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Drug Pricing and Update on State Legal Issues

Stephanie Trunk

Partner

Arent Fox LLP

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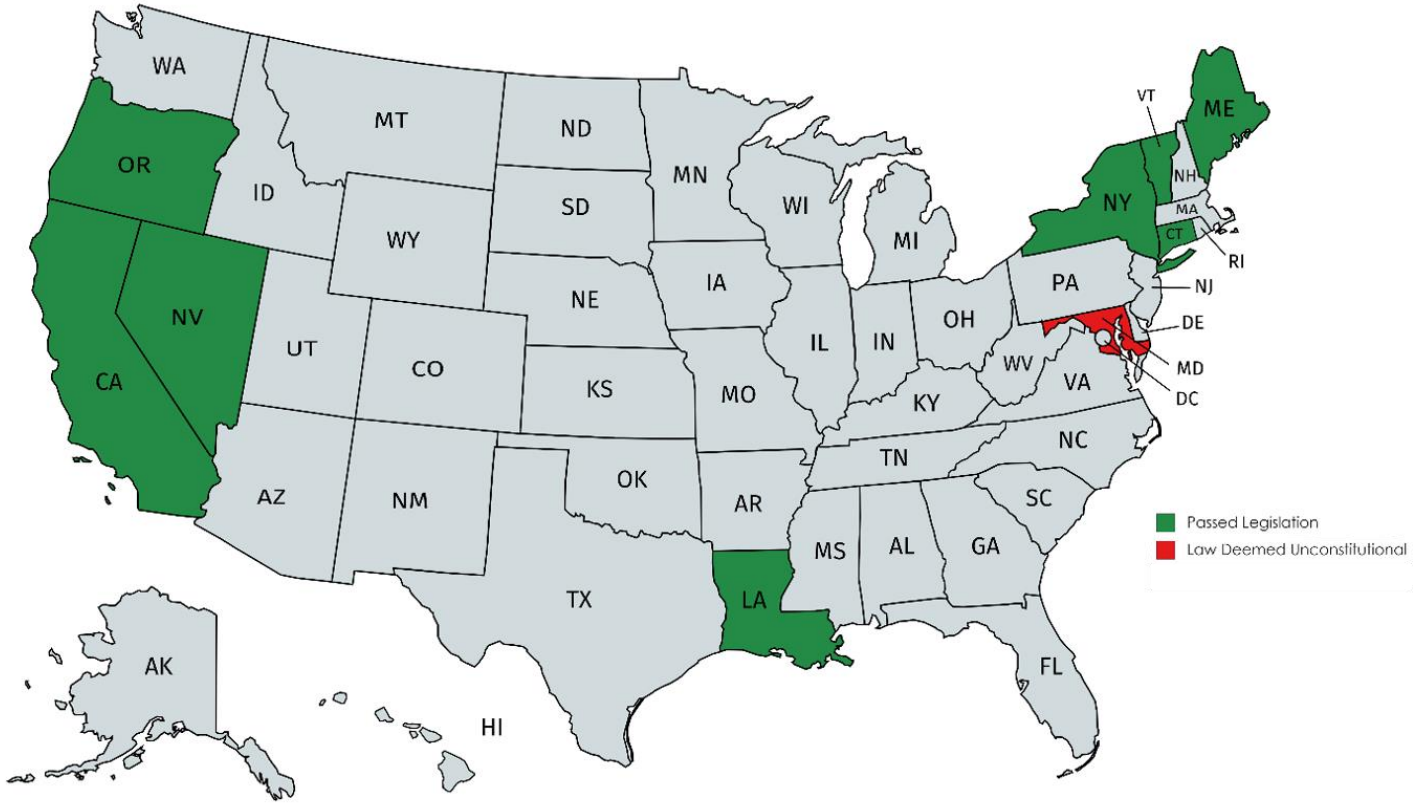
Current Manufacturer-Focused Drug Price Transparency Laws



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Themes of Drug Pricing Transparency Laws

- Advanced Notice of Price Increases- California

- Justify or explain price increase- Vermont, Maryland, Nevada, California, Connecticut, Oregon

- Penalty for “unconscionable increase”- Maryland

- Reporting for new drugs over a $ threshold- California

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Louisiana Mandates WAC Reporting

