



CLASSONE INSIGHT



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State Price Transparency Reporting

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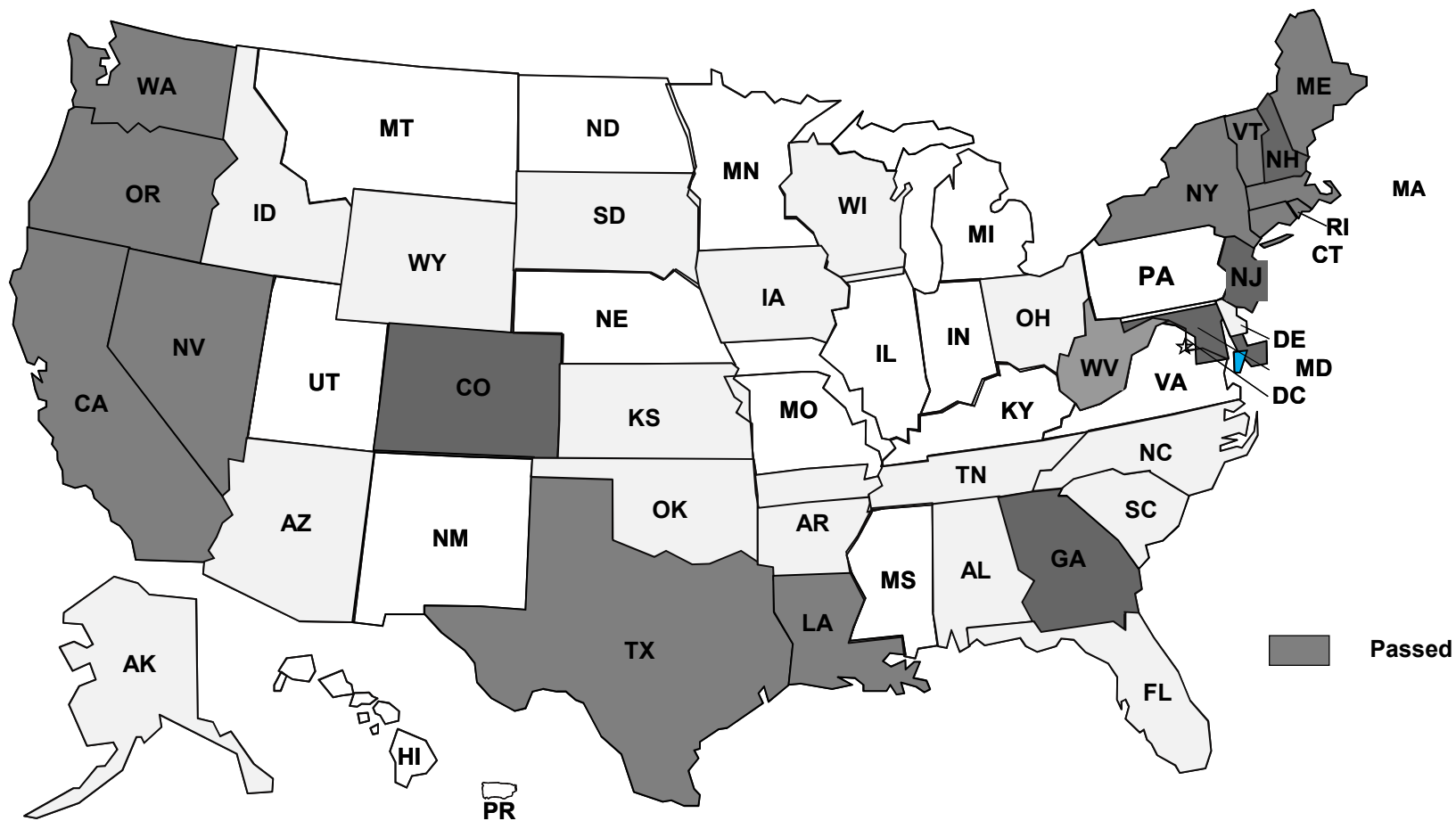
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Agenda

- ✓ State efforts towards transparency
- ✓ Reporting requirements
- ✓ New product considerations
- ✓ Enforcement, penalties, and legal challenges
- ✓ Best practices for compliance



State Drug Pricing and Access Laws



State Drug Pricing/Access Laws – Trends

▶ WAC

- All drugs marketed in the state – LA, TX, CO*

▶ Transparency

- Advanced Notice of Price Increases – CA, OR, WA
- Justify/explain price increase – CA, CT, ME, NH, NV, OR, VT, WA, WV
- Reporting for new drugs over a \$ threshold – CA, ME, NH, OR, WA
- Drugs specifically identified by the state – CT, ME, NV, VT

** Colorado currently requires manufacturers who are marketing their products to also provide names of at least 3 generics from same therapeutic class to prescribers at the time of any marketing, not report anything to the state, but there is pending legislation that will require reporting upon a price increase, similar to other states*



