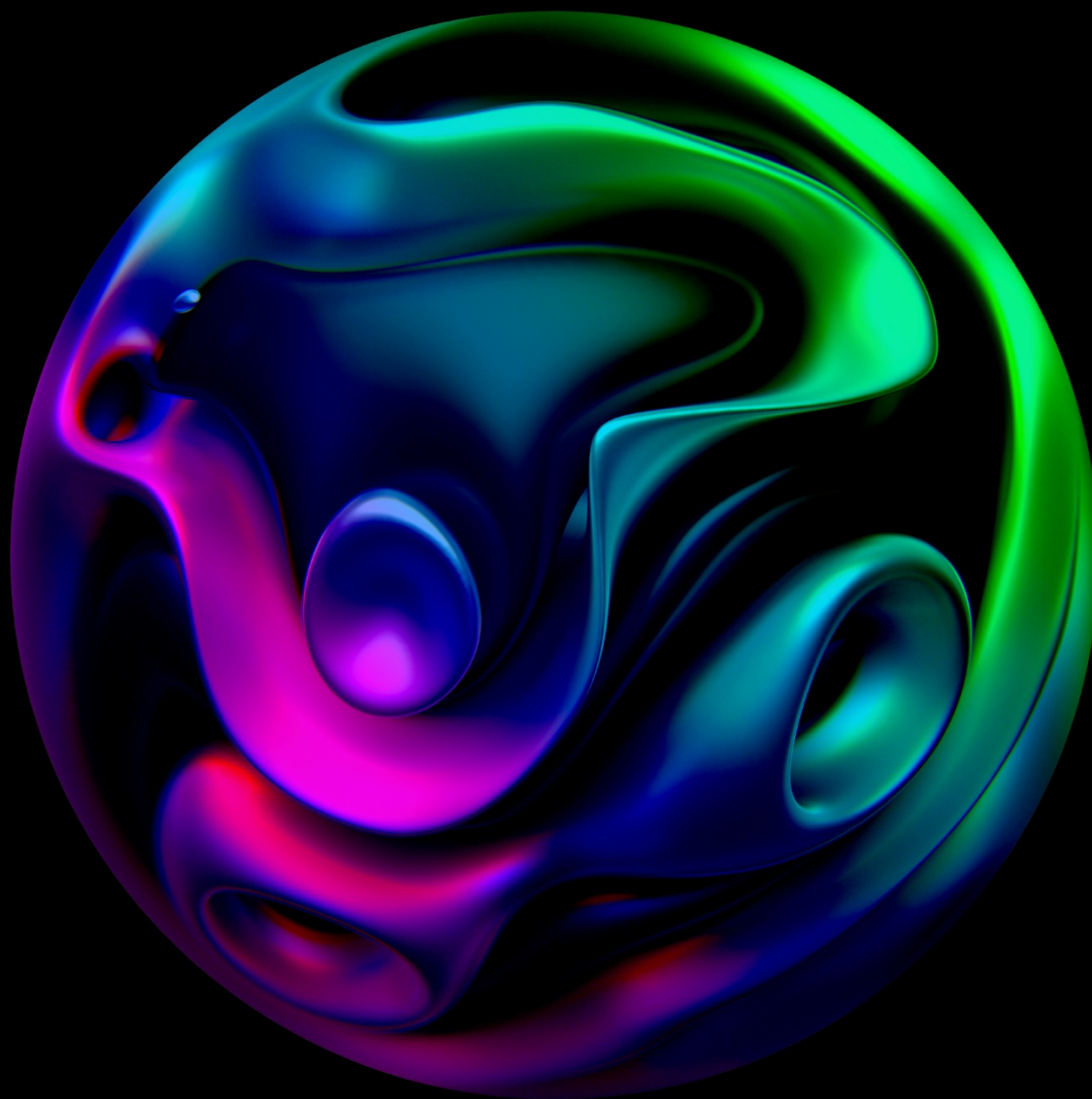


Deloitte.



**New and changing
state price transparency regulations**

How can pharma manufacturers keep up
and scale operationally in 2022?

