



Prescription Drug Price Transparency Notice and Reporting Requirements

(Last updated February 21, 2025)

This multi-state compilation gives the requirements for providing notice and reporting price information in states that have enacted laws requiring such information under certain circumstances. The resource provides links to relevant laws, regulations, bulletins, and other helpful websites and materials. Presence of a state board to investigate or review drug pricing is also noted.

The document addresses notice and reporting when it is required for a price increase, marketing of a new drug, or for regular reporting of all drugs or for a subset or list of drugs identified by the state.

Information is included which describes the following components:

- **Trigger** – price threshold for providing notice and/or reporting.
- **Content of Notice** – detailed listing of information to be included.
- **Notice Provided** – department, agency, or others to receive notice and/or reports.
- **Timing of Notice** – deadlines for giving notice.
- **Penalty** – extent of penalties that may be imposed for failure to give notice or report.
- **Registration** – links to online registration systems for manufacturers are provided when available.
- **Report Required** - subset or list of drugs to be included in report, when provided by state.
- **Content of Report** - detailed listing of information to be included and format or forms to be used, if provided.
- **Notes on Content** – limitations on the type of information to be reported.
- **Due Dates** – schedule and deadlines for filing reports.
- **Publication** – posting of reported information by department or agency.

A **Calendar of Due Dates** is also included as a guide for scheduling notices and reports.

This compilation does not constitute a legal opinion or conclusion by the Association for Accessible Medicines (AAM). Users are encouraged to refer to the full text of statutes and regulations for the most current and complete information.

Information updated in the last year is shown in **bold italic.*

CA California	PRICE INCREASE (additional pre-increase notification required)	
<p>Cal. Code, Health and Safety §§127675 et seq. §127677 (Pre-increase Notice) §127679 (Report and Penalties)</p> <p>Cal. Code of Regs. Tit. 22, Div. 7, Ch. 9.5 §96062 (Manufacturer Registration) §96065 (WAC Increase Notification) §96070 (WAC Increase Report) §96071 (Report Due Dates) §96080 - 87 (Penalties)</p> <p>Prescription Drug Pricing and Cost Transparency in California</p> <p>Prescription Drug Cost Transparency Public Reporting</p> <p>Cost Transparency: Prescription Drugs (CTRx) (Links to Datasets)</p> <p>Wholesale Acquisition Cost (WAC) Increase Report Data – Current Year</p> <p>Wholesale Acquisition Cost (WAC) Increase Report Data – Cumulative</p> <p>Quick Guide, Linking the Datasets</p> <p>Format and File Specifications for Submission of Reports</p> <p>HCAi System Registration</p> <p>Prescription Drug Wholesale Acquisition Cost (WAC) Increases – (Data Provided by OSHPD)</p> <p>ctrx@hcai.ca.gov (For Questions)</p>	<p>Trigger WAC > \$40 for course of therapy (30-day supply or course of treatment < 30 days) AND Increase > 16% within previous 2 calendar years.</p> <p>Notice Provided to Registered Purchasers</p> <ul style="list-style-type: none"> o State purchaser o Health care service plan o Health insurer o Pharmacy benefit manager <p>Content of Notice</p> <ul style="list-style-type: none"> o Date of increase o Current WAC o Increase in WAC o Change or improvement necessitating increase <p>Timing 60 days prior to the planned effective date of increase.</p> <p>Penalty \$1,000 per day for failure to report.</p>	<p>Registration On HCAi System Registration 5 days prior to due date of first submission.</p> <p>Content of Report Submit through HCAi SIERA portal</p> <ul style="list-style-type: none"> o The NDC o Description of the drug <ul style="list-style-type: none"> - Name - Strength - Dosage form - Package size o Effective date of WAC increase o Amount of WAC increase and resulting WAC o Financial and nonfinancial factors used for decision to increase WAC o IF MANUFACTURED FOR 5 YEARS <ul style="list-style-type: none"> - Schedule of WAC for previous 5 years o IF ACQUIRED W/IN PREVIOUS 5 YEARS <ul style="list-style-type: none"> - WAC at time of and in calendar year prior to acquisition - Company from which drug was acquired - Date acquired - Purchase price - Year and WAC when drug introduced to market o Patent expiration date o Status as multiple source drug, innovator multiple source drug, noninnovator multiple source drug, or single source drug o Change or improvement necessitating increase o Number of units sold in US for year prior to increase o Additional comments <p>Notes on Content May limit to that in public domain or publicly available.</p> <p>Due Dates January 31, April 30, July 31, and October 31,</p> <p>Publication Quarterly basis on website in a manner that identifies the information that is disclosed on a per-drug basis and not aggregated in a manner that allows identification of the drug.</p>

<p>CA California</p> <p>Cal. Code, Health and Safety §127675 et seq.</p> <p>§127681 (New to Market)</p> <p>Cal. Code of Regs. Tit. 22, Div. 7, Ch. 9.5 §96062 (Manufacturer Registration) §96075 (New Drug Notice) §96076 (New Drug Report) §96077 (Report Due Date) §96080 - 87 (Penalties)</p> <p>Prescription Drug Pricing and Cost Transparency in California</p> <p>Cost Transparency: Prescription Drugs (CTR_x) - (Links to Datasets)</p> <p>Quick Guide, Linking the Datasets</p> <p>Format and File Specifications for Submission of Prescription Drug Reports</p> <p>HCAi System Registration</p> <p>Prescription Drugs Introduced to Market</p> <p>ctrx@hcai.ca.gov (For Questions)</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D.</p> <p>Notice Provided to Office of Statewide Health Planning and Development (OSHPD)</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ The NDC ○ Date of introduction ○ WAC at introduction <p>Timing Within 3 days after release of drug or pending approval by FDA if introduction expected within 3 days of approval.</p> <p>Publication Quarterly basis on website.</p> <p>Penalty \$1,000 per day for failure to report.</p>	<p style="text-align: center;">NEW DRUG</p> <p>Registration Required on HCAi System Registration 5 business days prior to due date of first submission.</p> <p>Content of Report Submit through HCAi portal</p> <ul style="list-style-type: none"> ○ Description of marketing and pricing plans used in launch ○ Estimated volume of patients ○ Breakthrough therapy designation or priority review by FDA ○ Date and price of acquisition, if applicable <p>Notes on Content May limit to that in public domain or publicly available.</p> <p>Due Date Report within 30 days of notice to OSHPD.</p> <p>Publication Quarterly basis on website in a manner that identifies the information that is disclosed on a per-drug basis and not aggregated in a manner that allows identification of the drug.</p>
---	--	---

CO Colorado	PPRESCRIPTION DRUG AFFORDABILITY BOARD	
<p>Colo. Rev. Stat. 10-16-1406</p> <p>3 CCR 702-9 Effective 3/17/2023</p> <p>Colorado's Prescription Drug Affordability Board (PDAB)</p> <p>Colorado PDAB 2023 Eligible Drug Dashboard</p> <p>dora_ins_pdab@state.co.us (Questions about PDAB)</p>	<p>Trigger</p> <p>TO BE CONSIDERED FOR PDAB REVIEW</p> <p>GENERIC</p> <p>WAC \geq \$100 for 30-day supply or supply < 30 days based on the recommended dosage approved for labeling or one dose when no finite dosage</p> <p>AND</p> <p>Increase \geq 200% during preceding 12 months</p> <p>BIOSIMILAR</p> <p>Initial WAC \leq 15% below the WAC of the reference product</p>	<p>Report Required</p> <p>Upon request of PDAB</p> <p>Content of Report</p> <ul style="list-style-type: none"> ○ Pricing information not publicly available, as requested.

<p>CT Connecticut</p>	<p>PRICE INCREASE</p>	
<p>Conn. Gen. Stat. §19a-754b (d) (Report) (e) (Penalty) Amended by Public Act No. 23-171 (HB 6669), effective 10/1/2023</p> <p>2024 Top Ten List of Outpatient Prescription Drugs</p> <p>Prescription Drug Reporting System (Provided by Office of Health Strategy (OHS))</p> <p>Prescription Drug Costs Transparency Filings to the Office of Health Strategy (Manual and Guide for Submissions)</p> <p>HSP@ct.gov (For Questions)</p>	<p>Trigger Effective 10/1/2023 TO BE CONSIDERED FOR OHS LIST WAC ≥ \$40 for course of treatment AND Increase ≥ 16% cumulatively during preceding 2 calendar years.</p> <p>Note: Trigger prior to 2023 amendment: WAC ≥ \$60 for 30-day supply or course of treatment < 30 days AND Increase ≥ 20% during preceding calendar year or 50% during preceding 3 calendar years.</p> <p>Penalty Not more than \$7,500 per violation.</p>	<p>Registration Required on Prescription Drug Reporting System portal. Information to be provided in standardized form in Excel spreadsheet.</p> <p>Report Required for Outpatient, Rx drugs provided at substantial cost to state and critical to public health as listed by Office of Health Strategy (OHS). List will be no more than 10 drugs, but at least one generic to be listed and will be released by March 1 annually. A preliminary list will be made available for public comment.</p> <p>Content of Report</p> <ul style="list-style-type: none"> ○ Description of all factors that caused increase in WAC ○ Aggregate, company-level R&D costs ○ Other capital expenditures relevant for most recent year with final audited data <p>Notes on Content Quality and types of information and data submitted consistent with SEC Form 10-K.</p>

CT Connecticut	BIOSIMILARS	
Conn. Gen. Stat. §19a-754b (b)(2) (Biosimilar) (e) (Penalty)	<p>Notice Provided to Office of Health Strategy</p> <p>Content of Notice Written notice of filing of biologics license application (BLA) for a biosimilar drug.</p> <p>Timing Within 60 days of receipt of an action date from the FDA regarding such application.</p>	

