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2015-2016 Pharmaceutical Transparency Legislation

Legislators in at least 14 states proposed legislation to require varying degrees of transparency in the pharmaceutical industry, from price increases to the costs of research and development.

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About Knowledge Ecology International

Knowledge Ecology International (KEI) is a non-profit non-governmental organization that advocates for access to affordable medicines and access to knowledge with a focus on human rights and social justice. KEI advocates on behalf of consumers and patients at international organizations such as the United Nations, the World Health Organization, the World Intellectual Property Organization, and the World Trade Organization, as well as in the United States and dozens of other countries. KEI primarily focuses on the reform of knowledge governance mechanisms, particularly intellectual property rules as they relate to innovation and access in the pharmaceutical industry.

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Executive Summary

- 20 bills introduced in 14 states in 2015 and 2016 would enact varying degrees of transparency in the pharmaceutical sector for various costs associated with research and development (R&D) and marketing, and for prices.
- 18 bills would require disclosure of costs associated with R&D, marketing and advertising, and manufacturing.
- 19 bills would require disclosure of average wholesale price (AWP) or wholesale acquisition cost (WAC), or both.
- 4 bills would require the implementation of cost control measures for high-priced drugs or drugs that adversely affect state health care budgets.
- Overall, 11 of the 20 bills could be traced to 4 originator bills. One of the 20 bills became law in 2016.

Trends in State Pharmaceutical Transparency Legislation

Faced with high overall health care costs, quickly inflating drug prices, and increasing spending on the purchase and reimbursement of pharmaceutical products, states have responded by seeking to enact legislation to cap prescription drug spending.

From January 1, 2015 through August 5, 2016, both Democrat and Republican legislators in 14 states introduced 20 pieces of legislation (counting jointly introduced bills as one) related to transparency of data related to the research and development (R&D), manufacture, and sale of pharmaceutical products, as part of initial efforts to study the problems caused by high drug prices, the abuses of patent and related monopolies, and the results on patients and health care budgets of unreasonable and excessive drug prices.

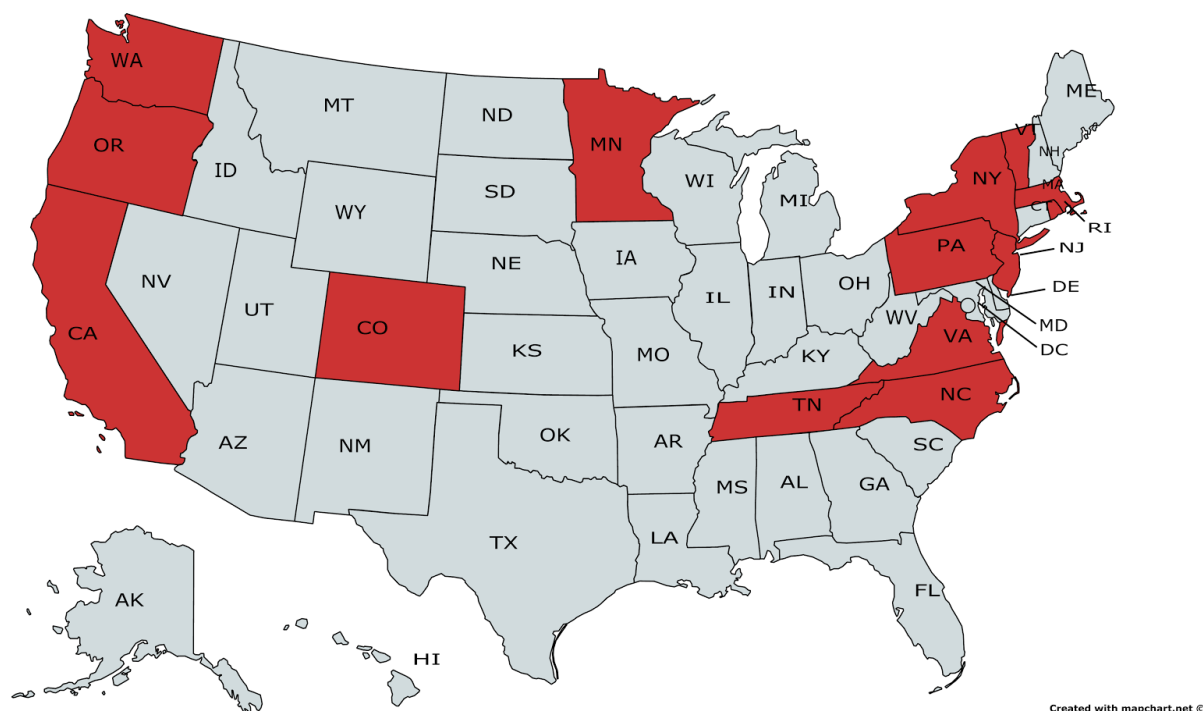
This recent spate of legislation followed years of legislation that mandate transparency in other areas of the provision of health care, such as transparency of pharmacy prices, hospital charges and payment data, and insurance formularies.¹