- Any manufacturer that markets a FDA-approved prescription drug in the State must report the current WAC on a quarterly basis (January 1st, April 1st, July 1st and October 1st)

- Report is submitted to the Louisiana Board of Pharmacy

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Drug Price Transparency- Vermont Law

- Vermont identifies a list of manufacturer specific drugs for which prices have increased over the last 5 year or over the previous 12 months and have had significant financial impact on the public health programs in the state. Up to 15 drugs may be selected and the drugs are to represent different drug classes

- All manufacturers/labelers with a product on the list were required to submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's WAC increase by December 1, 2016

- All information reported to the Attorney General is confidential

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Drug Price Transparency- Vermont Law

- The first list was posted on August 30, 2016 and included 10 products- 8 brands and 2 generics

- http://gmcboard.vermont.gov/publications/legislative-reports/Act165

- No second list…yet

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Drug Price Transparency- Vermont Law

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New York Medicaid Drug Cap

- New York Commissioner of Health establishes an aggregate annual drug spending limit

- To the extent the limit is exceeded, the Commissioner may identify and refer drugs to the Drug Utilization Review Board (DURB) for a recommendation on whether a supplemental rebate should be sought

- In the event a manufacturer and the DURB do not agree on a supplemental rebate amount, the DURB can require a report discussing-
  - developing, manufacturing and distribution costs
  - Administrative, marketing and advertising costs
  - Prices charged outside the United States
  - Prices charged purchasers in the State
  - Average profit margin over 5 year period and projected profit margin for the drug

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Maryland Price Gouging Bill

- **Declared Unconstitutional by 4th Circuit and en banc hearing denied on July 24, 2018**

- Effective October 1, 2017
- Prohibits an "unconscionable increase" in the price of a essential generic drug
- "Essential generic drug" is listed on the World Health Organization Model List of Medicines and designated by the Secretary as an essential medication due to efficacy in treating a life-threatening health condition or chronic health condition
- "Unconscionable Increase" means an increase in price that is excessive and not justified by product cost and results in consumers having no meaningful choice as to whether to purchase the drug given its importance to their health and not meaningful choice of alternatives
- Technically applies to manufacturers and wholesale distributors- though enumerated penalties only specific to manufacturers

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Maryland Price Gouging Bill

- Report- Maryland Medicaid is to notify the Attorney General when AMP or WAC increase 50% or more compared to the price in the prior 2 year period

- Attorney General can require the manufacturer to file a report substantiating the price increase, whether due to cost of production or otherwise

- If a Court finds "price gouging" occurred, it can-
  - File an injunction related to the price increase
  - Require manufacturer to pay the different between a validate price increase and the unconscionable price increase
  - Require the manufacturer to make the drug available to participants in a state health plan the drug at the former price for a period of one year
  - Impose a civil penalty of up to $10,000 for each violation

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Nevada Diabetes Drug Transparency

- Focus on insulin and biguanides

- Manufacturer Reporting
  - if WAC increases more than (1) CPI-U =for medical component in prior year or (2) twice the increase in CPI-U for the medical component in the 2 years prior
  - Then requires report on drug production costs, profits earned, total amount of financial assistance through patient assistance programs, costs associated with co-payment coupons and rebates to PBMs
  - And also reasons for WAC increase
  - Due April 1st of each year

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Nevada Diabetes Drug Transparency

- Sales Force Registration
  - Manufacturers must provide a list of sales representatives who market in the State
  - Each representative must disclose health care providers to whom he/she provided compensation with a value of $10/occurrence or $100/year
  - Record and disclose recipients of all free sample
  - Due March 1st each year

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Nevada Diabetes Drug Transparency

- PhRMA and BIO challenged the law as unconstitutional on dormant commerce clause grounds but dropped case after Nevada finalized regulations implementing the law

- Final regulations include a process for a manufacturer to designate portions of the annual report as trade secrets and require DHHS to notify a manufacturer if a third party requests a record designated as confidential

- No compliance enforcement until January 15, 2019

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California Drug Transparency Law

- **Advanced Notice of Price Increases**

- Requires manufacturers to give 60 days advance notice of a WAC increase of 16% or more on any drug more than $40 for course of therapy to state agencies, health plans/insurers and PBMs