<p>FL Florida</p>	<p>PRICE INCREASE</p>	
<p>FL Stat. §499.026, Effective 7/1/2023 Subsec. (1)(d) (Trigger) Subsec (2) (Notification) Subsec. (3) (Report)</p> <p><u>Division of Drugs, Devices, and Cosmetics (Drug Price Increase Reporting)</u></p>	<p>Trigger WAC \geq \$100 for 30-day supply or course of therapy AND Increase \geq 15% during preceding 12-month period or \geq 30% during preceding 3 calendar years.</p> <p>Notice Provided to Department of Business and Professional Regulation</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Proprietary and nonproprietary names ○ WAC before increase ○ Dollar amount of increase ○ Percentage increase ○ If change or improvement in the drug necessitates the increase ○ Description of change or improvement ○ Intended uses of drug <p>Timing On effective date of price increase.</p>	<p>Content of Report On Annual Notification of Reportable Drug Price Increases or Notification of Reportable Drug Price Increase</p> <ul style="list-style-type: none"> ○ Proprietary and nonproprietary names ○ Dollar amount of increase ○ Percentage increase ○ If applicable, percentage increase from earliest form filed to most recent form filed ○ Intended uses of drug ○ Length of time drug has been available for purchase ○ Factors contributing to price increase with an estimated percentage of influence of each and justification for each <ul style="list-style-type: none"> - Research and development - Manufacturing costs - Advertising and marketing - Competitive value - Increased rate of inflation or other economic dynamics - Changes in market dynamics - Supporting regulatory and safety commitments - Operating patient assistance and educational programs - Rebate increases - Medicaid, Medicare, or 340B Drug Pricing Program offsets - Profit - Other factors ○ Any action to extend a patent report after the first extension has been granted <p>Notes on Content May limit to that in public domain or publicly available.</p> <p>Due Date April 1</p> <p>Publication Posted on agency's website.</p>

LA Louisiana	PRICE INCREASE	
LA Rev. Stat. 22:1657.1 (C)(5)	<p>Trigger WAC \geq \$100 for 30-day supply AND Increase \geq 50%</p> <p>Notice Provided to Commissioner of Insurance</p> <p>Content of Notice Notice of change provided by email.</p> <p>Timing Within 30 days of price increase.</p>	

<p>LA Louisiana</p>	<p>ALL RX DRUGS</p>	
<p>LA Rev. Stat. 40:2255.1 et seq. LA Rev. Stat. 40:2255.1 (Definition of Marketing) LA Rev. Stat. 40:2255.11 (Report) druginfo@ulm.edu (For Questions)</p>	<p>Report Provided to Louisiana Board of Pharmacy</p>	<p>Report Required for Rx drugs marketed in the state.</p> <p>Content of Report</p> <ul style="list-style-type: none"> ○ Name of the drug ○ Price (WAC) of the drug <p>Due Date January 1, April 1, July 1, and October 1</p> <p>Publication Posted in database.</p> <p>Note: The Louisiana Pharmacy Drug Cost Transparency Database is no longer funded (July 2023).</p>

<p>ME Maine</p>	<p>ALL RX DRUGS</p>	
<p>Maine Rev. Stat. Tit. 22, Ch. 1683 Subch. 3 (Prescription Drug Pricing for Purchasers) §8732 (Notice and Report) §8734 (Registration) §8735 (Penalty)</p> <p>Maine Rule 90 590 Ch. 570 Uniform Reporting System for Prescription Drug Price Data Sets</p> <p>Maine Rule 90 590 Ch. 10 (Assessments)</p> <p>Maine Rule 90 590 Ch. 100 (Enforcement and Penalty)</p> <p>Maine List of Drug Product Families</p> <p>MHDO Prescription Drug Price Data Portal (Registration)</p> <p>MHDO Prescription Drug Costs and Utilization in Maine at Retail and Mail Order Pharmacies – (Annual Report)</p> <p>Maine Prescription Drug Affordability Board (Office of Affordable Health Care)</p> <p>2023 Prescription Drug Affordability Board Annual Report</p> <p>2022 Prescription Drug Affordability Board Annual Report</p>	<p>Trigger On the List of Drug Product Families as posted by MHDO. [NOTE: Prior to January 30, 2022, manufacturers were required to notify the MHDO of price increases and new drug introductions that met certain triggers.]</p> <p>Penalty Maximum fine of \$25,000 per occurrence for failure to pay assessment, register, or submit report. Up to \$30,000 per day for violations regarding accuracy of reporting.</p>	<p>Registration Registration must be updated annually by January 30 on MHDO Prescription Drug Price Data Portal. Manufacturers are assessed \$500 annually by MHDO. Payment is due within 30 days of request at the start of the fiscal year in July.</p> <p>Report Required for List of Drug Product Families posted by MHDO by February 15 and manufacturers notified of reporting requirements by email no sooner than 30 days after posting.</p> <p>Content of Report Pricing component data in an MHDO provided Excel template. Templates are customized to each reporting entity and are available for download, completion, and upload via the MHDO Prescription Drug Price Data Portal. Signed certification of accuracy is submitted with report.</p> <ul style="list-style-type: none"> ○ The NDC ○ Drug Indicator; 2=Generic ○ Estimated number of patients ○ Baseline WAC amount ○ Total WAC change amount ○ WAC after change ○ Unit sales volume in US ○ Revenue in US ○ Total rebate payable amount in US ○ Cost change factors (net of returns) <ul style="list-style-type: none"> - 0 – No change/not applicable - 1 – Change in administrative expenses - 2 – Scheduled price change - 3 – Change in ingredient costs - 4 – Change in manufacturing - 5 – Change in marketing & advertising costs - 6 – Change in financial assistance - 7 – Change in R&D costs - 8 – Change in rebates to PBMs/wholesalers - 9 – Other rebate change - 10 – Change in supply (shortage or surplus) - 11 – Change in sales costs

ME Maine	ALL RX DRUGS (continued)	
		<ul style="list-style-type: none"> - 12 – Change in state and federal taxes - 13 – Change in profit targets - 14 – Change in supplier price (repackaged NDC) - 15 – Other/Specify <ul style="list-style-type: none"> o IF ACQUIRED W/IN 5YEARS <ul style="list-style-type: none"> - Acquisition date - Company acquired from name - Company acquired from tax id number - Acquisition price - WAC at acquisition - WAC one year prior to acquisition - Acquisition comments o IF INTRODUCED OR ACQUIRED W/IN 5YEARS <ul style="list-style-type: none"> - Introduced to market date - WAC at market introduction o Acquisition comments o General comments <p>Notes on Content Drug Product Family means a group of one or more prescription drugs that share a unique generic drug description and drug form. Generic Drug includes a biosimilar product.</p> <p>Due Dates 60 days after email notification from MDHO.</p> <p>Publication Annually on website, in the aggregate, not in a manner that allows identification of the manufacturer.</p>

ME Maine	PRESCRIPTION DRUG AFFORDABILITY BOARD	
Maine Rev. Stat. Tit. 5, Ch. 167 §§2041 to 2042 Maine Prescription Drug Affordability Board (Office of Affordable Health Care) 2023 Prescription Drug Affordability Board Annual Report 2022 Prescription Drug Affordability Board Annual Report	A Prescription Drug Affordability Board was established in 2019. The mission of the Board is to determine annual spending targets for prescription drugs purchased by public payers and make recommendations to achieve the targets. The Board may consider any of the data compiled by MHDO.	-

MD Maryland	PRESCRIPTION DRUG AFFORDABILITY BOARD	
<p data-bbox="107 142 514 170">MD Health Gen § 21-2c-01 et seq.</p> <p data-bbox="107 203 489 263">COMAR 14.01.04 Cost Review Study Process</p> <p data-bbox="107 295 432 355">Maryland Prescription Drug Affordability Board</p> <p data-bbox="107 388 527 415">2023 Annual Cost Review Report</p> <p data-bbox="107 448 504 475">2022 Annual Cost Review Report</p> <p data-bbox="107 508 478 568">Study of the Operation of the Generics Drug Market</p> <p data-bbox="107 633 478 693">support.pdab@maryland.gov (For Questions)</p>	<p data-bbox="581 142 1066 289">A Prescription Drug Affordability Board was established in 2019. The Board may request information from entities, including manufacturers, to conduct a cost review.</p>	

<p>MA Massachusetts</p>	<p>HIGH-COST DRUGS</p>	
<p>MA Gen. Laws Ch. 6D, §8A</p> <p>958 MA Admin. Code 12.00 12.02 (Trigger/Definitions) 12.04 (Report) 12.13 (Penalty)</p> <p>101 MA Admin. Code 801.02 (Definition of High-Cost Drug)</p> <p>Health Policy Commission (HPC) Drug Pricing Review (includes Standard Reporting Form)</p> <p>HPC-DrugReview@mass.gov Phone: (617) 979-1400 (For Questions)</p>	<p>Trigger Coverage or anticipated coverage from MassHealth for eligible members. expected to exceed a post-rebate cost per utilizer of \$25,000 annually or an aggregate annual post-rebate cost to MassHealth of \$10,000,000</p> <p>Notice Provided to Health Policy Commission</p> <p>Penalty Reasonable monetary penalties not to exceed \$500,000 in each instance</p>	<p>Report Required for Drugs deemed to be High-Cost Drugs</p> <p>Content of Report On the Drug Pricing Review Standard Reporting Form and accompanied by an attestation that all information provided is true and correct</p> <ul style="list-style-type: none"> ○ Information on clinical efficacy, effectiveness and outcomes ○ WAC increases over previous 5 calendar years ○ Information regarding the drug's prices, net of rebates, internationally, nationally, and in Massachusetts ○ Information to support the referred Manufacturer's pricing ○ Information on utilization of the drug; ○ Aggregate, company-level R&D costs for the most recent year for with final audit data and funding sources ○ Acquisition cost, if applicable ○ Manufacturing, production and distribution budget and expenditures ○ Marketing budget and expenditures ○ Narrative describing factors that contributed to changes in WAC over previous 5 calendar years which is suitable for public release. ○ Other information requested by Commission ○ Other information manufacture wishes to provide <p>Notes on Content Report will be accompanied by an attestation that all information provided is true and correct.</p> <p>Due Date Annually by April 1.</p> <p>Publication Posted on website by June 1 annually, compiled report summarizing findings but not identifying specific prices nor be likely to compromise the financial, competitive or proprietary nature of the information.</p>

