preferred interest to take legislative action in order to curb drug price increases and to decrease their annual pharmaceutical spend. This momentum is likely to continue in the years ahead. As public and legislative scrutiny on drug prices continues, and as more states continue to introduce and pass legislation, it will be important for pharmaceutical manufacturers to understand the requirements and the implications for their current and future business.

Enacted regulations

Many of the enacted state price transparency regulations fall into the following categories:

- **Advance notice of price increases:**

Manufacturers that plan to take wholesale acquisition cost (WAC) increases that exceed defined thresholds are required to provide advance notice to certain purchasers or state agencies.

- **Price-increase reporting:**

Manufacturers that increase the price of a drug at a rate that exceeds a defined threshold (for example, 20 percent per unit over a calendar year) are required to report information regarding the drug and the price increase.

- **Drug pricing reports:** Manufacturers that sell drugs in certain states are required to periodically report pricing to the state.

- **New drug entry:** Triggered when a manufacturer launches a new drug product that has a price that exceeds a specific threshold (for example, WAC at launch exceeds the Medicare Part D specialty drug threshold).

- **Price disclosure to HCPs and states:**

Requires manufacturers to disclose WAC or the average wholesale price (AWP) of a drug to the state or health care providers (HCP).

While certain states may be in the early stages of enacted laws, states with more mature laws have begun posting reported information on public websites and have recently begun enforcing the penalty provisions contained in these regulations.

Pending legislation

Many states have modeled their proposed legislation on states with previously enacted laws that focus on delivering specific commercial or statutory prices to the state in a prescribed manner and timing, while others have developed unique triggers and reporting requirements. We continue to see states proposing price-increase and WAC reporting legislation. Recent proposals also include price-increase triggers based on government price calculations such as average manufacturer price (AMP) rather than WAC-based reporting. In addition, proposals that address prescription drug spending have been introduced at the federal level.

Over the past few years, several states have enacted state price transparency legislation to address prescription drug costs and spending. As more states continue to introduce and enact legislation, it will be important for pharmaceutical manufacturers to understand the requirements and the implications for their current and future business.

Recent enforcement

The potential penalties for noncompliance vary by state regulation. While certain regulations do not contain specific penalty clauses, most do and can contain penalties up to \$30,000 per day for noncompliance.

In October 2019, Nevada began enforcing the penalties of their enacted regulations and imposed more than roughly \$17 million in fines on manufacturers for noncompliance with drug price transparency reporting. Certain manufacturers were notified for failing to comply with Nevada reporting requirements. Manufacturers subject to this fine either submitted the required information after the deadline or failed to provide the information at all.

The Nevada Department of Health and Human Services (NVDHHS) reportedly gave manufacturers 30 days to settle the fines or 10 days to request a dispute resolution meeting with the state.

With Nevada's enforcement of its laws and increased public pressure to hold manufacturers accountable, this signals that there may be a greater risk for manufacturers if other states follow

Nevada's precedent and start imposing fines. These recent developments underscore the importance of having the appropriate compliance infrastructure in place to facilitate timely and careful reporting for state drug price transparency laws. Manufacturers should clearly understand the potential triggers and nuances of each regulation to avoid noncompliance.



Potential challenges and complexities

State price transparency reporting legislation is not consistent across states and requires careful analysis of each requirement to understand the intricacies and reasonable assumptions that will be required for compliant reporting.

Cross-functional complexity

Many of the regulations have cross-functional complexity that affects multiple departments throughout an organization, such as legal, compliance, government pricing, government affairs, and market access. A lack of interdepartmental understanding and communication may pose challenges implementing and maintaining consistent processes and documentation that is needed to report information in a consistent and timely fashion.

Implications for pricing strategies

With additional states drafting price transparency regulations, manufacturers should be conscious of their pricing strategy and the implications from a legal and public perception perspective. Future enacted regulations may affect future business decisions and pricing strategies. Additionally, in order to stay below statutory reporting thresholds, manufacturers may need to consider adjusting pricing strategies.

Impact of public disclosures

Manufacturers may need to address the complexities that could result from reported prices being available to the public and should assess the legal implications of what to report. The specific information that manufacturers are required to report varies and often touches upon sensitive information, ranging from the profit earned for a specific drug to the direct costs incurred to manufacture the drug. This may create competitive challenges and public relations issues or lead to information being misinterpreted.

