State price transparency reporting
Maintain compliance and operational readiness as regulatory pressure builds
Recently, an increasing number of reporting regulations have been introduced at the US state, county, and city levels to address prescription drug costs and spending. These changes have further complicated the regulatory landscape and pricing pressures, leading to the need for greater transparency and additional reporting capabilities.
State price transparency reporting | Maintain compliance and operational readiness as regulatory pressure builds

Current environment

In recent years, an increasing number of US states have passed—or are in the process of passing—new regulations designed to limit drug costs by requiring reporting on drug prices and drug price increases. This legislative push has largely been in response to the industry trend of increasing Wholesale Acquisition Cost (WAC) prices and the inability of drug pricing legislation to be passed at the federal level.

States have determined that it’s in their interest to take legislative action in order to curb drug price increases and to decrease their annual pharmaceutical spend as a result. It’s likely that this type of legislation will continue as more states seek to control the cost of pharmaceuticals in their annual budget.

There are two general types of regulations that have been increasing in frequency among the states: (1) transparency reporting requirements for activities and payments to health care providers and organizations and (2) state price transparency reporting requirements. There are distinct reporting and notification requirements for these two types of regulations. Manufacturers already familiar with government price and aggregate spend reporting can leverage synergies for these new requirements based on the processes they may already have in place.

Transparency reporting requirements for interactions with health care providers (HCPs)
HCP transparency legislation generally focuses on payments or other transfers of value from manufacturers and group purchasing organizations (GPOs) to HCPs. State aggregate spend compliance and reporting laws have been in effect for many years. The Physician Payment Sunshine Act was enacted in 2013 at the US federal level, and many manufacturers were expecting this law to simplify reporting and perhaps even replace state reporting requirements.

However, these expectations have not been fully realized (with the exception of federal pre-emption for physician-level prescribers). And states are adding to the complexity by expanding current regulations or introducing new laws that implement new reporting obligations and enforce prohibitions on activities and spending. As a result, there are significant increases to the administrative and operational burden, as well as to the overall cost of compliance. The requirements and timing of reports are not the same from state to state, and states’ reporting requirements differ from the federal Physician Payment Sunshine Act requirements.

State price transparency reporting requirements
State price transparency reporting legislation generally focuses on delivering specific commercial or statutory prices to the state in a prescribed manner and timing. The requirements of recently enacted legislation are similar to the historical requirements in Texas, New Mexico, and Vermont that focus on federal price types (i.e., Average Manufacturer Price or “AMP”). While most of the recent legislation is focused on WAC and increases in WAC, it’s important for manufacturers to understand these existing requirements and the processes for complying with each. Similar to the historical reporting required in the above-mentioned states, newly enacted regulations will require documentation, processes, and controls to enable reliable and consistent price reporting.

While some states have noted that this pricing information will be kept confidential, others have announced that this information will be published on public websites.

Several of these regulations have reporting requirements that go beyond the traditional reporting of statutorily-defined price types. While some states have noted that this pricing information will be kept confidential, others have announced that this information will be published on public websites. The impact to manufacturers is that drug price information will now be available to state agencies, and potentially to other manufacturers and consumers.
Potential challenges and complexities

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

Many of the reporting requirements have been designed to increase insights into pricing decisions and manufacturer interactions with HCPs through reporting, with no direct state action required as a result of the reports. Other regulations, such as regulation passed in New York (NY SB 2007), ties drug spending to additional requirements. For example, this New York law requires manufacturers of “high spend drugs,” which are identified by the state, to negotiate additional supplemental rebates. If a manufacturer is unable to negotiate a rebate with the New York state Medicaid department, its products may be subject to additional penalties including removal from managed care formularies, additional prior authorization requirements, or promotion of alternative “cost-effective” drugs.

Another example of increasing complexity for HCP-related transparency reporting is Nevada’s new law (SB 539), which combines state price transparency and HCP transparency into one new law. It imposes obligations for price reporting, annual registration of a manufacturer’s sales representatives, and the obligation to submit a report on payments made to HCPs by sales representatives operating in the state. The annual activity report is due on March 1 for payments made in the prior calendar year (Jan 1–Dec 31).