<p>MN Minnesota</p>	<p>PRICE INCREASE</p>	
<p>Minn. Stat. Ann. §62J.84 Subd. 3 (Increase Reporting) Subd. 5 (Newly Acquired Drug Reporting) Subd. 6 (Publication) Subd. 8 (Penalty)</p> <p>Prescription Drug Price Transparency</p> <p>Prescription Drug Public Interest Drug Lists (June 2024) Excel and PDF</p> <p>Prescription Drug Price Transparency Data & Dashboards</p> <p>Prescription Drug Price Transparency Publications</p> <p>Minnesota Prescription Drug Price Transparency Report to the Minnesota Legislature (May 2024)</p> <p>Prescription Drug Price Transparency Information for Reporting Entities</p> <p>Registration and Account Management Guide</p> <p>Form and Manner for Prescription Drug Price Data Sets (Updated 11/17/2023)</p> <p>Prescription Drug Price Transparency: Frequently Asked Questions</p> <p>Prescription Drug Price Transparency: Training Video</p> <p>health.rx@state.mn.us (For Questions)</p>	<p>Trigger GENERIC: WAC Price \geq \$100 for 30-day supply or course of treatment < 30 days AND Increase \geq 50% over previous 12-month period.</p> <p>Penalty Commissioner of Health to establish civil penalties, not to exceed \$10,000 per day.</p>	<p>Registration Register on MN Rx Transparency Registration and Reporting System.</p> <p>Content of Report From MN Rx Transparency Registration and Reporting System, download templates, add data and upload to the portal or enter data manually. From portal, users can view, edit, delete, and certify batches of data.</p> <ul style="list-style-type: none"> ○ Price (WAC) of the drug ○ Net increase as a percentage ○ Factors that contributed to the price increase ○ Name of any generic version of the drug on the market ○ Introductory price of the drug when it was approved for marketing by FDA ○ Net yearly increase, by calendar year, in the price of the drug during previous 5 years ○ Direct costs incurred by manufacturer associated with the drug (listed separately) <ul style="list-style-type: none"> - to manufacture the drug; - to market the drug (including advertising costs) - to distribute the drug ○ Total sales revenue for the drug during previous 12-month period ○ Net profit attributable to the drug during the previous 12-month period ○ Total amount of financial assistance manufacturer has provided through patient prescription assistance programs ○ Any agreement between manufacturer and another entity contingent upon any delay in offering to market a generic version of the drug ○ Patent expiration date of the drug if under patent ○ IF NEWLY ACQUIRED <ul style="list-style-type: none"> - Price (WAC) of the drug at time of acquisition and in calendar year prior to acquisition - Name of the company from which the drug was acquired - Date the drug was acquired

MN Minnesota	PRICE INCREASE (continued)	
		<ul style="list-style-type: none"> - Purchase price of acquisition - Year the prescription drug was introduced to market - Price of the drug at the time of introduction - Price of the drug for previous 5 years; - Any agreement between manufacturer and another entity contingent upon any delay in offering to market a generic version of the drug - Patent expiration date of the drug if under patent <p>Notes on Content Manufacturer may submit any documentation necessary to support reported information.</p> <p>Due Date 60 days after increase of WAC Price.</p> <p>Publication Public data, not trade secrets, posted on Prescription Drug Price Transparency Publications. Information may not be aggregated in a manner that prevents identification of the drug.</p>

<p>MN Minnesota</p>	<p>NEW DRUG</p>	
<p>Minn. Stat. Ann. §62J.84 Subd. 4 (New Drug Reporting) Subd. 6 (Publication) Subd. 8 (Penalty)</p> <p>Prescription Drug Price Transparency</p> <p>Prescription Drug Public Interest Drug Lists (June 2024) Excel and PDF</p> <p>Prescription Drug Price Transparency Data & Dashboards</p> <p>Prescription Drug Price Transparency Publications</p> <p>Minnesota Prescription Drug Price Transparency Report to the Minnesota Legislature (May 2024)</p> <p>Prescription Drug Price Transparency Information for Reporting Entities</p> <p>Registration and Account Management Guide</p> <p>Form and Manner for Prescription Drug Price Data Sets (Updated 11/17/2023)</p> <p>Prescription Drug Price Transparency: Frequently Asked Questions</p> <p>Prescription Drug Price Transparency: Training Video</p> <p>health.Rx@state.mn.us (Email for Questions)</p>	<p>Trigger GENERIC or BIOSIMILAR: WAC price > threshold for specialty drug under Medicare Part D for 30-day supply and < 15% below the price of the reference product at launch</p> <p>Penalty Commissioner of Health to establish civil penalties, not to exceed \$10,000 per day</p>	<p>Registration Register on MN Rx Transparency Registration and Reporting System.</p> <p>Content of Report From MN Rx Transparency Registration and Reporting System, download templates, add data and upload to the portal or enter data manually. From portal, users can view, edit, delete, and certify batches of data.</p> <ul style="list-style-type: none"> ○ Price (WAC) of the drug ○ Breakthrough therapy designation or priority review by FDA ○ Direct costs incurred by manufacturer associated with the drug (listed separately) <ul style="list-style-type: none"> - to manufacture the drug; - to market the drug (including advertising costs) - to distribute the drug ○ Patent expiration date of the drug if under patent <p>Notes on Content Manufacturer may submit any documentation necessary to support reported information. If manufacturer believes information should be withheld from public disclosure, manufacturer must clearly and specifically identify that information and describe the legal basis in writing at submission.</p> <p>Due Date Report within 60 days of introduction</p> <p>Publication Public data, not trade secrets, posted on Prescription Drug Price Transparency Publications. Information will not be aggregated in a manner that prevents the identification of the drug</p>

<p>MN Minnesota</p>	<p>DRUGS OF SUBSTANTIAL PUBLIC INTEREST</p>	
<p>Minn. Stat. Ann. §62J.84 Subd. 6 (Publication) Subd. 8 (Penalty) Subd. 10 (Identification) Subd. 11 (Reporting)</p> <p>Prescription Drug Price Transparency</p> <p>Prescription Drug Public Interest Drug Lists (June 2024) Excel and PDF</p> <p>Form and Manner for Prescription Drug Price Data Sets (Updated 11/17/2023)</p> <p>Prescription Drug Price Transparency, Public Interest Reporting: Frequently Asked Questions</p> <p>health.Rx@state.mn.us (For Questions)</p>	<p>Trigger GENERIC or BIOSIMILAR: <i>As identified by Commissioner based on Data reported under §62J.84 Subd. 3 for a price increase or §62J.84 Subd. 4 for a new drug and other factors.</i> <i>Commissioner shall consider drug product families.</i></p> <p>Penalty <i>Commissioner of Health to establish civil penalties, not to exceed \$10,000 per day</i></p>	<p>Report Required Upon request of the department by email sent 30 days after public posting of the list. Report required from manufacturer who manufactures or repackages and sets WAC. Not required if price increase report has been submitted within 120 days of the notification.</p> <p>Content of Report</p> <ul style="list-style-type: none"> ○ NDC ○ Name ○ Dosage form, strength, size ○ Price of the drug one year prior ○ Price of the drug as of notification ○ Introductory price of the drug ○ Price of the drug at end of each of the previous 5 years ○ Direct costs incurred during previous 12 months by manufacturer associated with the drug (listed separately) <ul style="list-style-type: none"> - to manufacture the drug; - to market the drug (including advertising costs) - to distribute the drug ○ Number of units sold during previous 12 months ○ Total sales revenue for the drug during previous 12 months ○ Total rebate paid during previous 12 months ○ Net profit attributable to the drug during the previous 12 months ○ Total sales revenue for the previous 12 months ○ Total amount of financial assistance provided during the previous 12 months ○ Any agreement between manufacturer and another entity contingent upon any delay in offering to market a generic version of the drug ○ Name and location of the company that manufactured the drug ○ Patent expiration date of the drug if under patent

MN Minnesota	DRUGS OF SUBSTANTIAL PUBLIC INTEREST (continued)	
		<ul style="list-style-type: none"> ○ IF NEWLY ACQUIRED <ul style="list-style-type: none"> - Price (WAC) of the drug at time of acquisition - Price in calendar year prior to acquisition - Name of the company from which the drug was acquired - Date the drug was acquired - Purchase price of acquisition <p>Notes on Content Manufacturer may submit any documentation necessary to support reported information.</p> <p>Due Date Report within 60 days of notification</p> <p>Publication Public data, not trade secrets, posted on MN Rx Transparency. Information will not be aggregated in a manner that prevents the identification of the drug</p>

MN Minnesota	PRESCRIPTION DRUG AFFORDABILITY BOARD	
<p data-bbox="109 142 499 201">2023 Minn. Session Laws Ch. 57 (SF 2744)</p> <p data-bbox="109 233 499 292"><i>Minnesota's Prescription Drug Affordability Board</i></p>	<p data-bbox="655 142 1037 350">A Prescription Drug Affordability Board is established. Initial appointments to the Board to be made by January 1, 2024. Commissioner of Health will provide information reported by manufacturers to the Board.</p>	

NV Nevada	LISTED DRUGS	
<p>NV Rev. Stat. 439B.600 et seq. 439B.630 (Triggers) 439B.635 (Report) 439B.640 (Report) 439B.695 (Penalty)</p> <p>NV Admin. Code 439.730 et seq. 439.735 (Confidentiality) 439.740 (Publication)</p> <p>State of Nevada Drug Transparency Program</p> <p>Nevada Drug Transparency Reports</p> <p>Nevada Drug Transparency 2023 Drug Lists</p> <p>Manufacturer Drug Transparency Guidelines, Reporting Information and Templates (Instructions and Templates)</p> <p>DrugTransparency@dhhs.nv.gov (For Report Submissions and Questions)</p>	<p>Trigger TO BE INCLUDED ON DHHS LIST WAC > \$40 for course of therapy (30-day supply or course of treatment < 30 days) AND Increase ≥ 10% during preceding calendar years or > 20% during preceding 2 calendar years.</p> <p>DRUGS ESSENTIAL FOR TREATING DIABETES: WAC Increase ≥ CPI during preceding calendar year or ≥ 2 x CPI during preceding 2 calendar years</p> <p>Penalty Not more than \$5,000 per day</p>	<p>Registration Register on Manufacturer Drug Transparency Guidelines, Reporting Information and Templates using template.</p> <p>Report Required for List of prescription drugs compiled by Department annually: 2023 Drug Lists.</p> <p>Content of Report Forms for submission available on website. Include a signed statement affirming the accuracy of the information in the report.</p> <ul style="list-style-type: none"> ○ The NDC ○ Description of the drug <ul style="list-style-type: none"> - Name - Strength - Dosage form - Package size ○ Costs of producing drug ○ Total administrative expenditures relating to drug, including marketing and advertising costs ○ Profit that the manufacturer has earned from drug and percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug ○ Total amount of financial assistance that manufacturer has provided through any patient prescription assistance program ○ Cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs ○ WAC of the drug ○ History of any increases in WAC of the drug over the 5 preceding years, including the amount of each increase expressed as a percentage of the total WAC of the drug, the month and year increase became effective and any explanation for increase