The states introducing pharmaceutical transparency legislation in 2015 and 2016 included California, Colorado, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, and Washington.

The proposed FY2017 New York Budget also included transparency provisions (modeled off of legislation proposed in other states) related to R&D, manufacturing, marketing, advertising, and other costs, as well as prices in New York and other states and countries, along with a novel value-based price control measure.

¹ National Conference of State Legislatures, "Transparency and Disclosure of Health Costs and Provider Payments: State Actions," August 2015, <http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx> (accessed August 8, 2016).

Image 1. Map of states that introduced transparency legislation in 2015-2016



Originator Legislation

12 of the 20 bills were modeled on 4 bills. 3 bills were unique, and 1 bill was enacted into law. In addition, 2 bills died in 2015 or 2016. Table 1 groups bills based on the 4 models.

Table 1. Legislation grouped by originator bill.

| CA AB 463 | MA S.1048 | WA HB2363 | NC H. 839 | Other |
|---------------------------|------------------------|---------------------------|-------------------------|-------------------------|
| CO HB1102-16 | TN HB 2206 | NY S. 7686 NY A. 10026 | VA SB 487 VA HB 1113 | VT Act 165 (enacted) |
| NY S. 5338A NY A .8265 | NJ A762 | | | VT H. 866 |
| MN SF 2942 MN HF 2526 | RI S 2560 RI H 7839 | | | CA SB 1010 |
| MN SF 2947 MN HF 2525 | | | | OR HB 3486 |
| PA SB893 | | | | |
| PA HB1042 | | | | |
| WA SB6471 | | | | |

CA AB 463: Bills in the California AB463 family of legislation would require disclosure of R&D costs, marketing and advertising costs, acquisition costs, and patient assistance costs, as well as total profits and average wholesale price and wholesale acquisition price increases, for drugs that met thresholds based upon the cost of treatment per year or month, ranging from \$1,000 per month of treatment to \$50,000 for a year of treatment or a full treatment course.

Pennsylvania Senate Bill SB893 also contained a cost control mechanism, in addition to the legislative language related to disclosures in AB463, but did not require price disclosures. The SB893 cost control mechanism would set a reasonable price threshold, based upon a percentage of the costs of R&D, and allow state agencies to refuse to reimburse drugs that have prices above the threshold.

MA S.1048: The Massachusetts bill and derivative bills are primarily designed to effectuate price control mechanisms for drugs that contribute to high overall healthcare spending, as identified by a state agency. The state would require disclosure of total R&D costs, total third party and government support, after-tax R&D costs on the pharmaceutical, and total direct-to-consumer and direct-to-prescriber advertising costs. The state would also require disclosure of prices net of rebates to pharmacy benefits managers within the state, overall state prices, and prices to other countries and/or states. The cost control measures would use that information to set a ceiling price either for drugs with excessive prices or drugs that “jeopardize” the health care budget of the state, based upon the investment in R&D, the reference prices, the medical benefits of the drug, and/or the number of years that the drug has been on the market. The Tennessee bill contains the same language related to disclosures as the Massachusetts bill, without cost control measures.

WA HB2636 and NY S. 7686/A. 10026: The Washington and 2016 New York bills contained the most in-depth reporting requirements for costs associated with R&D, marketing, and other costs, based upon a wholesale acquisition cost threshold for drugs that qualify under the bill.

NC H. 839 and VA SB 487/HB 1113: The North Carolina and Virginia bills would require minimal disclosures for the various cost categories identified in other legislation, as well as price and cost increases. The North Carolina bill would require a 5-year history of wholesale acquisition cost increases.