This law overlaps with existing Nevada legislation requiring annual submission of the AB128 form, Certification of Completion of Annual Audit Monitoring Compliance with Code of Conduct for Manufacturers and Wholesalers of Drugs, Medicines, Chemicals, Devices, or Appliances. The AB128 form requires manufacturers to certify that they have audited their payments and other transfers of value to Nevada-licensed HCPs and to submit the form by June 1 of each year. The timeframe for transactions included in the audit is from May 1 of the previous year to April 30 of the current year, which is different than the new legislation’s timeframe for activity reporting.

Adding to this complexity is the difference in applicability—Nevada’s pricing transparency law applies to pharmaceutical manufacturers. The AB128 form applies to a broader set of manufacturers and wholesalers as stated in the form’s title.

Similar to how the Centers for Medicare and Medicaid publishes HCP transactional data on its Open Payments website, many states plan to publish manufacturers’ WAC information online. Therefore, manufacturers will need to address the complexities that may result from reported prices being available to the public. This may create competitive challenges, public relations issues, and potentially provide information that could be misinterpreted. These types of challenges will have to be understood in order to respond to the regulations and act in a compliant manner.

One example of these complexities is a recently enacted law in California (CA SB176). Under this law, manufacturers are required to submit notification of price increases 60 days prior to the anticipated change. Effective January 1, 2019, this requirement will obligate manufacturers to develop reasonable assumptions surrounding price increases that may occur within the first 60 days of 2019. Manufacturers will need to develop a consistent methodology for complying with this requirement.
Recently enacted and pending state legislation

The following is a selection of states that have recently enacted or expanded state price transparency and HCP transparency reporting and compliance requirements. These laws are in addition to current state legislation.

Recently enacted and pending state price transparency legislation as of November 1, 2017

Responding to rapidly rising drug costs, more than 60 state price transparency reporting regulations are pending approval or have been approved for the purposes of:

- Revealing the factors that contribute to drug list prices and price increases
- Identifying trends in price increases over specific time periods and for certain classes of drugs

