Drug Price Disclosure Legislation

Four steps to staying ahead and staying compliant

Many states have moved to enact mandatory pharmaceutical price disclosure laws that would increase price transparency to address prescription drug costs (Fig. 1, pg. 3). In 2018, states continued that trend, with 41 states having proposed plans to lower drug costs, including 23 considering transparency legislation. Among the six states that passed legislation in 2018 were California and Oregon, notable not only for the pharmaceutical industry but also for the clients we serve.

The federal and state governments, holding differing views, have clashed over how to address prescription drug costs, leading legislators to propose hundreds of state laws aimed at lowering the cost of prescription drugs.

Price disclosure laws, while not directly targeted at lowering costs, will require transparency for certain price increases, which will reveal whether pricing has more to do with an assumption about a palatable price point than a pricing strategy based on science. These laws also may lead to increased pharmaceutical market competition.

In this paper, we will look at new laws in California and Oregon and what they require, as well as what manufacturers can and should do about this growing trend to remain compliant.

**Price Disclosure Law in California**

California passed Senate Bill 17, a law that states any manufacturer of a prescription drug must report, 60 days in advance, price increases over 16% (including the current year and previous two years) to all health insurers and government health plans in the state of California.

The manufacturer must include the date of the increase, the current wholesale distribution cost (WAC), and expected amount of the increase. A reason for the increase must be given, including whether a change or improvement requires it. All information is posted online for public view.

Other requirements include mandatory reporting for all new products with a WAC of over $670 (for a monthly supply) within three days of launch.

According to biopharmaceutical research company PhRMA, California voters care more about access to care and quality coverage than they do about prescription drug price transparency. However, any pricing-related legislation has the potential to effect more legislation and thus more need for manufacturers to understand what’s required to remain compliant.
**Price Disclosure Law in Oregon**

Oregon passed House Bill 4005, a law requiring manufacturers to report price increases on drugs with a WAC of $100 or more for a one-month supply, or a treatment lasting less than one month with a WAC that increases by 10 percent or more over the previous calendar year.

HB 4005 is considered the most far-reaching among drug pricing transparency legislation passed in 2018, with substantial implications for manufacturers.

Reports from manufacturers must include:
- Contributing factors for the price increase
- Costs for marketing, manufacturing and distribution for the prescription drug
- Costs for ongoing research related to drug safety and effectiveness
- The prescription drug's profit the previous year
- The prescription drug's 10 highest prices paid outside of the U.S. the previous year
- Supporting documentation

In addition to several other filing requirements, manufacturers must report to Oregon's Department of Consumer and Business Services within 30 days of introducing a new prescription drug for sale in the U.S. with a cost exceeding the Medicare Part D threshold for specialty drugs. For 2019, that cost is $670 per month.

This legislation also includes a temporary 18-member task force created to develop strategies for price transparency across the pharmaceutical product supply chain.³

Lastly, public disclosure in Oregon is unlike other transparency laws. HB 4005 requires the Oregon Department of Consumer and Business Services to publish online all information reported except in limited cases.⁴

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**Effects of Legislation**

It's difficult to say exactly what effect laws related to price transparency will have. Generally speaking, we believe more legislation aimed at lowering costs is forthcoming.

As of this writing, Senate Bill 5292 was making its way through Congress. This effort to increase transparency in drug pricing for the state of Washington just became law.

SB5292 is almost a blend of California and Oregon price disclosure laws with an apparently higher increase threshold and higher WAC thresholds for reporting new products. The bill proposed a WAC of $10,000 or more for new products and an increase threshold of 20 percent or more, including the prior two calendar year increases. Reporting obligations for manufacturers in Washington begin October 1, 2019.

Among additional aspects of SB5292:
- Drug manufacturers would be required to list justification of price increases to the Washington Healthcare Authority (HCA).
- Health insurance companies and pharmacy benefit managers would need to provide the HCA a list of drugs that are most frequently prescribed and costliest, and have the highest increases year over year.

Some states are exploring other means to address price transparency or control, such as adding proposals on public ballots.

Beyond the probable continued legislation around price transparency, it's likely that some legislation may produce unintended consequences.
For instance, transparency laws in California, Oregon and elsewhere require disclosure of the WAC. Reporting requirements are tied to WAC increases. However, the WAC doesn’t include rebates and might not correlate to the price insurers pay. Will this lead only to more legislation designed to publicly reveal net reimbursement rates paid by insurers? It’s one example of what the future might hold.\(^5\)

Not to mention, after the California transparency law took effect, some manufacturers changed course, cancelling price hikes or reducing the price increase. While we can only make assumptions about their rationales, it’s fair to presume that compliance plays a role in decision making.

![Map showing the current state of drug price disclosure legislation in the U.S.](image)

**Fig. 1** This maps shows the current state of drug price disclosure legislation in the U.S.


### Recommendations for Pharmaceutical Manufacturers

We believe legislation addressing drug prices will continue to increase across the country, creating new compliance challenges, thus adding to compliance pressure on pharmaceutical manufacturers.

Laws related to drug prices are not consistent from state to state in terms of which factors trigger a disclosure requirement and what information must be disclosed, as evinced by the differences between California and Oregon laws. Requirements can vary significantly.

Competitive pressures may increase too, as manufacturers may be required to disclose information considered proprietary.

Manufacturers should assess their own processes for complying with current and emerging requirements. Consistently achieving compliance can be a monotonous task with constant potential for error, and a strain on internal resources.
Four Ways to Prepare and Remain Compliant

1. Ensure your compliance department is aware of all state laws requiring price and other information disclosures.

2. Make sure that those tasked with price setting and/or changing are aware of price reporting disclosure triggers.

3. Include as standard in your contract language that requires the customer to notify the company prior to a disclosure of information to a state regarding one of the company’s drugs, and also provide a copy of the actual disclosure.

4. Corporate communications must be aware if the company is required to disclose its pricing and other corporate information and be prepared for media inquiries and potential negative coverage.

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If you’d like additional ideas for how to prepare for the changing environment of price disclosure laws, call us or email your questions to info@prescriptionanalytics.com. We’re here to help you achieve your business objectives.