VT Act 165: Vermont Act 165 establishes a list of drugs determined by the Green Mountain Health Care Board, for which drug manufacturers are required to justify any price increases. The Act only specifies that drug manufacturers must include any “factors” that contributed to the price in its justification, but does not specify what factors. Any reports submitted under Act 165 are confidential. Non-compliance is subject to fines and/or litigation.

VT H. 866 and OR HB 3486: The proposed Vermont and Oregon bills would require disclosure of various costs and drug prices. Both contain distinct legislative language from all other bills,

and have distinct thresholds to trigger reporting requirements and different rules for confidentiality of information.

Table 2: Timeline of bills by date of introduction, with bill type and status.

| State | Bill Number | Bill Type ² | Date Introduced | Status |
|-----------|---------------------|------------------------|--------------------------------------|---|
| MA | S.1048 | CD; PD; CC | January 1, 2015 | 6/6/2016 — Order to conduct study under review by Senate Committee on Rules |
| CA | AB 463 | CD; PD | February 23, 2015 | 2/1/2016 — From committee: Filed with the Chief Clerk pursuant to Joint Rule 56. [Dead] |
| OR | HB 3486 | CD; PD | March 11, 2015 | 7/6/2015 — In committee upon adjournment. [Dead] |
| NC | H. 839 | CD; PD | April 14, 2015 | 4/15/2015 — Referred to Health |
| PA | HB1042 | CD; PD | April 21, 2015 | 4/21/2015 — Referred to Insurance |
| NY | S. 5338A A. 8265 | CD; PD | May 13, 2015 June 16, 2015 | 1/20/2016 — Amended, recommitted to Health 1/6/2016 — Referred to Health |
| PA | SB893 | CD; CC | June 16, 2015 | 6/16/2015 — Referred to Banking and Insurance |
| CO | HB16-1102 | CD; PD | January 1, 2016 | 3/10/2016 — Health, Insurance & Environment postpone indefinitely |
| WA | HB 2363 | CD; PD | January 8, 2016 | 3/10/2016 — By resolution, reintroduced and retained in present status |
| VA | SB 487 HB 1113 | CD; PD | January 12, 2016 January 13, 2016 | 2/11/2016 — Continued to 2017 in Education & Health 2/4/2016 — Continued to 2017 in Commerce & Labor |
| VT | Act 165 | PD; PJ | January 15, 2016 | 6/2/2016 — Signed by Governor |
| WA | SB 6471 | CD; PD | January 21, 2016 | 3/10/2016 — By resolution, reintroduced and retained in present status |
| TN | HB2206 SB2242 | CD; PD | January 21, 2016 | 1/27/2016 — Referred to Health/Government Operations |
| NJ | A762 | CD; PD; CC | January 27, 2016 | 1/27/2016 — Introduced; Referred to Health and Senior Services |

Table 2 continued on following page.

² CD = disclosure of costs and/or profits; PI = disclosure of price increases; PJ = disclosure of price justifications; CC = use of cost control.

Table 2. Timeline of bills by date of introduction, with bill type and status (continued).

| State | Bill Number | Bill Type | Date Introduced | Status |
|-------|---------------------|---------------|-----------------------------|--|
| CA | SB 1010 | PD; PJ | February 11, 2016 | 8/17/2016 — Legislation delayed ³ |
| RI | S 2560 | CD; PD; CC | February 25, 2016 | 4/2/2016 — Health & Human Services recommended measure be held for further study |
| | H 7839 | | March 3, 2016 | 3/3/2016 — Corporations recommended measure be held for further study |
| MN | SF 2942 | CD; PD | March 17, 2016 | 3/30/2016 — Reported favorably as amended by Health, Human Services and Housing to Finance |
| | HF 2526 | | March 8, 2016 | 3/8/2016 — Introduced |
| MN | SF 2947 | CD; PD | March 17, 2016 | 3/17/2016 — Referred to Health, Human Services and Housing |
| | HF 2525 | | March 8, 2016 | 3/8/2016 — Referred to Health and Human Services Reform |
| VT | H. 866 | CD; PD | March 15, 2016 | 5/2/2016 — Referred to Health Care |
| NY | S. 7686 A. 10026 | CD; PD | May 12, 2016 May 6, 2016 | 5/12/2016 — Referred to Health 5/6/2016 — Referred to Health |

