



Twentieth Annual Pharmaceutical and Medical Device Compliance Congress

*Workshop 3: Navigating Drug
Price Transparency Laws and the
Role of Compliance*

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State Law Overview

(Enacted Laws Only)

Drug Price Reporting and Transparency Laws



- 11+ states have some variation, more likely to follow. Broadly, two types:
 - **Reporting Required**: new drug of a certain price and/or existing drug price increases above a threshold triggers reporting requirements. Some of these reports require disclosure of detailed company information, e.g. cost of marketing the drug
 - **Disclosure Required**: requires disclosure of price to prescribers and the price/name of generics. CO's new law requires this disclosure to be printed and applies to interactions beyond just face-to-face detailing

Drug Price Reporting and Transparency

State laws



Louisiana

Deadline:

Quarterly: Jan.1, April 1, July 1, Oct. 1

Summary:

Drug Cost Transparency, Act 220 (2017)

- Each mfg. or drug marketer must provide BOP with current WAC price of product marketed in the state
- NDC, generic and trade names, form, strength, package size, branded/generic, etc.



New Mexico

Deadline:

Annually: January 15

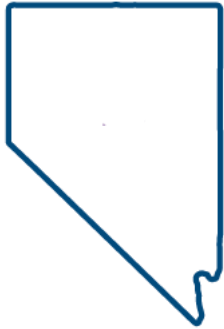
Summary:

Reporting Prescription Drug Information Act, HB 666 (2003)

- Every mfg. that sells drugs in the state must submit pricing info for reporting period July 1st through September 30th (of previous year)
- AMP, price paid by each wholesale or PBM, and price paid by entity that sells drugs without using a wholesaler, etc.

Drug Price Reporting and Transparency

State laws, continued



Nevada

Deadline:

Annually: April 1

Summary:

Diabetes Drug Price Disclosure, NRS 439B.635 (2017)

- Mfgs. of “essential” diabetes drugs must submit a report to NVDHHS including WAC, production cost, marketing cost, total financial assistance through PAPs, all PBM rebates, coupons, annual profit from drug, history of WAC increases, etc.
- If a drug in the list underwent a “significant price increase” a justification must also be submitted



Oregon

Deadline:

Annually: January 15

Summary:

Reporting Prescription Drug Information Act, HB 666 (2003)

- Every mfg. that sells drugs in the state must submit pricing info for reporting period July 1st through September 30th (of previous year)
- AMP, price paid by each wholesale or PBM, and price paid by entity that sells drugs without using a wholesaler, etc.

Drug Price Reporting and Transparency

State laws, continued



Oregon

Deadline:

Annually: January 15

Summary:

Price Increase Transparency Report, HB 4005 (2019)

- Mfgs. must report WAC increase 10% more or during previous calendar year for product >\$100 for month supply/course of treatment
- Must include, among other things: factors contributing to price increase, R&D expenses, revenue from drug, cost incurred to manufacture, marketing costs, other costs, 10 highest cost ex-US, etc.
- If there is a PAP: total # of state consumers participating, cost of program, value of discounts etc., eligibility requirements, etc.
- Must disclose all info and claim **trade secret** protection; no non-public info exemption



New York

Deadline:

State determines

Summary:

Medicaid Drug Cap (2011) and Supplemental Rebates (2018)

- If in a fiscal year, spending exceeds the Medicaid Cap (first implemented in 2011) the review Board makes a recommendation of target drugs. Manufacturers negotiate with DOH for supplemental rebates. If manufacturer does not agree to supplemental rebates, DOH can require reporting on cost of development and other proprietary information.