State Drug Pricing/Access Laws – Trends

▶ Price Controls

- State affordability boards to set ceiling on price – MA, MD

▶ Biosimilar and Generic Market Entry and Competition

- Notice of a BLA application upon Action Date – CT
- Restrictions on patent settlement agreements – CA

▶ Wholesaler/PBM Reporting

- PBM reporting on rebates received and retained – GA, TX, WA
- Wholesaler/PBM reporting “pricing component data/pricing unit of a drug” – ME



State Drug Pricing/Access Laws - Trends

▶ Drug Price “Caps”

- Most commonly related to the cost of insulin
- CO and IL have passed laws capping cost of insulin at \$100 for 30-day supply; but applies only to private insurance plans, not Medicare, Medicaid or ERISA plans
- Feb. 2020, KY House passed similar measure
- Feb. 2020, NM passed law capping insulin co-pay at \$25 per 30-day supply for insured patients covered by group health plans



Reporting Requirements for Existing Products

- ✓ **WAC Reporting for All Products with Fixed Due Dates**
 - Louisiana (Quarterly – January, April, July, October)
 - Texas (Annually – January)
- ✓ **Upon Price Increase with Fixed Due Dates**
 - California (Quarterly – January, April, July, October)
 - Maine (Annually – January)
 - Nevada – Essential Drugs (Annually – April)
 - Oregon (Annually – March)
 - West Virginia (Annually – January)



Reporting for Price Increases for Existing Drugs with Dynamic Due Dates

Trigger	State	Due Date
1) WAC > \$40/course of therapy AND	CA	60 days prior to price increase
2) WAC increases >16% from current year and prior 2 calendar years		
1) Brand Drug: WAC increase > 10% OR increase > \$10,000 during the previous 12 months	OR	60 days prior to price increase
2) Generic Drug: WAC increase > 25% AND increase > \$300 during the previous 12 months		
1) WAC > \$100/course of therapy AND	WA	60 days prior to price increase
2) WAC increases >20% in prior calendar year OR WAC increase > 50% or more in the prior 3 calendar years		
1) WAC > \$100/course of therapy AND	TX	30 days after price increase
2) WAC increases >15% in prior calendar year OR WAC increase > 40% or more in the prior 3 calendar years		



New Product Considerations

- ▶ Understand Price Determination Methodology
 - ▶ Work with appropriate persons/departments to understand pricing methodology
 - ▶ Will help you when filling out transparency reports
 - ▶ Ask to sit in on the meetings when the market research results are reported
 - ▶ Make sure whatever you put in transparency files has back-up documentation
 - ▶ A casual conversation with a Marketing Manager is not documentation



New Product Considerations

- ▶ Need to File?
 - ▶ Timing of Filing – before or after approval
 - ▶ Price Threshold
- ▶ Information Required – May be financial and/or narrative
 - ▶ Have the appropriate teams gathering information during development and throughout launch planning phases
 - ▶ R&D
 - ▶ Regulatory
 - ▶ Medical
 - ▶ Marketing/Commercial
 - ▶ Market Access
 - ▶ Patient Advocacy



New Product Considerations

- ▶ **Gain Internal Approvals**
 - ▶ Part of the Pricing Transparency Policy/SOP should include internal approval process
 - ▶ Global, Local, Both
 - ▶ Pricing Committee
 - ▶ Executives
- ▶ **Document Approvals**
- ▶ **Document Assumptions**
- ▶ **Archive All Information**



New Product Considerations

Brand Name of Product
Generic Name
Route of Administration
Projected PDUFA Date
Projected Market Date
NDC (if more than one add at bottom of file)
WAC (if more than one add at bottom of file)
If launched by other company and acquired by reporter, list company acquired from, date and price at acquisition
Strength
Unit type
Pack Size (if more than one add at bottom of file)
Case Size (if more than one add at bottom of file)
Sellable Size
Indication (as filed)
Patent Numbers and Expiry (list all)
Exclusivity Status (FDA)
Breakthrough, Priority Review, Orphan, or Fast-Track?
How was WAC derived? Method used to determine
Marketing Plan (key targets, campaign types, reach)
Project number of patients year one and peak
Primary Disease State
Secondary Disease State
Amount of R&D Costs supported with Public funding by supporter (new drug launch only)
Total R&D Costs (new drug launch only)
Trial Comparators
Cost to Make Drug
Which of above information is or will be in public domain

Create a New Product Worksheet

What will you need to complete a State Pricing Transparency Submission for a New Product?