Types of Legislation

The proposed bills can be broadly categorized based upon the type of information disclosure that the legislation would require as well as the action that the legislation would authorize based upon that information. All 20 pieces of legislation would require a combination of disclosure of various costs, including those associated with R&D, manufacturing, and marketing; disclosure or justification of changes in average wholesale price (AWP) or wholesale acquisition cost (WAC); and government use of methods to control costs of statewide health programs, such as price ceilings or adjustments to reimbursements.

- All 20 bills would require some combination of:
 1. disclosure of costs/profits;
 2. disclosure of prices and price increases and/or justifications; or
 3. the use of cost control methods by state health agencies.

³ See the bill sponsor's website: <http://sd22.senate.ca.gov/news/2016-08-17-statement-senate-bill-1010>.

- 18 of the 20 bills would require disclosure of R&D/other costs (administrative, marketing, etc.), with 12 also requiring disclosure of profits.
- 4 bills would require a state agency to use cost control measures based upon disclosed R&D and cost data, an analysis of budget implications, and reference prices in other states or countries.
- 19 bills would require companies to disclose price increases, while only 2 pieces of legislation (including Act 165 of Vermont, which was signed by the governor in June 2016) would require companies to justify reported price increases.

Cost/Profit Disclosure

Legislation that would require disclosure of costs associated with the development and sale of drugs comprised the largest category of proposed legislation, with 18 of the 20 bills requiring some form of cost or profit disclosure. All but one of those 18 bills would require the disclosure of WAC or AWP, or both. 12 of those bills would also require the disclosure of profits, both in dollar amounts and as a percentage of overall company profits. Only one bill would require the disclosure of the cost of failures.

Cost disclosure bills would require varying degrees of transparency for costs associated with production, R&D, manufacturing, marketing, and administration.

R&D Transparency:

- All 18 cost/profit bills broadly would require disclosure of the costs of R&D. 12 of the bills would require separate line items for the costs associated with the current manufacturer and any predecessor manufacturers or developers of the qualifying drug.
- 15 bills would require the total costs of "production," a broad category that for many bills included R&D costs, clinical trial costs, regulatory, materials, manufacturing, and various other costs. 7 bills included marketing costs as part of the costs of "production." The four Massachusetts family bills would require disclosure of the approximate cost of production per dose.
- 13 of the cost/profit bills would require disclosure of the total costs of clinical trials, while 2 would require disclosure of total pre-clinical study costs, 3 would require total FDA-mandated post-approval (marketing surveillance) study costs, 2 would require total post-approval study costs "earmarked for publication," and 1 would require total non-FDA-mandated post-approval study costs. Additionally, 11 bills would require disclosure of all regulatory costs, of which clinical trial costs are the most significant.

Only 2 of the 13 bills that would require disclosure of clinical trial costs did not also require disclosure of other regulatory costs.

- 12 of the bills would require disclosure of manufacturing costs, with 10 requiring the cost of “materials” and 3 requiring the costs of distribution. 11 bills would require disclosure of administration costs.

Taxpayer Support Transparency:

- 14 bills would require the disclosure of total third party support, while 17 specified that drug manufacturers would be required to disclose total government (i.e., state and federal) support, including 14 which would additionally require the explicit disclosure of government subsidies and grants.
- The four bills in the Massachusetts family of legislation also would require disclosure of post-tax R&D costs.

Acquisition Cost Transparency:

- 13 of the bills would require disclosure of total acquisition costs, including corporate mergers and acquisitions, the purchase of patent rights, and the total spend on licensing agreements.

Advertising and Marketing Costs

- 16 bills would require the disclosure of total advertising and total marketing costs.
- 14 of the bills would require the disclosure of total direct-to-consumer advertising costs, and 13 direct-to-prescriber advertising costs (with some including direct-to-prescriber costs as a subset of direct-to-consumer costs).
- 13 of the bills would also require manufacturers to disclose the costs of distributing and providing refunds based on coupons.
- The four bills in the Massachusetts family of legislation would also require disclosure of marketing and advertising costs specific to patients and providers within the state.
- The 2016 New York legislation (S. 7686/A. 10026) would also require disclosure of prescriber and professional education costs, lobbying costs contributions to patient advocacy, disease, and other consumer groups, and the total monetary equivalent of sample trial doses provided to patients and providers.