Regulations in effect + pending legislation

Pending potential regulation

Regulations in effect
<table>
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<tr>
<th>State law</th>
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<tr>
<td>California</td>
<td>Pricing transparency</td>
<td><strong>State price transparency</strong> Requires advance notification and reporting of price increases (&gt;16 percent WAC) as well as commercial data reporting for new drugs whose WAC exceeds the Medicare Part D specialty drug threshold. HCP transparency Establishes significant limitations on activities and annual spend limits per HCP.</td>
<td>SB 17 enacted October 2017 SB 790 pending</td>
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<td>SB 17; SB 790</td>
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<td>Illinois (Chicago)</td>
<td>Pricing transparency and HCP transparency</td>
<td><strong>State price transparency</strong> Requires notification of WAC increases or launch of new products with a 12-month WAC exceeding a certain threshold. Thresholds vary for brand and generic drugs. HCP transparency Representatives who market or promote products to HCPs in the city of Chicago in classes listed at CDPH's website must report to prescribers. Representatives must pay an annual fee and meet certain continuing education requirements to be eligible to register.</td>
<td>SO2016-7983 enacted November 2016; O2017-4915 introduced June 2017</td>
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<td>Ordinances SO2016-7983 and O2017-4915</td>
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<td>Louisiana</td>
<td>Pricing transparency</td>
<td><strong>State price transparency</strong> Manufacturers who market to prescribers must report the current WAC for drugs marketed in the state (quarterly); will be published to state website.</td>
<td>Enacted June 2017</td>
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<td>SB 59; HB 436</td>
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<td>Maine</td>
<td>HCP transparency</td>
<td><strong>HCP transparency</strong> Prohibition on gifts to health care practitioners. Certain exclusions apply. Rules for compliance certification or report submission are expected in early to mid-2018.</td>
<td>Enacted June 2017</td>
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<td>LD 911</td>
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<td>Maryland</td>
<td>Pricing transparency</td>
<td><strong>State price transparency</strong> Prohibits price gouging in the sale of an essential off-patent or generic drug; authorizes notification to the Attorney General of an “excessive” increase in the price of an essential off-patent or generic drug.</td>
<td>Enacted April 2017</td>
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<td>HB 631</td>
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<td>Missouri</td>
<td>HCP transparency</td>
<td><strong>HCP transparency</strong> Gift ban; certain exclusions apply.</td>
<td>Pending</td>
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<td>House Bill No. 1021</td>
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<td>State law</td>
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<td>Nevada</td>
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<td><strong>State price transparency</strong>&lt;br&gt;Annually, the Nevada Department of Health will compile a list of essential diabetes drugs for which manufacturers must provide certain information related to pricing. Pharmacy Benefit Managers must provide certain information on rebates on an annual basis.</td>
<td><strong>Enacted June 2017</strong></td>
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<td>SB 539</td>
<td>HCP transparency</td>
<td><strong>HCP transparency</strong>&lt;br&gt;Manufacturers must provide a list pharmaceutical sales representatives operating in Nevada annually; representatives must report providers/entities that receive compensation in excess of $10 per transaction or $100 in aggregate and free samples. It’s unclear how federal pre-emption will be applied due to differences in threshold amounts. Nonprofit organizations must provide information on contributions received from specific types of organizations and the percentage of total gross income attributable to those contributions.</td>
<td><strong>Pending</strong></td>
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<td>New Jersey</td>
<td>HCP transparency</td>
<td><strong>HCP transparency</strong>&lt;br&gt;Establishes a $10,000 cap on the dollar amount that a prescriber can accept from pharmaceutical manufacturers in a calendar year for bona fide services; defines prohibited and permitted gifts and payments; extends definition of “prescriber” to advanced practice nurses, dentists, and optometrists.</td>
<td><strong>Pending</strong></td>
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<td>New York</td>
<td>Pricing transparency</td>
<td><strong>State price transparency</strong>&lt;br&gt;Establishes an annual projected target for Medicaid pharmaceutical spend and identify drugs that disproportionately contribute to annual spend; if manufacturer does not agree to supplemental rebates, the drug could be subject to transparency reporting, prior authorization, or other restrictions; large increases to AMP will be targeted.</td>
<td><strong>Enacted April 2017</strong></td>
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<tr>
<td>Vermont</td>
<td>Pricing transparency</td>
<td><strong>State price transparency</strong>&lt;br&gt;Requires the state to identify up to 15 drugs on which the state spends significant dollars; manufacturers must submit justification for price increases (&gt;50 percent WAC). Requires pharmaceutical marketers to provide doctors with comparative price information (long and short forms)—note these forms use AWP.</td>
<td>SB 216: enacted May 2016&lt;br&gt;18 V.S.A. § 4633: enacted in 2003 and amended most recently in 2012</td>
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Lead your industry through the forces of change

How are manufacturers responding?

**Tracking and assessment**

Many manufacturers have begun tracking and reviewing both pending legislation to understand the likelihood of them being enacted and the enacted legislation to understand the new requirements. Due to the unique nature of each piece of legislation, manufacturers should consider starting with the state laws that were enacted and require reporting to 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 the drug that may go into its pricing strategy, and finally, an understanding of products that may still be in the pipeline.

**Cross-functional considerations**

Manufacturers realize that a diverse set of knowledge and skills are 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.

For state price transparency law review, many manufacturers have included 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 the operational aspects of each piece of legislation.

For HCP transparency law review, many manufacturers are likely to depend on compliance and legal counsel. These teams have also been tasked to determine what functional area(s) need to be involved.

Many manufacturers have concluded that the government pricing function should have final responsibility for compliance with each piece of state price transparency reporting due to the function’s experience and knowledge in operationalizing similar requirements. Similarly, the compliance function is typically assigned responsibility for HCP transparency reporting.

Deloitte Risk and Financial Advisory can assist manufacturers in navigating enacted state requirements and in understanding the potential short- and long-term operational impact and compliance considerations.
Reporting methodologies
In order to comply with new state requirements, manufacturers are likely to need to develop new reporting methodologies. These methodologies should specify the type, content, frequency, and recipient(s) for each report required. Additionally, the methodologies and reasonable assumptions should be tailored to each state requirement. Many manufacturers have begun developing policies and standard operating procedures to support the required methodologies. These documents identify the functional groups within each organization that are responsible for completing the steps required for compliant reporting.

Pricing strategy design
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 in order to stay below statutory thresholds for reporting, while other manufacturers may determine that it’s inappropriate to change their future pricing decisions in response to these external factors.