NV Nevada	LISTED DRUGS (continued)	
		<ul style="list-style-type: none"> ○ Aggregate amount of all rebates that the manufacturer has provided to PBMS for sales within the state ○ IF ACQUIRED W/IN PREVIOUS 5 YEARS <ul style="list-style-type: none"> - Name of entity from which drug was acquired - Date acquired - Purchase price - WAC at time acquisition - WAC one year prior to acquisition - Year and WAC when drug made available for sale ○ Other information prescribed by regulation for the purpose of analyzing the cost of prescription drugs that appear on the list, trends in those costs and rebates available <p>Notes on Content Manufacturer may submit request to keep information confidential if there is a belief of misappropriation of a trade secret from public disclosure.</p> <p>Due Date Annually by April 1.</p> <p>Publication Compiled report, by June 1 annually, of aggregated data that does not disclose the identity of any drug, manufacturer.</p>

<p>NH New Hampshire</p>	<p>PRICE INCREASE</p>	
<p>NH Rev. Stat. 126-BB:9</p> <p><i>NH Rev. Stat. 126-BB:9 is suspended for the biennium ending June 30, 2025</i></p> <p>NH Rev. Stat. 126-BB:9 (I) (Trigger) NH Rev. Stat. 126-BB:9 (II) (Report) NH Rev. Stat. 126-BB:9 (IV) (Confidentiality) NH Rev. Stat. 126-BB:9 (VIII) (Publication)</p> <p>NH Rev. Stat. 126-BB-1 (Definition of “pricing unit”)</p> <p>New Hampshire Prescription Drug Affordability Board (PDAB)</p> <p>PDAB Manufacturer Letter</p>	<p>Trigger GENERIC WAC ≥ \$10 per pricing unit AND Increase > 20%</p> <p>Penalty Repealed effective 7/1/23.</p>	<p>Registration Must register annually with (PDAB) Prescription Drug Affordability Registration</p> <p>Content of Report <i>Suspended for the biennium ending June 30, 2025</i> Submission of Attestation Form required when no drug is subject to reporting requirements.</p> <ul style="list-style-type: none"> ○ NDC ○ Brand or generic ○ Strength ○ Size of the pricing unit ○ Doses per pricing unit ○ WAC on January 1 of prior year ○ WAC on December 31 of prior year ○ Signed certification of report's accuracy <p>UPON REQUEST OF PDAB</p> <ul style="list-style-type: none"> ○ Narrative description of all factors that caused the increase in WAC ○ Aggregate, company-level R&D costs and other capital expenditures for the most recent year with final audited data <p>Notes on Content Quality and types of information and data submitted limited to that submitted with SEC Form 10-K or other public disclosure. Any confidential or proprietary information contained in a notification or report shall be clearly identified as such.</p> <p>Due Date Annually by January 31 with additional information supplied 60 days after request from PDAB.</p> <p>Publication Report posted on website may not disclose information attributable to any particular manufacturer and may not make public any information that is confidential.</p>

<p>NH New Hampshire</p>	<p>NEW DRUG</p>	
<p>NH Rev. Stat. 318:67 and 318:68 NH Rev. Stat. 318:68 (II) (Report) NH Rev. Stat. 318:68 (IV) (Publication)</p> <p>NH Bulletin INS 20-017-AB (Revised)</p> <p>New Hampshire Insurance Department High-Cost Prescription Drugs</p> <p>Maureen.A.Mustard@ins.nh.gov (For Questions to Insurance Department)</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D.</p> <p>Notice Provided to New Hampshire Insurance Department doi.healthcareanalytics@ins.nh.gov.</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Name of manufacturer ○ Name of drug ○ Anticipated date of release <p>Timing Within 3 days after release of drug or pending approval by FDA if introduction expected within 3 days of approval.</p> <p>Penalty Not more than \$1,000 per day.</p>	<p>Reports Required to New Hampshire Insurance Department and New Hampshire Prescription Drug Affordability Board (PDAB)</p> <p><u>INSURANCE DEPARTMENT REPORT</u></p> <p>Content of Insurance Department Report Information to Insurance Department must be submitted using provided spreadsheet High-Cost Prescription Drug File Template</p> <ul style="list-style-type: none"> ○ Name of manufacturer ○ NDC ○ Name of drug ○ Strength ○ Pack Size/Volume ○ WAC ○ Date of commercial availability ○ Estimated volume of patients ○ Date and price of acquisition, if applicable ○ Description of marketing and pricing plans used in launch ○ Breakthrough therapy designation or priority review by FDA <p>Notes on Content May limit to that in public domain or publicly available</p> <p>Due Date Report within 30 days of notice.</p> <p>Publication Posted on website, at least quarterly, in a manner that identifies the information on a per-drug basis and does not aggregate in a manner that would not allow identification of the drug.</p>

<p>NH New Hampshire</p>	<p>NEW DRUG (continued)</p>	
<p>NH Rev. Stat. 126-BB:9</p> <p><i>NH Rev. Stat. 126-BB:9 is suspended for the biennium ending June 30, 2025</i></p> <p>NH Rev. Stat. 126-BB:9 (I) (Trigger) NH Rev. Stat. 126-BB:9 (II) (Report) NH Rev. Stat. 126-BB:9 (IV) (Confidentiality) NH Rev. Stat. 126-BB:9 (VIII) (Publication)</p> <p>New Hampshire Prescription Drug Affordability Board (PDAB)</p> <p>PDAB Manufacturer Letter</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D.</p> <p>Penalty Repealed effective 7/1/23.</p>	<p><u>PDAB REPORT</u></p> <p>Registration Must register annually with (PDAB) Prescription Drug Affordability Registration</p> <p>Content of Report <i>Suspended for the biennium ending June 30, 2025</i> Submission of Attestation Form required when no drug is subject to reporting requirements.</p> <ul style="list-style-type: none"> ○ NDC ○ Brand or generic ○ Strength ○ Size of the pricing unit ○ Doses per pricing unit ○ WAC on January 1 of prior year ○ WAC on December 31 of prior year ○ Signed certification of report's accuracy <p>UPON REQUEST OF PDAB</p> <ul style="list-style-type: none"> ○ Narrative description of all factors that caused the increase in WAC ○ Aggregate, company-level R&D costs and other capital expenditures for the most recent year with final audited data <p>Notes on Content Quality and types of information and data submitted limited to that submitted with SEC Form 10-K or other public disclosure. Any confidential or proprietary information contained in a notification or report shall be clearly identified as such.</p> <p>Due Date Annually by January 31 with additional information supplied 60 days after request from PDAB.</p> <p>Publication Report posted on website, may not disclose information attributable to any particular manufacturer and may not make public any information that is confidential.</p>

NH New Hampshire	PRESCRIPTION DRUG AFFORDABILITY BOARD	
NH Rev. Stat. 126-BB:1 et seq. New Hampshire Prescription Drug Affordability Board (PDAB) PDAB Manufacturer Letter	A Prescription Drug Affordability Board was established in 2020. The Board shall meet in review prescription drug information and make recommendations.	

<p>NJ New Jersey</p>	<p>PRICE INCREASE</p>	
<p><u>NJ Stat. 45:14-82.2 et seq.</u></p> <p>NJ Stat. 45:14-82.3 (Triggers and Report) NJ Stat. 45:14-82.8 (Penalties) NJ Stat. 45:14-82.10 (Publication)</p>	<p>Trigger GENERIC WAC > \$10 but < \$100 per pricing unit AND Increase > 40% within a 12-month period OR WAC ≥ \$100 per pricing unit AND Increase > 10% within a 12-month period</p> <p>Pricing unit defined as the smallest dispensable amount of a prescription drug that could be dispensed.</p> <p>Notice Provided to Division of Consumer Affairs in the Department of Law and Public Safety</p> <p>Timing 10 days following the increase.</p> <p>Penalty \$10,000 for the first day, for subsequent days of non-compliance, an amount starting at \$11,000 and increasing by \$1,000 for each additional day of non-compliance, not to exceed \$100,000 per day.</p>	<p>Content of Report</p> <ul style="list-style-type: none"> ○ National drug code ○ Proprietary drug name ○ Non-proprietary drug name ○ Pricing unit of the drug ○ Sales volume in the state for previous calendar year ○ Projected sales volume in the state for current calendar year ○ Wholesale price and related information <ul style="list-style-type: none"> - Year of market introduction - WAC at market introduction - WAC in previous calendar year - Current WAC ○ Total sales revenue of drug during previous calendar year ○ Projected sales revenue of drug for current calendar year ○ Cost associated with sales during previous calendar year ○ Projected cost associated with sales for current calendar year ○ Current calendar-year projections or incurred cost year to date ○ Reason for increase in WAC <p>Notes on Content Division may permit the manufacturer to report the data on a national level upon proof satisfactory that state-specific data is unavailable.</p> <p>Due Date Within 20 days following the price increase.</p> <p>Publication Report posted annually on website may not make public any information that is confidential.</p>