- Notice must include scheduled price increase, current WAC of the drug, dollar amount of the increase and cumulative increases in past 2 years

- Must include statement as to whether change or improvement in the drug necessitates the price increase

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California Drug Transparency Law

- **Annual Reports For Drugs with Price Increases that Triggered Advanced Notice**

- Starting no earlier than January 1, 2019
- Manufacturers increasing WAC for drugs greater than 16% must report the following-
- Explanation for price increase
- Schedule of WAC increases in previous 5 years
- Patent expiration, if applicable
- Drug category- single source, innovator, non-innovator
- Any change or improvement in drug
- Sales volume in the United States in prior year
- Information will be published online

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California Drug Transparency Law

- **Reporting for New Drugs**

- Reporting for new drugs greater than the Medicare D specialty drug threshold- $670/month for 2018 with 3 days of release to commercial market
  - Marketing and pricing plans used in the launch of the drug
  - Estimated volume of patients
  - Whether the drug has breakthrough status
  - Date and price of acquisition, if applicable

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California Drug Transparency Law

- Pharmacies and other purchasers will "stock up" in advance of price increases. Could impact wholesaler supply

- Will cause competing generic manufacturers to raise WAC immediately to avoid run on cheaper products/failure to supply penalties

- Proposed regulations but comment period ended August 29, 2018
  - Would be able to limit reports to publicly available information

- **Challenged by PhRMA on dormant commerce clause grounds and forcing speech in violation of the First Amendment**

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Oregon Drug Transparency Law

- Mandatory reporting for any drug with a WAC of $100 or more per one month supply that has a WAC increase of 10% or more over the prior year

- First report due July 1, 2019 for prices increases over 2018

- Report includes
  - Length of time drug has been on market
  - Factors contributing to price increase
  - Research and development costs associated with the drug paid for with public funds
  - Manufacturer profit drug the prior year
  - 10 highest prices paid for the drug outside the United States
  - Costs to manufacture, market and distribute the drug

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Maine Drug Price Transparency

- **Reporting to Maine Health Data Organization**
  - The Maine Health Data Organization must develop a plan to collect data from manufacturers related to the cost and pricing of drugs for 25 most frequently prescribed drugs and 25 costliest drugs as determined by total amount spent on those drugs in Maine
  - Plan must be set by April 1, 2019

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Connecticut Drug Price Transparency

- **Reporting of NDA/BLA Submission**
  - Beginning January 1, 2020
  - Sponsors filing NDAs/BLAs (including biosimilar applications) must provide written notice of submission to the FDA no later than 60 days of filing with FDA

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Connecticut Drug Price Transparency

- **Reporting to Office Of Health Strategy**
  - Office of Health Strategy can prepare a list of up to 10 outpatient prescription drugs that (1) it determines are at substantial cost to the state, (2) the WAC less rebates paid to the state increased 20% in the past year or 50% in the past 3 years and (3) the WAC less rebates was at least $60 for a 30 day course of treatment
  - Report must include narrative of factors causing the WAC increase and aggregate, company-wide research and development and capital expenditures
  - Reporting begins March 1, 202 and annually thereafter

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Drug Pricing Update

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Medicaid Reimbursement for Covered Outpatient Drugs

- Under ACA, states must have Actual Acquisition Cost (AAC)-based methodology for drug reimbursement but physician administered drugs exempt

- Under ACA, states must consider whether drug acquired under 340B program but physician administered drugs exempt

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ACC-Based Pharmacy Reimbursement Under Medicaid

- State's methodology to implement AAC should be transparent, comprehensive and provide adequate reimbursement to Medicaid pharmacy providers

- States have varying AAC methodologies and some are "lower of"
  - NADAC: Alaska, California, Florida, Maryland, Michigan, New York, Texas
  - State AAC Surveys: Alabama, Colorado, Georgia, Louisiana, Montana
  - WAC-based: Hawaii, Massachusetts
  - AWP-based: Arizona, Connecticut, Maine
  - https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html

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Medicaid Reimbursement for Covered Outpatient Drugs

- NADAC and State AAC surveys are criticized because it is invoice prices only, no retrospective rebates, and responses are voluntary