Current environment

Over the last five plus years, an increasing number of US states have passed—or are in the process of passing—new regulations designed to increase pricing transparency associated with pharmaceutical manufacturers.

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 enact legislation and expand beyond existing requirements, it will be important for pharmaceutical manufacturers to understand the implications for their current and future business operations.

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.
- **Periodic reports:** Manufacturers that sell or market drugs in certain states are required to periodically report WAC pricing and other drug information to the state.

- **New drug reporting:** Manufacturers that launch a new drug product at a price that exceeds a specific threshold (WAC at launch exceeds the Medicare Part D specialty drug threshold) are required to report WAC pricing and other drug information to the state.
- **Price/information 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).

Several state laws require manufacturers to report on certain types of drugs identified by the state (e.g., high-cost drugs or drugs with significant state spending). Reporting under these requirements is either initiated by the manufacturer in response to the state lists and requirements or in response to direct outreach from state boards/agencies.

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

Updates to existing regulations

In addition to newly enacted laws, many states with laws already in place have and are expected to continue to release additional guidance and information that manufacturers need to be aware of to update state price transparency operations and processes regularly. This specifically includes creation of electronic portals for pricing submission or releasing sub-regulatory guidance, including but not limited to, FAQs, user manuals/guides, and webinars.

Over the past five plus years, an increasing number of states have enacted new state price transparency legislations or amended current legislations to address prescription drug costs and spending, which poses operational challenges for manufacturers to establish and maintain an efficient process to remain compliant with the legislative requirements. It is important for pharmaceutical manufacturers to understand the requirements and the implications for their 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 \$25,000 per violation for noncompliance¹.

Over the past two years, states have begun imposing fines as well as amending current regulations to include penalties. In October 2019, Nevada Department of Health and Human Services fined 21 pharmaceutical companies a total of \$17.4 million for failing to provide the state with explanations for recent price hikes on a set of diabetes drugs with penalties ranging from \$735,000 to \$910,000². In 2020, the California Office of Statewide Health Planning & Development (OSHPD) began enforcing drug price transparency laws that the state had passed in 2017, with a number of pharmaceutical manufacturers being notified that they could face fines totaling approximately \$17.5 million for failing to comply with the reporting requirements³. Manufacturers should clearly understand the importance of having the appropriate infrastructure in place for compliance with state drug price transparency laws.



¹ Certain states' potential penalties can reach \$25,000 per violation. For example, noncompliance with the New Hampshire annual new drug notification requirements may result in a fine that may not exceed \$25,000 for any one occurrence. <https://legiscan.com/NH/text/HB1280/id/2194044>

² Nevada levies \$17 million in fines on drug companies for noncompliance with diabetes drug transparency law," *The Nevada Independent*. <https://thenevadaindependent.com/article/nevada-levies-17-million-in-fines-on-drug-companies-for-noncompliance-with-diabetes-drug-transparency-law>

³ California fines more than a dozen drug makers for not providing drug pricing data," *STAT News*. <https://www.statnews.com/pharmalot/2020/04/28/california-drug-prices-transparency-nevada/>

Potential operational challenges

State price transparency reporting legislation is not consistent across states and this poses an increase in operational challenges for manufacturers to remain compliant in accordance with new and changing legislation that varies state to state.

Complexity and disparate nature of ever-changing regulations

State price transparency reporting is inconsistent across states and often involves legal interpretation of requirements to understand the intricacies and develop reasonable assumptions to help support compliant state price transparency reporting.

Penalties for noncompliance

Noncompliance with reporting requirements may lead to fines and/or penalties.

Ability to scale existing processes

Manufacturers are primarily performing processes manually (e.g., in spreadsheets and outside of a system solution) and should consider implementing a scalable and adaptable tool to help manage future state price transparency reporting.

Lack of consistent processes and systems

Manufacturers tend to struggle to develop consistent approaches for complying with state-specific reporting requirements and often do not have tools or systems in place to facilitate end-to-end trigger assessment and reporting processes.