<p>NJ New Jersey</p>	<p>BIOSIMILARS</p>	
<p><u>NJ Stat. 45:14-82.2 et seq.</u></p> <p>NJ Stat. 45:14-82.3 (Triggers and Report) NJ Stat. 45:14-82.8 (Penalties) NJ Stat. 45:14-82.10 (Publication)</p>	<p>Trigger BIOSIMILAR: WAC at launch < 15% below the WAC of the reference product.</p> <p>Notice Provided to Division of Consumer Affairs in the Department of Law and Public Safety</p> <p>Timing 10 days following introduction.</p> <p>Penalty \$10,000 for the first day, for subsequent days of non-compliance, an amount starting at \$11,000 and increasing by \$1,000 for each additional day of non-compliance, not to exceed \$100,000 per day.</p>	<p>Content of Report</p> <ul style="list-style-type: none"> ○ National drug code ○ Proprietary drug name ○ Non-proprietary drug name ○ Pricing unit of the drug ○ Projected patient volume in the current year ○ Projected revenue for current year ○ Cost associated with sales during previous calendar year ○ WAC at market introduction <p>Notes on Content Division may permit the manufacturer to report the data on a national level upon proof satisfactory that state-specific data is unavailable.</p> <p>Due Date Within 20 days of introduction.</p> <p>Publication Report posted annually on website may not make public any information that is confidential.</p>

<p>NJ New Jersey</p>	<p>NEW DRUG</p>	
<p><u>NJ Stat. 45:14-82.2 et seq.</u></p> <p>NJ Stat. 45:14-82.3 (Triggers and Report) NJ Stat. 45:14-82.8 (Penalties) NJ Stat. 45:14-82.10 (Publication)</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D.</p> <p>Notice Provided to Division of Consumer Affairs in the Department of Law and Public Safety</p> <p>Timing 10 days following introduction.</p> <p>Penalty \$10,000 for the first day, for subsequent days of non-compliance, an amount starting at \$11,000 and increasing by \$1,000 for each additional day of non-compliance, not to exceed \$100,000 per day.</p>	<p>Content of Report</p> <ul style="list-style-type: none"> ○ National drug code ○ Proprietary drug name ○ Non-proprietary drug name ○ Pricing unit of the drug ○ Projected patient volume in the current year ○ Projected revenue for current year ○ Cost associated with sales during previous calendar year ○ WAC at market introduction <p>Notes on Content Division may permit the manufacturer to report the data on a national level upon proof satisfactory that state-specific data is unavailable.</p> <p>Due Date Within 20 days of introduction.</p> <p>Publication Report posted annually on website may not make public any information that is confidential.</p>

NJ New Jersey	PRESCRIPTION DRUG AFFORDABILITY BOARD	
<u>NJ Stat. 45:14-82.11</u>	Drug Affordability Council has been established to formulate legislative and regulatory policy recommendations. The Council will review the data reported by manufacturers to the Division.	

<p>NM New Mexico</p>	<p>PRICE INCREASE</p>	
<p><u>NM Stat. Ann. 59A-59A-1 et seq.</u> NM Stat. Ann. 59A-59A-2 (Definitions) NM Stat. Ann. 59A-59A-3 (Triggers and Report) NM Stat. Ann. 59A-59A-8 (Penalties)</p>	<p>Trigger GENERIC and BIOSIMILAR WAC \geq \$400 per 30-day supply AND Increase \geq 30% in previous calendar year</p> <p>Notice Provided to Superintendent of Insurance</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Date of the increase ○ Current WAC ○ \$ amount of future increase ○ Statement of whether change or improvement in drug necessitates increase and description of change or improvement <p>Timing Date increase becomes effective.</p> <p>Penalty Per 59A-1-18, \$5,000 per violation, \$10,000 if willful and intentional.</p>	<p>Content of Report</p> <ul style="list-style-type: none"> ○ WAC at market introduction ○ Annual WAC increase over the previous 5 calendar years. ○ Direct costs associated with manufacturing, marketing, and distribution ○ Total revenue from drug over previous calendar year ○ Net profit attributable to drug over previous calendar year ○ Patent expiration date ○ 10 highest government-negotiated prices of the drug in EU and UK ○ Agreement that involves a delay in marketing a generic version of the drug ○ Names and prices of generic equivalents ○ Total amount of manufacturer-supported financial assistance provided to consumers of the drug ○ Other information requested <p>Notes on Content Superintendent shall keep confidential all the information provided.</p> <p>Due Date May 1</p>

NM New Mexico	NEW DRUG	
<p>NM Stat. Ann. 59A-59A-1 et seq. NM Stat. Ann. 59A-59A-2 (Definitions) NM Stat. Ann. 59A-59A-3 (Triggers and Report) NM Stat. Ann. 59A-59A-8 (Penalties)</p>	<p>Trigger GENERIC and BIOSIMILAR WAC > threshold for specialty drug under Medicare Part D AND WAC at launch \leq 15% below the WAC of the reference product.</p> <p>Notice Provided to Superintendent of Insurance</p> <p>Timing 3 days following introduction.</p> <p>Penalty Per 59A-1-18, \$5,000 per violation, \$10,000 if willful and intentional.</p>	<p>Content of Report</p> <ul style="list-style-type: none"> ○ Name of the drug <p>Notes on Content Superintendent shall keep confidential all of the information provided.</p> <p>Due Date Within 3 days of introduction.</p> <p>Note that until electronic reporting portal is available, the drug name can be reported by email to Alejandro.Amparan@osi.nm.gov</p>

<p>NY New York</p>	<p>PRICE INCREASE (pre-increase notification required)</p>	
<p><u>NY Insurance §111-a</u> (b)(1) (Trigger) (b)(2) (Notice) (b)(2)(ii) and (b)(4) (Publication) (b)(5) (Penalty)</p>	<p>Trigger NOTICE: WAC Increase > 16% within previous 24 months for a course of therapy</p> <p>Notice Provided to Superintendent of Insurance</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Proposed increase ○ Cumulative increases within previous 24 months ○ Date of the increase ○ Current WAC ○ \$ amount of future increase ○ Description of change or improvement in drug which necessitates increase <p>Timing 60 days prior to the increase.</p> <p>Publication Within 5 days of receipt on website. Information designated as a trade secret exempt from disclosure unless in the aggregate.</p> <p>Penalty Up to \$5,000 per day for every day after reporting period that information is not reported.</p>	

<p>ND North Dakota</p>	<p>PRICE INCREASE</p>	
<p>ND Cent. Code §26.1-36.10-01 et seq. §26.1-36.10-02 (2) (Trigger and Report) §26.1-36.10-08 (Penalty)</p> <p>Prescription Drug Cost Transparency</p> <p>Manufacturer's Disclosure User Guide</p> <p>Information for Manufacturers</p> <p>Filed Disclosure Reports</p> <p>Drug Manufacturer's Price Increase Reports</p>	<p>Trigger WAC ≥ \$70 per manufacturer-packaged drug container AND Increase ≥ 40% over the preceding 5 calendar years or ≥10% in the preceding twelve months</p> <p>Penalty Civil penalties imposed by Attorney General, not to exceed \$10,000 per violation</p>	<p>Content of Report Template is provided in Information for Manufacturers</p> <ul style="list-style-type: none"> ○ Name of the drug ○ Brand or generic ○ Effective date of WAC change ○ Aggregate, company-level R&D costs for the previous calendar year ○ Aggregate rebate amounts paid to each PBM for the previous calendar year ○ Name of each of the manufacturer's drugs approved by FDA in the previous 5 calendar years ○ Names of manufacturer's drugs that lost patent exclusivity in the US in the previous 5 calendar years ○ Concise statement of rationale regarding the factors that caused WAC increase <p>Notes on Content Quality and types of information and data submitted same as that submitted with SEC Form 10-K or other public disclosure.</p> <p>Due Date 30 days after increase.</p> <p>Publication Posted on website within 60 days of report, may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information.</p>

<p>ND North Dakota</p>	<p>NEW DRUG</p>	
<p>ND Cent. Code §26.1-36.10-01 et seq. §26.1-36.10-02 (3) (Trigger and Notice) §26.1-36.10-08 (Penalty)</p> <p>Prescription Drug Cost Transparency</p> <p>Manufacturer's Disclosure User Guide</p> <p>Information for Manufacturers</p> <p>Filed Disclosure Reports</p> <p>Drug Manufacturer's New Drug Disclosure Reports</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D</p> <p>Notice Provided to Insurance Commissioner</p> <p>Content of Notice Concise statement of rationale regarding the factors that caused the new drug to exceed the Medicare part D program price</p> <p>Timing Within 3 days after release of drug or pending approval by FDA if introduction expected within 3 days of approval.</p> <p>Penalty Civil penalties imposed by Attorney General, not to exceed \$10,000 per violation.</p>	<p>Publication Posted on website within 60 days of report, may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information.</p>

<p>ND North Dakota</p>	<p>ALL RX DRUGS</p>	
<p>ND Cent. Code §26.1-36.10-01 et seq. §26.1-36.10-02 (1) (Report) §26.1-36.10-08 (Penalty)</p> <p>Prescription Drug Cost Transparency</p> <p>Manufacturer's Disclosure User Guide</p> <p>Information for Manufacturers</p> <p>Filed Disclosure Reports</p> <p>Drug Manufacturer's Price Disclosure Reports</p>	<p>Penalty Civil penalties imposed by Attorney General, not to exceed \$10,000 per violation</p>	<p>Content of Report Template is provided in Information for Manufacturers</p> <ul style="list-style-type: none"> ○ Current WAC <p>Due Date January 15, April 15, July 15, and October 15.</p> <p>Publication Posted on website within 60 days of report, may not disclose or tend to disclose trade secret, proprietary, commercial, financial, or confidential information.</p>

OH Ohio	PRESCRIPTION DRUG AFFORDABILITY BOARD	
OH Rev. Code Ann. §125.95 Prescription Drug Transparency and Affordability Council 2020 Report of Recommendations	The Prescription Drug Transparency and Affordability Advisory Council was established in 2019 and created a report.	