- WAC is manufacturer reported; a “list price”

- AWP is by and large not reported by manufacturers but created by compendia publishers- 20-25% above WAC

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Medicaid Reimbursement for Covered Outpatient Drugs

- The Brookings Institute June 2017 Solution- https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf

- Require wholesalers to report at least for multi-source generic drugs net sales data, capturing all rebates that flow among manufacturers, wholesaler and pharmacies

- Could be part of federal licensing requirements under the Drug Quality and Security Act

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Medicaid Reimbursement for Covered Outpatient Drugs

- Currently, state Medicaid programs must reimburse for all covered outpatient drugs sold by a manufacturer that has executed a Medicaid Drug Rebate Program Agreements
  - Can subject drugs to prior authorization in cases of clinical superiority and under CMS approved state supplemental rebate programs

- Massachusetts Section 1115 waiver request, available at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/ma-masshealth-pa3.pdf
  - Closed Formulary with one drug per therapeutic class selected based on cost effectiveness
  - Limited specialty pharmacy network
  - Formulary exception process for medical necessity
  - Arizona also sent letter to CMS to discuss a more limited formulary for Medicaid suggesting 2 drugs per therapeutic class
  - **SPA was rejected by CMS as presumed it didn't have authority to approve under Section 1115; potential Center for Medicare & Medicaid Innovation (CMMI) demonstration?**

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Medicaid Reimbursement for Covered Outpatient Drugs

- President Trump's Budget Proposal
  - A 5 state compact for Medicaid programs to negotiate rebates with manufacturers
  - Would permit limited formularies
  - Require exception process for coverage of non-formulary items in cases of medical necessity

  - **Ripe for a CMMI demonstration**

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Medicare Part B Changes

- Effective Jan. 1, 2018, rural referral centers, Critical Access Hospitals and Disproportionate Share Hospitals participating in the 340B Program will be reimbursed by Medicare Part B at ASP- 22.5% rather than ASP + 6%
  - Drugs with Pass Through Status are excluded; biosimilars are eligible for pass through status and other new drugs whose cost are "not insignificant" compared to existing reimbursement for procedure/existing drug therapies

- All 340B hospital entities required to include claim modifier if drug was purchased at 340B price
- **American Hospital Association sued and suit dismissed for lack of standing, appealed to D.C. Circuit in January 2018, dismissal affirmed**

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Medicare Part B Changes

- Proposed for 2019 that Reimbursement to rural referral centers, Critical Access Hospitals and Disproportionate Share Hospitals participating in the 340B Program remain at Medicare Part B at ASP- 22.5% rather than ASP + 6%
  - Would extend to the child sites (physician offices associated with the 340B Covered Entities and entitled to buy drug at the 340B price)
  - Reimbursement for biosimilars without pass through status would be ASP – 22.5% of the biosimilar's ASP, rather than the reference product's ASP

- Proposed for 2019 that if WAC is used in lieu of ASP to reimburse for a drug, the reimbursement be WAC +3% rather than WAC + 6%

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Medicare Part B Changes- CAP 2.0?

- 2019 Proposed HOPPS Rule includes a RFI on leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals as the basis for a CMMI demonstration

- June 2017 MedPAC Proposal
- Drug Value Program
  - Voluntary enrollment
  - Private vendors negotiate drug prices with manufacturers
  - Permitted to use formularies with the aim of promoting cost effective therapies
  - Shared savings with providers

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Medicare Part D Changes

- Bipartisan Budget Act of 2018
  - Increased CGDP discounts from 50% to 70% of the "negotiated price" beginning in 2019
  - Corrected the biosimilar inequity- biosimilars now subject to the CGDP
  - President Trump's Budget Proposes that CGDP discounts do not count toward enrollee true out of pocket costs, which would keep enrollees in the coverage gap significantly longer

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Medicare Part C Changes

- Beginning in 2019, Medicare Advantage plans will be permitted to subject Part B drugs to prior authorization and/or step edits
- Can subject certain drugs to prior authorization or step edit based on cost, absence of a rebate from the manufacturer to the plan
  - Similar to state supplemental Medicaid programs

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Questions?

Stephanie Trunk
Partner
Arent Fox LLP
stephanie.trunk@arentfox.com
(202) 857-6171