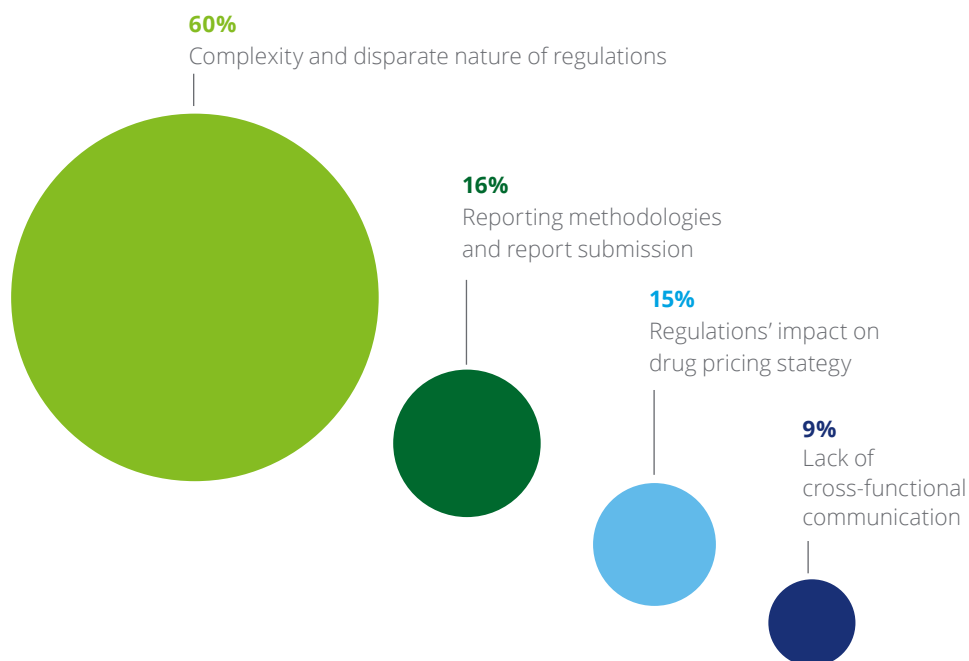
Complex and evolving reporting requirements

Reporting requirements are complex, rapidly evolving, and often include penalties for noncompliance. Resource constraints may limit a manufacturer's ability to actively monitor newly enacted or enhanced legislation and understand the details of each reporting requirement.

Manufacturers can face fines for failure to report specified information, failure to report information on time, or failure to report complete information. This may require in-depth legal and operational assessment of the reporting requirements.

Operational consideration:

What is the biggest challenge related to state price transparency for your business?



Source: Registrant responses to the Deloitte webinar "State drug price transparency: A briefing on important considerations going into 2020," held on December 3, 2019.

Achieving operational readiness in an evolving regulatory landscape

How can manufacturers achieve operational readiness?

Review the current regulations and assess organizational impact

Due to the individual nature of each piece of legislation, manufacturers should assess each set of requirements on an individual basis. Understanding the impact of each piece of legislation requires an in-depth assessment of the reporting requirements contained in the legislation. The manufacturer should consider its product portfolio, its future pricing strategy, inputs into the cost of developing of the drug that may go into its pricing strategy, and finally, an understanding of products that may still be in the pipeline.

Many manufacturers have also begun to analyze the impact on future business decisions and the potential need to reevaluate pricing strategies as a result of changes in transparency and reporting requirements. For example, some manufacturers may determine that they need to adjust their pricing strategies, while other manufacturers may determine that it's inappropriate to change their future pricing decisions in response to these external factors.

Manufacturers realize that a diverse set of knowledge and skills is required to comply with state price transparency reporting and, consequently, have begun to organize cross-functional workgroups to evaluate enacted and pending legislation. Many manufacturers have found that the nuances of each piece of legislation are addressed more effectively by a cross-functional team.