OR Oregon	PRICE INCREASE (additional pre-increase notification required)	
<p>OR Rev. Stat. §646A.683 (Pre-Increase Trigger and Notice)</p> <p>OR Rev. Stat. §646A.689 (Trigger, Report, Publication) Price Increase Reporting has been suspended, see OR Bulletin 2024-3</p> <p>OR Rev. Stat. §646A.692 (Penalty)</p> <p>OAR 836-200-0500 et seq. OAR 836-200-0505 (Definitions) OAR 836-200-0510 (Account) OAR 836-200-0515 (Report Trigger) OAR 836-200-0525 (Report) OAR 836-200-0530 (Report) OAR 836-200-0540 (Trade Secret) OAR 836-200-0560 (Penalty) OAR 836-200-0545 (Publication)</p> <p>OR Bulletin 2020-12 (Pre-Increase Notice)</p> <p>DFR Prescription Drug Price Transparency</p> <p>DFR Prescription Drug Price Transparency Manufacturers</p> <p>2023 Drug Price Transparency Program Report</p> <p>Frequently Asked Questions</p> <p>DCBS Manufacturer User Guide</p> <p>DCBS 60-Day Notice - User Guide</p> <p>rxprices@oregon.gov (Obtain an Account/Add Contact)</p>	<p>Trigger NOTICE: GENERIC WAC Increase $\geq 25\%$ AND $\geq \\$300$ within a 12-month period Exempts retail drugs manufactured by 4 or more companies that are either:</p> <ul style="list-style-type: none"> ○ Marketed and distributed under ANDA ○ Authorized generic drug ○ Entered market before 1962 <p>REPORT: WAC $\geq \\$100$ for one-month supply or course of treatment AND Increase $\geq 10\%$ within previous calendar year.</p> <p>Notice Provided to Department of Consumer and Business Services</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Effective date of increase ○ Current WAC ○ \$ Increase in WAC ○ Change or improvement necessitating increase ○ Year drug became available in US <p>Timing 60 days prior to the increase.</p> <p>Penalty Not to exceed \$10,000 per day of violation per schedule given in OAR 836-200-0560.</p>	<p>Registration Must create manufacturer account with department no later than February 15 of the year filing.</p> <p>Content of Report Price Increase Reporting has been suspended, see OR Bulletin 2024-3 In electronic format via iReg reporting system and including a certification of compliance document.</p> <ul style="list-style-type: none"> ○ Name of the drug ○ Trade name ○ Chemical name ○ Industry standard identification information ○ Price of drug at beginning of previous calendar year ○ Price of drug at end of previous calendar year ○ Highest and lowest prices of drug during previous calendar year ○ Percentage increase in WAC over previous calendar year ○ Length of time on market ○ Factors contributing to increase, financial and nonfinancial ○ Name of any generic version or biosimilar available on market ○ R&D costs paid using public funds ○ Costs incurred and total dollars expended for <ul style="list-style-type: none"> - Manufacture - Marketing - Distribution - Ongoing safety and effectiveness research ○ Total sales revenue of drug during previous calendar year ○ Profit attributable to drug during previous calendar year ○ Introductory price for drug when approved for marketing by FDA ○ Net yearly increase in price during previous 5 years ○ Ten highest prices paid for drug during previous calendar year in countries other than US ○ Other information deemed relevant by manufacturer ○ Documentation necessary to support reported information ○ Information about patient assistance program <ul style="list-style-type: none"> - Number of consumers participated - Total value of coupons, discounts, copayment assistance or other reduction in cost - Number of refills that qualify for program

OR Oregon	PRICE INCREASE (additional pre-increase notification required - continued)	
		<ul style="list-style-type: none"> - Period program is available to each consumer - Eligibility criteria for program <p>Notes on Content May limit to that in public domain or publicly available. May include request that information claimed as trade secret be exempted from publication.</p> <p>Due Dates Annually by March 15</p> <p>Publication Posted to website excluding information exempt from disclosure as a trade secret.</p>

<p>OR Oregon</p>	<p>NEW DRUG</p>	
<p>OR Rev. Stat. §646A.689 (6) OR Rev. Stat. §646A.692 (Penalty)</p> <p>OAR 836-200-0500 et seq. OAR 836-200-0505 (Definitions) OAR 836-200-0510 (Account) OAR 836-200-0520 (Trigger) OAR 836-200-0525 (Report) OAR 836-200-0530 (Report) OAR 836-200-0540 (Trade Secret) OAR 836-200-0560 (Penalty) OAR 836-200-0545 (Publication)</p> <p>DFR Prescription Drug Price Transparency</p> <p>2023 Drug Price Transparency Program Report</p> <p>DFR Prescription Drug Price Transparency Manufacturers</p> <p>Frequently Asked Questions</p> <p>DCBS Manufacturer User Guide</p> <p>rxprices@oregon.gov (Obtain an Account/Add Contact)</p>	<p>Trigger WAC for 30-day supply or course of treatment > threshold for specialty drug under Medicare Part D.</p> <p>Note: Per the DCBS Manufacturer User Guide, the threshold is \$670, the threshold in 2018, at the time of enactment of the law, for new drugs introduced before January 1, 2025.</p> <p><i>For drugs introduced on or after January 1, 2025, the threshold is \$950. Updates to OAR 836-200-0520 and the DCBS Manufacturer User Guide to change the threshold to match the dollar amount specified for minimum Medicare Part D specialty tier eligibility in the 2024 Final Call Letter from the Centers for Medicare and Medicaid Services are in process.</i></p> <p>Penalty Not to exceed \$10,000 per day of violation per schedule given in OAR 836-200-0560</p>	<p>Registration Must create manufacturer account with department 10 days prior to submitting the report.</p> <p>Content of Report In electronic format via iReg reporting system and including a certification of compliance document.</p> <ul style="list-style-type: none"> ○ Description of marketing. ○ Methodology used to establish price. ○ Breakthrough therapy designation or priority review by FDA ○ Date and price of acquisition, if applicable ○ Estimated number of patients ○ R&D costs paid using public funds <p>Notes on Content May limit to that in public domain or publicly available. May include request that information claimed as trade secret be exempted from publication.</p> <p>Due Date Report within 30 days of introduction.</p> <p>Publication Posted to website excluding information exempt from disclosure as a trade secret.</p>

OR Oregon	PRESCRIPTION DRUG AFFORDABILITY BOARD	
<p>Oregon Prescription Drug Affordability Board</p> <p>Prescription Drug Data</p> <p>OR Rev. Stat. §646A.697 (Generic Drug Study)</p> <p>2023 SB 192 (Upper Payment Limit Study)</p> <p>2024 Generic Drug Report</p> <p>Legislative Reports</p> <p>Upper Payment Limit Study</p> <p>Frequently Asked Questions</p>	<p>A Prescription Drug Affordability Board was established in 2021 to evaluate the cost of prescription drugs and determine whether they present an affordability challenge for consumers and health systems in Oregon.</p>	

<p>TX Texas</p>	<p>PRICE INCREASE</p>	
<p>TX. Health & Safety Code Ann. §441.0001 et seq. §441.0053 (Trigger and Report) §441.0054 (Publication) §441.0055 (Fee) §441.0102 (Penalty)</p> <p>Prescription Drug Price Disclosure Program</p> <p>Manufacturers - Submit Your Data (Templates)</p> <p>Frequently Asked Questions (Current Fee)</p> <p>How-to Guide</p> <p>Data Overview (Includes Price Increase Report and Annual Wholesale Acquisition)</p>	<p>Trigger WAC ≥ \$100 for 30-day supply AND Increase ≥ 15% during preceding calendar year or ≥ 40% over preceding 3 calendar years.</p> <p>Penalty Not to exceed \$1,000 per day for each violation</p>	<p>Registration Register for an Account with the Texas Prescription Drug Price Disclosure program to submit reports.</p> <p>Fee A flat fee of \$250 per report with an \$8 transaction fee (total \$258) is required by credit card or ACH with submission of each report.</p> <p>Content of Report Reports should use the Excel Price Increase Report Template provided.</p> <ul style="list-style-type: none"> ○ Name of the drug ○ Brand or generic ○ Effective date of WAC change ○ Description and significance of each factor that led to the increase <p>[NOTE: Drugs that meet increase trigger must meet additional requirements for annual report.]</p> <p>Notes on Content Quality and types of information and data submitted consistent with SEC Form 10-K or other public disclosure.</p> <p>Due Date 30 days after increase of WAC.</p> <p>Publication Annually on website within 60 days of receipt of report.</p>

<p>TX Texas</p>	<p>ALL RX DRUGS</p>	
<p>TX. Health & Safety Code Ann. §441.0001 et seq. §441.0051 (Annual Report) §441.0054 (Publication) §441.0055 (Fee) §441.0102 (Penalty)</p> <p>Prescription Drug Price Disclosure Program</p> <p>Manufacturers - Submit Your Data (Templates) (Current Fee)</p> <p>Frequently Asked Questions (Current Fee)</p> <p>How-to Guide</p>	<p>Penalty Not to exceed \$1,000 per day for each violation</p>	<p>Registration Register for an Account with the Texas Prescription Drug Price Disclosure program to submit reports.</p> <p>Fee A flat fee of \$250 per report with an \$8 transaction fee (total \$258) is required by credit card or ACH with submission of each report.</p> <p>Content of Report Reports should use the Annual WAC Report Template Example</p> <ul style="list-style-type: none"> ○ Current WAC <p>IF PRICE INCREASE TRIGGER MET</p> <ul style="list-style-type: none"> ○ Aggregate, company-level R&D costs for the most recent year for with final audit data ○ Name of each of the manufacturer's drugs approved by FDA within the preceding 3 calendar years ○ Names of manufacturer's drugs that lost patent exclusivity in the US during the preceding 3 calendar years. <p>Due Date Annually by January 15.</p> <p>Publication Annually on website within 60 days of receipt of report.</p>

<p>UT Utah</p>	<p>PRICE INCREASE</p>	
<p>Utah Code §31A-48-101 et seq. §31A-48-103 (Report)</p> <p>Utah Admin. Code R590-287</p> <p>Utah Insurance Bulletin 2020-10(b)</p> <p>Utah Pharmacy Drug Information</p> <p>Drug Transparency Reports by Month</p> <p>Pharmacy Drug Manufacturer Reporting Requirements</p> <p>UID Pharmacy Web Portal User Guide</p> <p>uid.healthresearch@utah.gov (For Questions)</p>	<p>Trigger WAC ≥ \$100 for 30-day supply AND Increase > 16% over preceding 2 calendar years or > 10% over preceding calendar year</p>	<p>Registration Manufacturers were to register with the Insurance Department prior to October 30, 2020 using the Pharmacy Drug Manufacturer Registration Form.</p> <p>Content of Report Reports submitted through UID Pharmacy Web Portal</p> <ul style="list-style-type: none"> ○ WAC history <ul style="list-style-type: none"> - Name of manufacturer - NDC - Description of the drug <ul style="list-style-type: none"> - Name - Strength - Dosage form - Package size - Brand or generic - Effective date of WAC increase - Amount of the WAC increase - WAC resulting from the increase - WAC one calendar year prior to effective date of increase - WAC two calendar years prior to effective date increase - Description and significance of each factor that led to the increase (suitable for public release) - Aggregate, company-wide R&D costs for the most recent year for with final audit data ○ Approval history – date drug was approved by FDA ○ Name of each of the manufacturer’s drugs approved by FDA within the preceding 3 calendar years ○ Patent history - names of manufacturer's drugs that lost patent exclusivity in the US during the preceding 3 calendar years and date each patent expired. <p>Notes on Content Obligations are satisfied by submission of data consistent with that provided on SEC Form 10-K or other public disclosure.</p> <p>Due Date 30 days after increase of WAC.</p>