Limited staff and resources

Manufacturers generally do not have enough full-time state price transparency resources who have defined roles and responsibilities to maintain compliance with enacted and ongoing legislations.

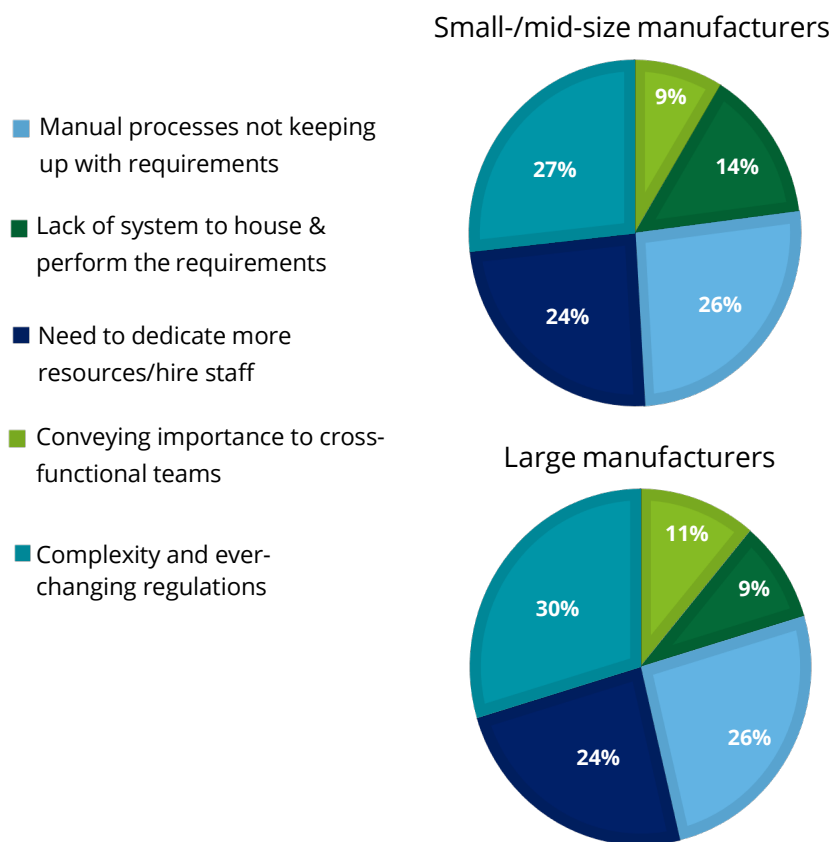
Integration with broader pricing strategy

Pricing strategy decisions are important and the ability for manufacturers to include state price transparency reporting requirements into that process can maximize efficiencies.

Reputational and competitive impact

Manufacturers should consider the impact of reported prices being available to the public—including potential competitive advantage challenges and public relations issues.

What is the biggest operational challenge related to the increasing requirements?



Source: Responses to registration questions for the 6/3/2020 webinar "Take control of drug price transparency reporting: operational considerations as states continue to enact new laws in 2020."

Our perspective

How can manufacturers build effective and efficient processes, leveraging technology and other solutions?

Today, most manufacturers have already evaluated the various state price transparency laws and created processes—along with some form of documentation—to comply with reporting requirements. However, because of the evolving complexity and cross-functional nature of the capabilities necessary to interpret and assess requirements (and provide the required reports), the people involved are under tremendous strain. Also, different functional areas are not always fully aligned on what is needed (and when) in order to meet the individual state deadlines. In addition, most state price transparency processes remain highly manual, and many pharmaceutical manufacturers are hoping that there are automated systems and advanced tools that could help them rethink their overall governance and operations related to state price transparency reporting. Therefore, many manufacturers have been looking into ways to automate and enhance the processes by integrating technology and analytics into the following aspects:

Automated system

Reporting requirements are complex, rapidly evolving, and often are a challenge to scale with current business changes. 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 should consider deploying automated solutions, including systems and tools, to handle the end-to-end process of evaluating applicability, loading pricing and product data, assessing triggers, and generating reports for review or submission. The solutions should also be scalable and adaptable as the legislative environment changes. This can help manufacturers stay compliant with state price transparency requirements, streamline the processes, and help reduce the burden of limited staff and resources.