Reporting for New Products

Event	Trigger	State	Due Date
Drug Application	Receive action (PDUFA) date from FDA re. NDA or BLA for pipeline drug or biosimilar	CT	Within 60 days of receipt of action (PDUFA) date
	File NDA or BLA for pipeline drug or biologic	WA	Within 60 days of FDA approval Date
New Drug Launch	Introduction of new drug with a WAC > specialty drug threshold for Medicare Part D (\$670 for 2019 & 2020)	CA & NH	Within 3 days of launch, initial notice Within 30 days of initial notice, full report
		ME	By Mar 31, 2020 for first year By Jan. 30 of the following year thereafter
		OR & VT	Within 30 days of launch
	Introduction of new drug with a WAC > \$10,000/course of treatment or 30 day supply	WA	Within 30 days of launch
Marketing to Prescribers	Engage in prescription drug marketing to a CO prescriber, including providing educational/marketing info	CO	At the time the marketing begins
	Engage in prescription drug marketing directly to a VT prescriber	VT	At the time the marketing begins



Enforcement

▶ California

- In December 2019, non-compliant manufacturers were notified of their failure to comply and the penalty is being at \$1,000/day/NDC.
- A dozen companies have been fined a total of \$17.5 million in the last 6 months
 - Collegium Pharmaceutical was fined \$3.6 million
 - Celgene was fined \$3.5 million & settled for \$600,000
 - Supernus Pharmaceutical was fined \$2.4 million, but is appealing
 - Another small manufacturer was fined more than \$500,000 & is appealing

▶ Nevada

- In Aug 2019, NV Department of Health & Human Services sent letters to non-compliant manufacturers to let them know they may be assessed a penalty of \$675,000 or more unless they comply with the law.



Challenges in the Courts

- ▶ California – ongoing litigation
 - ▶ *Pharmaceutical Research and Manufacturers of America v. David*, 2:17-cv-02573-MCE-KJN
 - ▶ Case has been active since initial filing in 2017
 - ▶ Challenging whether the law is constitutional from a First Amendment perspective
 - ▶ PhRMA has filed motion for summary judgment; motion hearing set for May 14, 2020 – pre-COVID
- ▶ Maryland – price gouging law declared unconstitutional
 - ▶ *Association for Accessible Medicines v. Frosh*, 1:17-CV-01860
 - ▶ Feb. 2019 – SCOTUS denied request for review of lower court’s ruling



Challenges in the Courts

▶ Oregon – ongoing litigation

- ▶ *Pharmaceutical Research and Manufacturers of America v. Lou Savage*, 6:19-cv-01996
- ▶ Allegation that disclosure law compels manufacturers to disclose confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third-party payers and competitors
- ▶ As of 3/24/2020 PhRMA has filed motion for partial summary judgment and requested oral arguments; awaiting further action from the court



Best Practices & Recommendations

- ▶ Document, Document, Document
 - Comprehensive Product Master & Historical Price List*
 - SPTR Policy
 - Assumptions
 - Any correspondence with states
 - Legal counsel guidance
- ▶ Educate Other Departments and Senior Management
- ▶ Sign up for notifications from states & vendors, where available

** Ensure you have WAC at launch, even if it was more than 5 years ago, or if the product was acquired from another manufacturer*



Differences & Nuances in Requirements

- ✓ Definitions are similar across some states but may be different or even missing from others
 - Manufacturer vs. Distributor vs. Repackager/Relabeler
 - “Covered” drug – piggyback onto Medicaid, outpatient, retail
- ✓ Year – Calendar Year, Weighted Average in Calendar Year, Rolling 12 Months, Rolling 12 Month Weighted Average
- ✓ How to treat an acquired drug – CA, OR, ME, & VT treat as a new drug; WA treats it as an existing drug; Unclear in CT & TX
 - For those states where it is treated as an existing drug, manufacturers must ensure they have sufficient WAC history for SPTR



Product Master Components That May Require Clarity & Documentation of Assumptions

Cost of Production	Costs of Clinical Trials & Regulations
Cost per Dose	Administrative Costs
Course of Therapy	Marketing & Advertising Costs
R&D Costs for Product	Total Profit of Product & Manufacturer
Company Level R&D Costs	US & International Marketing Plans
R&D Costs Specific to Product & Paid for with Public Funds	Methodology to Set WAC
Distribution Costs	Trade secret protections
Ongoing Safety & Effectiveness Costs	Purchase Price, if acquired product
Factors Contributing to WAC Increase, Explanation of Each, % of Total Increase Attributable to Each	If PAP, Co-Pay, Coupon Program: Costs Value of assistance



Suggested Price List Master Contents

NDC	Factors considered when raising WAC
WAC	Profit for CY in which increase occurred
WAC Start Date	Prior CY Sales Dollars and Units for the product
WAC End Date	Total Revenue for CY in which the increase occurred
Details if WAC Increase is related to change or improvement	Total Rebates & Chargebacks (paid & accrued) for CY in which increase occurred

Ensure you have WAC at launch, even if it was more than 5 years ago, or if the product was acquired from another manufacturer



Thank You

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