UT Utah	PRICE INCREASE (continued)	
		<p>Publication Posted on the Insurance Department website within 60 days of submission. May not be released in a manner that would allow for identification of drug, drug class, or manufacture nor compromise the financial, competitive, or proprietary nature of the information</p>

<p>VT Vermont</p>	<p>PRICE INCREASE</p>	
<p>Vt. Stat. tit. 18, §4635 §4635(c) (Report) §4635(d) (Publication) §4635(f) (Penalty)</p> <p>Prescription Drug Cost Transparency- Manufacturer and Health Insurer Annual Reporting</p> <p>Green Mountain Care Board Prescription Drug Technical Advisory Group</p> <p>Attorney General’s Report on Prescription Drug Cost Transparency (2023)</p> <p>Attorney General’s Report on Prescription Drug Cost Transparency (2022)</p> <p>Attorney General’s Report on Prescription Drug Cost Transparency (2021)</p>	<p>Trigger TO BE CONSIDERED FOR INCLUSION ON LIST WAC Increase \geq 50% over past 5 years or \geq 15% during previous calendar year</p> <p>Penalty Not more than \$10,000 per violation</p>	<p>Report Required for List of 15 Drugs identified by Office of the Attorney General</p> <p>Content of Report Submitted to AGO.highcostprescriptiondrugs@vermont.gov.</p> <ul style="list-style-type: none"> ○ Justification for increase in net cost to Department of Vermont Health Access and/or one or more health insurers. <ul style="list-style-type: none"> - Each factor that caused increase - Percentage of increase attributable to each factor - Explanation of role of each factor in increase ○ Additional information as requested by Office of the Attorney General. <p>Notes on Content Manufacturer may provide version to be made public with redacted proprietary or confidential information. An explanation for each redaction must be provided.</p> <p>Publication Posted on websites of Office of the Attorney General and Green Mountain Care Board with redactions.</p>

<p>VT Vermont</p>	<p>NEW DRUG</p>	
<p>Vt. Stat. tit. 18, §4637 §4637(b) (Notice) §4637(c) (Report) §4637(e) (Publication) §4637(f) (Penalty)</p> <p>Reporting Required by Manufacturers of New High-Cost Prescription Drugs</p> <p>Quarterly Notices</p>	<p>Trigger WAC > threshold for specialty drug under Medicare Part D</p> <p>Notice Provided to Office of the Attorney General</p> <p>Timing Within 3 days after release of drug or pending approval by FDA if introduction expected within 3 days of approval.</p> <p>Penalty Not more than \$1,000 per day</p>	<p>Content of Report In a format prescribed by Office of the Attorney General.</p> <ul style="list-style-type: none"> ○ Description of marketing and pricing plans used in launch ○ Estimated volume of patients ○ Breakthrough therapy designation or priority review by FDA ○ Date and price of acquisition, if applicable <p>Notes on Content May limit to that in public domain or publicly available</p> <p>Due Date Report within 30 days of notice to Office of the Attorney General</p> <p>Publication Quarterly basis on website of Office of the Attorney General in a manner that identifies information on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.</p>

<p>VA Virginia</p>	<p>PRICE INCREASE</p>	
<p>VA Code Ann. §54.1-3442.02 (Trigger and Report)</p> <p>VA Code Ann. §32.1-23.4 (Publication and Penalty)</p> <p>12 VA Admin. Code 5-219 (Emergency, effective 1/17/22 to 7/16/23) 12VAC5-219-20 (Registration) 12VAC5-219-70 (Trigger and Report) 12VAC5-219-130 (Penalty)</p> <p>Prescription Drug Price Transparency Submission Manual</p> <p>Prescription Drug Price Transparency Reporting (Portal)</p> <p>2021 Prescription Drug Price Transparency Report</p> <p>rxpricing@vhi.org (For Questions)</p>	<p>Trigger GENERIC: WAC \geq \$100 for 30-day supply AND Increase \geq 200% within preceding 12 months</p> <p>Penalty Not to exceed \$2,500 per day</p>	<p>Registration Register and maintain information with Virginia Health Information (VHI). Contact rxpricing@vhi.org for login credentials</p> <p>Content of Report All manufacturers are expected to report in a .csv file via secure upload at Prescription Drug Price Transparency Reporting portal and include a certification of accuracy. A check box is available if there is no data to submit.</p> <ul style="list-style-type: none"> ○ Name of the prescription drug ○ Brand or generic ○ Effective date of WAC change ○ Aggregate, company-level R&D costs for the most recent year for with final audit data ○ Name of each of the manufacturer's new prescription drugs approved by FDA within the previous 3 calendar years ○ Name of each of the manufacturer's prescription drugs became subject to generic competition within the previous 3 calendar years and for which there is a therapeutically equivalent generic version ○ Concise statement of factors that caused increase in WAC <p>Notes on Content Obligations are satisfied by submission of data consistent with that provided on SEC Form 10-K or other public disclosure.</p> <p>Due Date Annually by April 1, in a form and manner that does not disclose or tend to disclose proprietary or confidential information.</p> <p>Publication Posted on website annually in aggregate in a form and manner that does not disclose or tend to disclose proprietary or confidential information.</p>

<p>VA Virginia</p>	<p>BIOSIMILARS</p>	
<p>VA Code Ann. §54.1-3442.02 (Trigger and Report)</p> <p>VA Code Ann. §32.1-23.4 (Publication and Penalty)</p> <p>12 VA Admin. Code 5-219 (Emergency, effective 1/17/22 to 7/16/23) 12VAC5-219-20 (Registration) 12VAC5-219-70 (Trigger and Report)</p> <p>Prescription Drug Price Transparency Submission Manual</p> <p>Prescription Drug Price Transparency Reporting (Portal)</p> <p>2021 Prescription Drug Price Transparency Report</p> <p>rxpricing@vhi.org (For Questions)</p>	<p>Trigger BIOSIMILAR: WAC at launch < 15% below the WAC of the reference product</p> <p>Penalty Not to exceed \$2,500 per day</p>	<p>Registration Register and maintain information with Virginia Health Information (VHI). Contact rxpricing@vhi.org for login credentials</p> <p>Content of Report All manufacturers are expected to report in a .csv file via secure upload at Prescription Drug Price Transparency Reporting portal and include a certification of accuracy. A check box is available if there is no data to submit.</p> <ul style="list-style-type: none"> ○ Name of the prescription drug ○ Brand or generic ○ Effective date of WAC change ○ Aggregate, company-level R&D costs for the most recent year for with final audit data ○ Name of each of the manufacturer's new prescription drugs approved by FDA within the previous 3 calendar years ○ Name of each of the manufacturer's prescription drugs became subject to generic competition within the previous 3 calendar years and for which there is a therapeutically equivalent generic version ○ Concise statement of factors that caused increase in WAC <p>Notes on Content Obligations are satisfied by submission of data consistent with that provided on SEC Form 10-K or other public disclosure.</p> <p>Due Date Annually by April 1, in a form and manner that does not disclose or tend to disclose proprietary or confidential information.</p> <p>Publication Posted on website annually in aggregate in a form and manner that does not disclose or tend to disclose proprietary or confidential information.</p>

WA Washington	PRICE INCREASE (additional pre-increase notification required)	
<p>RCW 43.71C RCW 43.71C.010 (Trigger) RCW 43.71C.050 (Report and Timing) RCW 43.71C.070 (Notice of Price Increase) RCW 43.71C.090 (Penalty) RCW 43.71C.100 (Publication)</p> <p>Wash. Admin. Code Chapter 182-51 Wash. Admin. Code §182-51-0200 (Registration) Wash. Admin. Code §182-51-0600 (Report) Wash. Admin. Code §182-51-1000 (Data Submission) Wash. Admin. Code §§182-51-1100 to -1800 (Penalty)</p> <p>Washington State Health Care Authority Manufacturer Data Submission Guide</p> <p>Washington Health Care Authority Prescription Drug Price Transparency</p> <p>Washington State Drug Price Transparency Program: Submitter registration FAQ</p> <p>Drug Price Transparency Stakeholder Webinar for Manufacturers (2/26/2020) Slide Deck and Recording (Reporting Templates for Download)</p>	<p>Trigger WAC ≥ \$100 for course of treatment lasting less than one month or a 30- day supply AND Increase ≥ 20% cumulative over 1 prior calendar year or 50% cumulative over 3 prior calendar years</p> <p>Content of Notice</p> <ul style="list-style-type: none"> ○ Date of increase ○ Current WAC ○ \$ Increase in WAC ○ Change or improvement necessitating increase <p>Notice Provided to Washington State Health Care Authority (HCA)</p> <p>Timing 60 days prior to the planned effective date of increase. If notification is not possible 60 days prior to price increase, submission must be made as soon as known but not later than date of price increase.</p> <p>Penalty Up to \$1,000 per day per Wash. Admin Code §182-51-1300 and Wash. Admin. Code §182-51-1400</p>	<p>Registration Drug Price Transparency Submitter Registration required by August 1 with Washington State Health Care Authority (HCA)</p> <p>Content of Report In accordance with Manufacturer Data Submission Guide</p> <ul style="list-style-type: none"> ○ Description of financial and nonfinancial factors used to make the decision to increase WAC ○ Amount of WAC increase and explanation of how factors explain WAC increase ○ Patent expiration date of the drug if under patent; ○ Status of drug as a multiple source drug, an innovator multiple source drug, a non innovator multiple source drug, or a single source drug ○ Itemized cost for production and sales <ul style="list-style-type: none"> - Annual manufacturing costs - Annual marketing and advertising costs - Total R&D costs - Total costs of clinical trials and regulation - Total cost for acquisition of the drug ○ Total financial assistance given by manufacturer through assistance programs, rebates, and coupons. IF DRUG PRICE INCREASE <ul style="list-style-type: none"> - Year the drug was introduced to market - WAC at time of introduction. IF PRICE INCREASE AND MANUFACTURED 5 YEARS <ul style="list-style-type: none"> - Schedule of WAC increases for previous five years. IF PRICE INCREASE AND ACQUIRED W/IN 5YEARS <ul style="list-style-type: none"> - WAC at time of acquisition and in calendar year prior to acquisition - Name of the company from which drug was acquired - Date drug acquired - Purchase price. <p>Due Date At least 60 days in advance of increase.</p> <p>Publication Report posted annually on website, data aggregated and must not reveal information specific to individual manufacturers.</p>