Reasonable assumptions
Finally, 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. As with reasonable assumptions that manufacturers have developed in response to the other government agency reporting, legal counsel will likely need to drive development of the assumptions to determine what will make sense for their business given the intent of the legislation.
Navigate the impact on business operations and mitigate compliance risk

How Deloitte Risk and Financial Advisory can help

Tailored solutions
The complexity of each piece of legislation, as well as the potential operational impact for each manufacturer, can vary significantly. While some of these laws target sub-sectors in the pharmaceutical industry, such as generic and off-patent drugs or products essential for treating diabetes, others are more general and will likely affect many manufacturers. Some states, such as New York, will only require reactionary action; whereas others, such as California, will require proactive monitoring of price increases and new product launches. It’s also important to note that some of the new HCP transparency laws target pharmaceutical manufacturers, contrasting with other states that require reporting from both pharmaceutical and medical device manufacturers.

Defined roles and responsibilities
Deloitte Risk and Financial Advisory can assist clients in identifying impacted departments or functions to determine whether existing roles and responsibilities meet the state reporting requirements. While reporting will likely require a cross-functional effort, it’s a leading practice that ownership and responsibility of currently enacted state reporting requirements should reside within an organization’s government pricing (GP) function. GP professionals typically have the skills to aggregate and gather commercial pricing data needed for statutory price reporting. These professionals also have experience with policies and methodologies for consistent and correct price reporting. Additionally, the GP function may be able to leverage the documentation and processes that they already have in place for other state price reporting obligations that have been in place for years (i.e., Texas, New Mexico, and Vermont reporting requirements mentioned earlier in this paper).

When assigning roles and responsibilities for HCP transparency reporting and data capture processes for the associated transactional data, there’s more flexibility to spread the day-to-day responsibilities across several functions. However, it’s a leading practice that the compliance function should retain responsibility for compliance with regulatory reporting timelines and attestation to report content.

Operational readiness
Deloitte Risk and Financial Advisory assists manufacturers in the development of operational readiness documents that can help them understand the implications to their business and operationalize the requirements in a compliant and timely manner. The complexity and uniqueness of each piece of legislation requires individual analysis and documentation. Thus, operational readiness documents will vary greatly by state and by reporting requirement. These operational readiness documents may 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
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Policies and standard operating procedures
Deloitte Risk and Financial Advisory assists manufacturers in the development of policies that document the reporting requirements, reasonable assumptions, and high-level reporting steps. Additionally, Deloitte Risk and Financial Advisory works with manufacturers to develop standard operating procedures that outline detailed operational steps and responsible individuals for each state reporting requirement.

Ongoing support
In response to rapidly rising drug costs, and due to the absence of federal intervention in this area, it's likely more states will continue to attempt to regulate pharmaceutical pricing. As new legislation is proposed and enacted, Deloitte Risk and 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 tools and 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
- Ongoing monitoring and implementation support

Transparency Managed Risk Services
Deloitte Risk and Financial Advisory also offers a managed risk service that includes the areas mentioned above. Our offering is designed to help manufacturers manage the reporting process, reduce the impact of changing legislation on internal business operations, and help mitigate compliance risk. It includes:

- Managed risk services and custom transparency reporting solutions
- Effective project management for status updates, business insights, regulatory updates, and operational and technical engagement oversight
- Active data monitoring for trends and identification of new and potential threshold-based reporting requirements
- Policy and procedural documentation to establish program governance and methodologies
- Training programs and reference materials

In response to rapidly rising drug costs, and due to the absence of federal intervention in this area, it’s likely more states will continue to attempt to regulate pharmaceutical pricing.
Endnotes

1. Section 6002 of the Patient Protection and Affordable Care Act (Public Law No. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Public Law No. 111-152)
2. Texas TAC 354.1921(a)(c)(1)), Addition of Drugs to the Texas Drug Code Index
3. New Mexico HB666, Reporting Prescription Drug Information Act
4. Vermont S.216 (Act 165), An act relating to prescription drugs
5. New York SB 2007, Regulation Modernization
6. California SB 17, Health care: prescription drug costs
7. Nevada SB539, Revises provisions relating to prescription drugs
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