Patient Assistance Program Costs:

- 12 bills would require the disclosure of total patient assistance costs.

Price Disclosure/Justification

Price Disclosure:

- 19 bills would require varying degrees of disclosure of wholesale acquisition cost (WAC) and/or average wholesale price (AWP).
- 11 states would require disclosure of AWP increases, by date or month and with the percent increase for the past year, and 11 states would require the same for WAC increases.
- 5 bills, including those in the Massachusetts family and the Vermont bill, would require disclosure of prices for other countries, representative state purchasers, and the true net typical prices to pharmacy benefits managers, net of rebates and payments, within the state.
- 2 bills would require a 5-year WAC increase history.

Price Increase Justification:

- Only 2 bills are designed to require companies to justify increases in price or cost.
- CA SB1010 would require justification for price increases for drugs with price increases of greater than 10% of the current price or greater than \$10,000, and a schedule of price increases for the previous 5 years.
- VT Act 165 requires manufacturers for high-priced drugs or drugs that significantly contribute to health care expenditures to justify their prices.

Cost Control Measures

Four of the 20 bills contain mechanisms that would require states to act to lower unreasonable drug prices, or the prices for drugs that have the potential to jeopardize the state health care budget.

The Massachusetts and Rhode Island bills would require the states to set price ceilings for drugs that jeopardize the health care budget, based upon reference prices from other countries, the medical benefits of the drug, and the costs associated with R&D.

The New Jersey bill would require the state to set a maximum price for high-cost drugs with excessively high prices. The price would be set based upon reference prices, the costs of R&D, and the number of years the drug has been on the market.

PA SB893 would allow payors to deny reimbursement for drugs that fail a reasonable price threshold test, set at 20% of the costs associated with R&D.

Trigger Mechanisms

The various bills would trigger based upon certain criteria, some with multiple triggers.

14 of the 20 bills would require disclosure of information for drugs with an annual or treatment course wholesale acquisition cost (WAC) of \$10,000 or more, or for drugs designated as having public interest implications by a state agency or commission.

- Only 1 bill (PA SB893) applies to all drugs. 1 other bill (NC H. 839) triggers for certain classes of medicines.
- 8 bills would trigger for drugs with WACs of \$10,000 or more per year or treatment course, 2 for WACs of \$1,000 or more per month or treatment course of less than 30 days,⁴ 1 for WACS of \$50,000 or more per year or treatment course, and 1 for WACs of \$5,000 or more per year or treatment course.
- 2 bills would trigger based upon price increases.
- 6 bills would trigger based upon drugs added to a public interest list, as populated by a state agency.

Compliance and Audits

Only 9 of the bills outlined penalties for non-compliance, including fines, provisions for litigation, and right to refuse to reimburse. Only 8 bills would require independent, third-party audits for the required reports.

⁴ Note that MN HF 2526 sets the threshold at \$1,000 per year or treatment course, and is likely an error.

Confidentiality and Public Reporting Requirements

Confidentiality:

- Ten of the bills included no confidentiality rules within the legislation. It is beyond the scope of this note to examine the transparency rules for those 10 states, which may or may not restrict access to any records generated under the proposed legislation.
- 6 bills would designate all submissions as entirely confidential and not subject to public records laws.
- 4 bills would designate some information, largely upon the designation of a state official, as confidential.
- 7 would allow state agencies to release confidential/proprietary in the aggregate.
- None of the bills contained language that would indicate that all of the reported information would be publicly accessible.

Public Reporting Requirements:

- 17 of the bills would require state agencies to report to the state legislature and release those reports online. The 2016 New York legislation would require quarterly updates to the annual report.
- CA SB1010 would require the state to notify the public of price increases.

Sponsorship

11 bills had only Democrat sponsors or co-sponsors. 8 bills had both Democrat and Republican sponsors or co-sponsors.⁵ Vermont's enacted bill had a Republican sponsor and no cosponsors.

⁵ VT H. 866 is sponsored by the full House Committee on Health Care.