Establish processes and identify responsibility

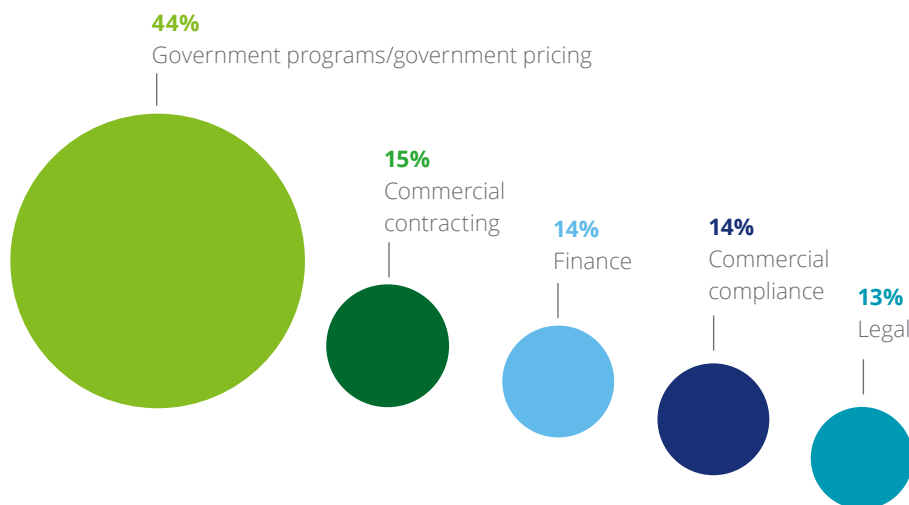
For reviewing state price transparency regulations, many manufacturers have included the following: internal and/or external legal counsel and/or government affairs to interpret legislation, individuals from commercial functions to consider pricing and product pipeline decisions, channel operations to manage customer relationships, and individuals from government pricing to explain and assist with the operational aspects of each piece of legislation. Manufacturers should determine what processes need to be established

and/or if updates to existing processes, documentation, and systems or tools are required as additional states enact further reporting requirements.

While state price transparency compliance requires a cross-functional effort, manufacturers should identify specific responsible parties to own specific tasks (for example, gathering reporting information, submitting reports, and tracking new regulations). Many manufacturers have assigned the government pricing function final responsibility for reporting necessary information for each piece of

Operational consideration:

Which department within your organization is responsible for state price transparency requirements?



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state price transparency law, due to the function's experience and knowledge in operationalizing similar government price reporting requirements.

Operationalize defined processes

In order to comply with new state price transparency requirements, manufacturers need to develop new reporting processes to confirm appropriate information is reported to each of the states. These processes should specify the requirement, the reporting trigger, content needing to be reported, frequency, responsibility (including approver), and recipient(s) for each state report required.

Many manufacturers have begun developing policies and standard operating procedures to support their operations. These documents identify the policies by state and outline functional groups within each organization that are responsible for completing the steps required for compliant reporting. Where legislation may not be

explicit in the timing or manner of reporting, manufacturers have begun to develop reasonable assumptions that will guide their activities related to compliance with specific state legislation.

Develop systems or tools to automate and enhance processes

As new reporting requirements are enacted and continue to be different from state to state, many manufacturers have begun to look into ways to automate state price transparency processes, including having pricing and applicable reporting information in one centralized repository via a system or tool. Manufacturers are developing systems and tools that provide a single-source, integrated solution that contains relevant historical and current commercial pricing information, can run pricing scenarios, generates reports and information required to report to relevant states, and acts as workflow management around both pricing approvals and state price transparency approvals.

Monitor reporting and continuously evolving regulations

As an increasing number of states continue to pass legislation, it will become increasingly difficult to analyze the impact of each regulation and the anticipated implementation timelines. Manufacturers should assign responsibilities to support the ongoing monitoring and tracking of compliance. This includes monitoring existing regulations that may not apply to a manufacturer's business at the time of implementation. Some states have passed additional legislation that expands the scope of existing regulations. For example, Nevada expanded the scope of its existing regulations for diabetes drugs to include asthma medications. Manufacturers can create templates to support the delivery of periodic status reports to internal, cross-functional stakeholders or committees to promote awareness and inclusion across the organization.



Navigate the impact on business operations and mitigate compliance risk

How Deloitte Risk & Financial Advisory can help

Tailored offerings

The complexity of each piece of legislation, as well as the potential operational impact for each manufacturer, can vary significantly. While large manufacturers may have available staff and resources to monitor regulations and develop systems and tools, their complex organizational structures may lead to a greater variety of compliance risk. Conversely, small manufacturers typically have fewer resources available to dedicate to monitoring and may need to explore other options to remain compliant with state price transparency regulations.

Manufacturers should also clearly understand what triggers each regulation. For example, some of the enacted laws target subsectors in the pharmaceutical industry, such as generic and off-patent drugs, specific disease states, or products with high WAC prices, while others are more general and will likely affect many manufacturers. Additionally, some states will only require reactionary action, whereas others will require proactive monitoring of price increases and new product launches. Manufacturers should consider the nuances of their business and product portfolio as they design solutions to comply with state price transparency regulations.