WA Washington	NEW DRUG (introduction to market)	
<p>RCW 43.71C RCW 43.71C.010 (Trigger) RCW 43.71C.050 (Report and Timing) RCW 43.71C.090 (Penalty) RCW 43.71C.100 (Publication)</p> <p>Wash. Admin. Code Chapter 182-51 Wash. Admin. Code §182-51-0200 (Registration) Wash. Admin. Code §182-51-0600 (Report) Wash. Admin. Code §182-51-1000 (Data Submission) Wash. Admin. Code §§182-51-1100 to -1800 (Penalty)</p> <p>Washington State Health Care Authority Manufacturer Data Submission Guide (3/1/2022)</p> <p>Washington Health Care Authority Prescription Drug Price Transparency</p> <p>Washington State Drug Price Transparency Program: Submitter registration FAQ</p> <p>Drug Price Transparency Stakeholder Webinar for Manufacturers (2/26/2020) Slide Deck and Recording (Reporting Templates for Download)</p>	<p>Trigger WAC ≥ \$10,000 for course of treatment lasting less than one month or a 30-day supply</p> <p>Penalty Up to \$1,000 per day per Wash. Admin Code §182-51-1300 and Wash. Admin. Code §182-51-1400</p>	<p>Registration Drug Price Transparency Submitter Registration required by August 1 with Washington State Health Care Authority (HCA)</p> <p>Content of Report In accordance with Manufacturer Data Submission Guide</p> <ul style="list-style-type: none"> ○ Description of financial and nonfinancial factors used to make the decision to set WAC ○ Patent expiration date of the drug if under patent ○ Status of drug as a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug ○ Itemized cost for production and sales <ul style="list-style-type: none"> - Annual manufacturing costs - Annual marketing and advertising costs - Total R&D costs - Total costs of clinical trials and regulation - Total cost for acquisition of the drug - Total financial assistance given by manufacturer through assistance programs, rebates, and coupons. <p>IF ACQUIRED W/IN 5YEARS</p> <ul style="list-style-type: none"> - WAC at time of acquisition and in calendar year prior to acquisition - Name of the company from which the drug was acquired - Date drug acquired - Purchase price <p>Due Date Within 30 days of release of a new covered drug to the market.</p> <p>Publication Report posted annually on website, data aggregated and must not reveal information specific to individual manufacturers.</p>

<p>WA Washington</p>	<p>BIOSIMILARS</p>	
<p>RCW 43.71C RCW 43.71C.060(New Drug Application) RCW 43.71C.090 (Penalty) RCW 43.71C.100 (Publication)</p> <p>Wash. Admin. Code Chapter 182-51 Wash. Admin. Code §182-51-0200 (Registration) Wash. Admin. Code §182-51-1000 (Data Submission) Wash. Admin. Code §§182-51-1100 to -1800 (Penalty)</p> <p>Washington State Health Care Authority Manufacturer Data Submission Guide (3/1/2022)</p> <p>Washington Health Care Authority Prescription Drug Price Transparency</p> <p>Washington State Drug Price Transparency Program: Submitter registration FAQ</p> <p>Drug Price Transparency Stakeholder Webinar for Manufacturers (2/26/2020) Slide Deck and Recording (Reporting Templates for Download)</p>	<p>Notice Provided to Washington State Health Care Authority (HCA)</p> <p>Content of Notice Written notice of filing of biologics license application (BLA) for a biosimilar drug.</p> <p>Timing Within 60 days of receipt of applicable FDA approval date.</p>	<p>Registration Drug Price Transparency Submitter Registration required by August 1 with Washington State Health Care Authority (HCA)</p> <p>Content of Report Upon receipt of notice, HCA may request:</p> <ul style="list-style-type: none"> ○ Primary disease, condition, or therapeutic area studied ○ Whether drug is therapeutically indicated for such disease, condition, or therapeutic area; ○ Route(s) of administration studied ○ Clinical trial comparators ○ Date FDA must complete its review ○ FDA designation as orphan drug, fast track product, or breakthrough therapy ○ FDA has designation for accelerated approval, priority review ○ If drug contains a new molecular entity <p>Note on Content May limit the information reported to that which is otherwise in the public domain or publicly reported.</p> <p>Publication Report posted annually on website, data aggregated and must not reveal information specific to individual manufacturers.</p>

WA Oregon	PRESCRIPTION DRUG AFFORDABILITY BOARD	
Washington Prescription Drug Affordability Board RCW 70.405 Wash. Admin. Code Chapter 182-52	A Prescription Drug Affordability Board was established in 2022. Its mission is to monitor and mitigate unsupported price increases of prescription drugs for Washingtonians.	

<p>WV West Virginia</p>	<p>DRUGS MEETING TRIGGER</p>	
<p>WV Code §33-54-1 et seq. §33-54-3 (Trigger and Report)</p> <p>Pharmaceutical Manufacturers Reporting User Guide (For Download)</p> <p>Pharmaceutical Manufacturer / Health Benefit Plan Issuer Transparency – (Reports)</p>	<p>Trigger WAC \geq \$100 for 30-day supply OR Increase \geq 40% over preceding 3 calendar years or \geq 15% in previous calendar year Note: The Auditor in West Virginia requires reporting if either trigger is reached.</p>	<p>Content of Report Submit via portal provided by State Auditor</p> <ul style="list-style-type: none"> ○ Name of the drug ○ Brand or generic ○ Effective date of WAC change ○ Introductory price of the drug when approved for marketing by FDA ○ The NDC ○ Aggregate, company-level R&D costs for the most recent year for with final audit data ○ Name and annual US sales/revenue of each of the manufacturer's drugs that lost patent exclusivity within the previous 3 calendar years ○ Statement of factors that caused any increase in WAC <p>Notes on Content Quality and types of information and data submitted consistent with SEC Form 10-K.</p> <p>Due Date Report by January 15 each year</p> <p>Publication Posted by July 1 on West Virginia Checkbook transparency site</p>

CALENDAR OF DUE DATES

January 1	LA	WAC Report of all drugs to Board of Pharmacy
January 15	ND	WAC Report of all drugs
	TX	WAC Report of all drugs, additional reporting for price increase
January 30	ME	Registration updated
January 31	CA	Report for price increases effective January through March
	NH	Report of price increase, additional reporting 60 days after request (suspended until 6/30/25)
	NH	New drug report to PDAB (suspended until 6/30/25)
February 15	OR	Creation of manufacturer account
March 15	OR	Report of price increase
April 1	FL	Report of price increase
	LA	WAC Report of all drugs to Board of Pharmacy
	MA	Report for high-cost drugs
	NV	Report for listed drugs
	VA	Report of price increase
	VA	Biosimilar launch report
April 15	ND	WAC Report of all drugs
April 30	CA	Report for price increases effective January through March
May 1	NM	Report of price increase (effective 2025)
July 1	LA	WAC Report of all drugs to Board of Pharmacy
July 15	ND	WAC Report of all drugs
July 31	CA	Report for price increases effective April through June
August 1	WA	Registration with HCA
October 1	LA	WAC Report of all drugs to Board of Pharmacy
October 15	ND	WAC Report of all drugs
October 31	CA	Report for increases effective October through December

CALENDAR OF DUE DATES (continued)

Within 3 days of release/FDA approval	CA	Notice of new drug
	NH	Notice of new drug
	ND	Notice of new drug
	VT	Notice of new drug
5 days prior to submission	CA	Registration on HCAi
Within 30 days of notice	CA	Report for new drug
	NH	Report for new drug to Insurance Department
	VT	Report for new drug
Upon price increase	FL	Notice of price increase (effective 7/1/2023)
Within 10 days of price increase	NJ	Notice of price increase (effective 8/1/2024)
Within 20 days of price increase	NJ	Report of price increase (effective 8/1/2024)
Within 30 days of price increase	LA	Notification of price increase to Commissioner of Insurance
	ND	Report of price increase
	TX	Report of price increase
	UT	Report of price increase
60 days in advance of price increase	CA	Notice of price increase
	NY	Notice of price increase
	OR	Notice of price increase
	WA	Notice of price increase and report for increase
60 days after price increase	MN	Report of price increase
60 days after email notification	ME	Report, including drug families, customized to each manufacturer
	MN	Report of Drugs of Substantial Public Interest
Within 3 days of introduction	NM	Notice of new drug (effective 1/1/2025)
Within 10 days of introduction	NJ	Notice of new drug (effective 8/1/2024)
	NJ	Notice of new biosimilar (effective 8/1/2024)
Within 20 days of introduction	NJ	Report of new drug (effective 8/1/2024)
	NJ	Report of new biosimilar (effective 8/1/2024)
Within 30 days of introduction	OR	Report of new drug
	WA	Report of new drug
Within 60 days of introduction	MN	Notice of new drug
	WA	Notice of new drug
Within 60 days of FDA action	CT	Notice of BLA filing for biosimilar
	WA	Notice of BLA filing for biosimilar

CALENDAR OF DUE DATES (continued)

No specified date	CO	Report of information for affordability review upon request of PDAB
	CT	Report of price increase in response to list prepared by OHS by March 1
	VT	Report of price increase