Centralized location of all information

Manufacturers working with counsel, should document the interpretations of the laws and reasonable assumptions to enable a consistent understanding of the legislative requirements across functional groups. Manufacturers should also consider building a centralized repository and/or an integrated solution to store the state price transparency laws, along with business and legal interpretations and other supporting information provided by the states, so that they can be leveraged for reporting. In addition, the historic submissions to each state should also be cataloged and stored for record retention.

Pricing strategy modeling

Some states publicly disclose information and data that is submitted to them for state price transparency. The effects of this have both a reputational and competitive impact on the

manufacturer. Therefore, 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. In fact, many manufacturers have also begun to maximize efficiencies by integrating pricing decisions to include state price transparency reporting requirements. To facilitate pricing strategy decisions, manufacturers should consider developing a solution to optimize pricing decisions with analytics capabilities, such as automating cumulative price revision calculations, which can provide trend analysis of product price revisions.

Workflow management

Manufacturers generally do not have full-time state price transparency resources who have defined roles and responsibilities to maintain compliance with the state price transparency requirements, so the functional groups within each organization tend to take turns in completing the related activities. The lack of dedicated staff could potentially lead to failure to report information on time or know where certain resources are within the process of reporting. Also, sometimes not all filings to the states have gone through appropriate internal reviews and approvals, posing a risk of submitting inaccurate and/or unintended information to the states. Therefore, manufacturers should consider leveraging technology to assist in managing the workflow, including but not limited to report preparation, reviews, and approvals, to identify and send reminders to the accountable/responsible party for each task and help manufacturers keep on top of key upcoming milestones.

Periodic compliance check

Given this has been around for over 5 year now and the associated compliance risks and fines, manufacturers should be aware of key risks and know that they have demonstrated appropriate level of due diligence to comply with reporting requirements. Manufacturers should have an effective program in place to evaluate, report, and comply with all of the reporting requirements. This includes having oversight of the program, proper review and certification of the reports submitted, and having documentation around the program.

Enhance operations and mitigate compliance risk

How Deloitte Risk & Financial Advisory can help

Compliance risk assessment

Deloitte Risk & Financial Advisory can assist manufacturers with a compliance assessment to review a manufacturer's state price transparency environment to evaluate and understand the manufacturer's due diligence and good faith effort, while helping the manufacturer understand if it has the capabilities to support a compliant state price transparency environment. Its intent is to identify potential risk and exposure related to state price transparency reporting, applicability with requirements, reporting submissions, processes, responsibilities, governance, documentation, oversight, and accountability.

Operational readiness assessment

Deloitte Risk & Financial Advisory can assist manufacturers with performing an operational assessment that can help 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 strategies
- 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 creation (policy, procedure, reasonable assumptions)

Deloitte Risk & Financial Advisory assists manufacturers in the development of policies, procedures, and reasonable assumptions that document the reporting requirements by state, information that is required to be reported, operational steps and responsibility of individuals for each state reporting requirement, and anything that is interpretive either in the requirements or reporting.

System evaluation and implementation support services

Deloitte Risk and Financial Advisory assists manufacturers with evaluation of system vendors and assistance as they implement their state price transparency systems. It helps provide project management and implementation assistance services including evaluating that requirements are transferred from policy to system and it is configured and tested appropriately.

Tools, templates, and ongoing assistance

Deloitte Risk & Financial Advisory assists manufacturers in ongoing assistance including updates on changing state laws and regulations, developing tools and templates that can run pricing scenarios, assist with tracking reporting requirement due dates, and generate reports and information required to report to relevant states. Features of these tools and templates can include the ability to calculate price-increase scenarios based on cumulative price-increase reporting requirements, stay on top of upcoming due dates, and generate reports based on state-specific requirements.

Start the conversation

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