Operational readiness and assessment

Deloitte Risk & Financial Advisory can assist manufacturers with an initial assessment through the development of operational readiness documents that can help them understand the implications

to their business and document ways to operationalize the requirements in a compliant and timely manner. The complexity and uniqueness of each piece of state legislation requires individual analysis, process, and documentation. Thus, operational readiness documents may vary by state and by reporting requirement. These operational readiness documents typically address the following for each of the enacted state reporting requirements:

- The impact of each state's reporting requirements on a manufacturer's existing and future business
- Operational considerations, including updates needed to current processes, documentation, and systems
- Controls for monitoring commercial decisions for activity that may trigger specific reporting requirements
- Operational roadmap and process flow outlining operational changes once each requirement is triggered

Documentation (policies, procedures, and reasonable assumptions)

Deloitte Risk & Financial Advisory assists manufacturers in the development of policies that document the reporting requirements by state; information that is requirement to be reported; and required, reasonable assumptions. Additionally, Deloitte Risk & Financial Advisory works with manufacturers to help them develop standard operating procedures that outline detailed operational steps and responsible individuals for each state reporting requirement.

Deloitte Risk & Financial Advisory can assist manufacturers in navigating enacted state requirements and in understanding the potential short- and long-term operational impacts and considerations.

Systems and tools

Deloitte Risk & Financial Advisory assists manufacturers in developing systems or tools that contain relevant pricing information and can run pricing scenarios, generate reports and information required to report to relevant states, and act as a workflow management around pricing approvals and state price transparency approvals. Features of these systems and tools can include the ability to calculate price-increase scenarios based on cumulative price-increase reporting requirements and differing interpretations, generate reports based on state-specific requirements, and provide notifications that reports are ready to be reviewed and need approval.

Ongoing support

As new legislation is proposed and enacted, Deloitte Risk & Financial Advisory can help manufacturers in evaluating the legislation and assist with operationalizing data-gathering and reporting requirements.

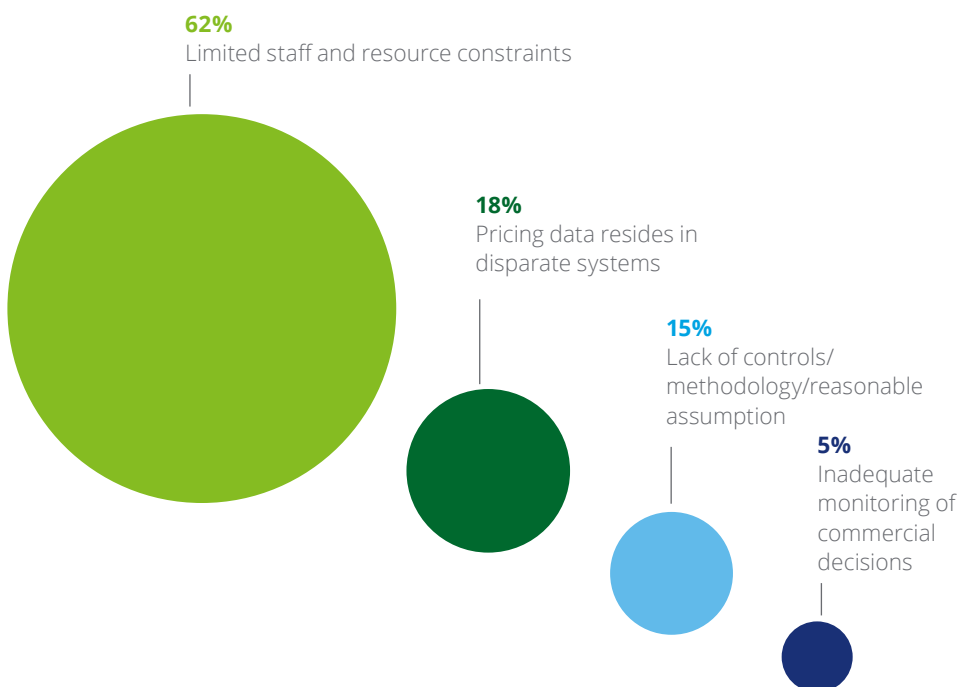
We can proactively assist in the development of controls that can decrease the workload for each new piece of legislation. The following templates can be developed with a manufacturer's specific business needs to help comply with current legislation and to prepare for future legislation:

- Templates to support the ongoing monitoring and tracking of compliance with each applicable state regulation
- Templates to support the delivery of periodic status reports to the manufacturer's cross-functional team and project leader
- Price-increase scenario reports
- Assistance with ongoing reporting



Operational consideration:

Which risk factor causes the most operational strain?



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