Drug Price Reporting and Transparency

State laws, continued



California

Deadline:
Ongoing

Summary:

New Drug Price Notification and Report, SB 17 (2017)

- Notify OSHPD within 3 days of introducing new drug at a WAC that exceeds Medicare Part D specialty drug threshold (\$670)
- Within 30 days of the notification, mfg. must submit a report that includes a description of the marketing and pricing plan
- Information may be limited to what is in public domain or publicly available



California

Deadline:
Quarterly: April 30, July 31, Oct. 31, Jan. 31

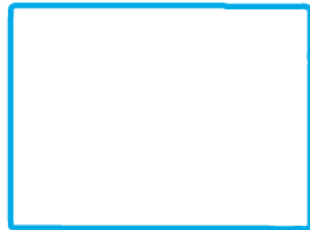
Summary:

Quarterly Price Increase Reports, SB 17 (2017)

- Notify purchasers 60 days prior to WAC increase greater than 16% over previous 2yrs
- File quarterly report that includes NDC, product details, amount of WAC increase, patent information, source of drug, reasons for increase, change/improvements in drugs, WAC increase schedule for previous 5 years, acquisition information, etc.
- Information may be limited to what is in public domain or publicly available

Drug Price Reporting and Transparency

State laws, continued



Colorado

Deadline:

No reporting required

Summary:

Drug Price Transparency Law HB 19-1131 (2019)

- Mfg. representatives must provide the WAC and name of at least 3 generics in writing when conducting drug marketing
- Effective August 2, 2019



Texas

Deadline:

Increase: within 30 days; Annual WAC: Jan. 15

Summary:

Drug Price Transparency Law HB 2536 (2019)

- Report if WAC increases more than 15% in one year or more than 30% over three years with 30 days of increase
- Report not later than Jan. 15 annually the WAC price of all drugs sold in TX
- Effective September 1, 2019

Drug Price Reporting and Transparency

State laws, continued



Washington

Deadline:

Annually: October 1

Summary:

Prescription Drug Pricing, HB 1224 (2019)

- **New drugs**, 30 days prior to release of covered drug (i.e. >10k for 30-day supply)
- **Existing drugs**, 60 days prior to increase notify if cumulative total of increase is greater than 20%; cumulative total over three years is greater than 50%
- Effective October 1, 2019



Maine

Deadline:

Annually: Jan 30

Summary:

Act to Further Expand Drug Price Transparency, L.D. 1162 (2019)

- Brand name: report WAC increase > 20%
- Generic that costs at least \$10: report WAC increase > 20%
- Effective January 30, 2020

Drug Price Reporting and Transparency

State laws, continued



Connecticut

Deadline:

Annually: March 1 (list publication by state)

With 60 days of FDA action date for new drug application

Summary:

An Act Concerning Prescription Drug Prices, HB 5384 (2018)

- State to compile an annual list of 10 prescription drugs with significant impact on statewide health expenditures
- Drug must have WAC increase >20% previous year, or 50% last three years, and >\$60 for 30 day supply
- Must report for public release, all factors leading to WAC increase, R&D, other expenditures, etc.
- Must also notify state of new drug application with 60 days of FDA; report pipeline
- Effective January 1, 2020

Drug Price Reporting and Transparency

State laws, continued



Vermont

Deadline:

Report released on Nov. 5 annually.

Summary:

Prescription Drug Cost Transparency, 18 V.S.A. § 4635 (2017)

- DVHA to compile a list of 10 drugs on which state spends “significant” health care dollars and for which WAC increased by >50% in five years, or >15% in one year
- DHVA must also create a list of 10 drugs on which it spends “significant” health care dollars and DHVA’s net costs have increased by >50% in five years, or >15% in one year
- Manufacturers of drugs on state lists must submit a report that provides a justification for the increase in price with supporting documentation. Report will be released on website.
- Redactions are permitted but they must be accompanied by explanations
- New Drugs: mfg. must notify AG within 3 days of commercial release of a drug that exceeds specialty drug threshold under Medicare Part D (\$670). Within 30 days, the mfg. must follow up with a description of the marketing and pricing plan for us and ex-us. Information on purchase price required, if applicable.

Drug Price Reporting and Transparency

State laws, continued



Vermont

Deadline:
Quarterly

Summary:

Average Wholesale Price Disclosure 18 V.S.A §4633, (2003)

- Pharmaceutical marketers engaged in relevant activities with a physicians/other qualifying persons, must disclose AWP **per pill** of drug marketed and others in therapeutic class
- Forms (long and short) must be updated every 3 months