

Washington State

Prescription Drug Price Transparency Legislation: Review and Recommendations

A report to the Legislature

As required by Substitute Senate Bill 5883
(Chapter 1, Laws of 2017, 3rd Special Session)



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Forecasting and Research Division
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Executive summary

In 2001, prescription drug costs represented 13 percent of the health care cost for an average American family; by 2017, those costs had grown to 17 percent.¹ Given prescription drugs' burgeoning share of health care costs — and the collective outrage over inexplicable price hikes highlighted recently in various media reports — concerns over prescription drug prices have been mounting. Absent any federal initiatives, states are now exploring options to address these rising prices. One such approach has been *price transparency*, which, broadly, requires manufacturers to justify price increases above a set threshold.¹

In 2017, the Washington State Legislature included a proviso in the state budget directing the Office of Financial Management to determine if the newly established all payers claims database (WA-APCD) could be used to initiate such a price transparency process. In that context, the WA-APCD would allow for:

- Reporting of consumer out-of-pocket expenditures for prescription drugs;
- Identification of the most commonly prescribed drugs;
- Annual charges for prescription drugs; and
- Identification of those drugs with charges that are increasing at a higher-than-average rate.

However, transparency in prescription drug costs typically requires manufacturers and, at times, others involved in bringing a drug to market to report detailed financial information on costs for researching, manufacturing, advertising and marketing those drugs. To go beyond the measures now available through the WA-APCD and require such information from manufacturers and, potentially, others would necessitate new or revised legislation.

To that end, this report provides an overview of factors to consider in developing such legislation, beginning with possible metrics for use in monitoring drug prices and including a discussion on how such metrics are surprisingly complicated to identify because what a drug cost varies widely throughout the process of taking it from manufacturer to patient.

The report also highlights the statutes, together with their attendant successes and shortcomings, of four states that recently put forward prescription drug transparency legislation: Oregon, California, Nevada and Vermont. While similar in some regards, they differ in others and collectively provide a set of lessons learned in the development of transparency legislation.

In addition, since the proviso references Canada's drug pricing practices, a review of that system is included. Although Canada is often touted as a potential model system, its prescription drug prices — and the approaches taken to control them — would face a host of challenges, under federal law, if they were to be implemented in the United States.

Although not requested in the proviso, the report provides a brief summary of Washington's current drug purchasing strategy, which focuses more on exercising market forces as a major purchaser than on using transparency to control costs.

¹ Currently, the Washington State Health Care Authority is examining transparency in its Public Employees Benefits Board and Medicaid drug purchasing programs, but these programs do not make manufacturer prices transparent. In fact, a proviso from the current state budget (see [SSB 5883](#), Pages 108–109) requires pharmacy data from the Medicaid managed care plans for reports to the Legislature “without disclosure of proprietary or confidential drug-specific information.”

Below are brief summaries of the report's key findings.

Among the various price metrics, the wholesale acquisition cost (WAC) and average acquisition cost (AAC) are the two most commonly used cost measures. The WAC, which is the most widely used, is akin to the invoice price a dealership pays a car manufacturer. This list price does not reflect any discounts or rebates negotiated between the drug manufacturer and either the wholesaler or the pharmacy benefits manager. A more recently developed measure, the AAC, is based upon surveys of pricing data from independent and chain retail pharmacies and reflects the actual transactional price of drugs. The Centers for Medicare and Medicaid began providing AAC price data on a public website in 2013 for drugs it covers; however, while seemingly extensive, that list is relatively limited.

Most states with enacted or proposed transparency legislation have used the WAC as their metric. In the Oregon proposed bill, the WACs from comparison countries are proposed for use in establishing price thresholds; any increases or new drugs introduced above those thresholds would trigger a justification process involving the reporting of detailed development and marketing costs. Such an approach mirrors, to a degree, that taken in Canada. Although the Oregon bill did not pass out of committee, the span of opposition is worth noting — from patient advocates fearful that specialty drugs would lose coverage, to start-up pharmaceutical companies concerned about excess costs in monitoring and reporting detailed financial information, to drug lobbyists noting the shortcomings of the WAC as an inaccurate cost measure.

California's newly passed legislation, which has garnered much attention, is broad in scope, encompassing any drug with a WAC of more than \$40 per course of therapy and a price increase of more than 16 percent over the course of two years. But the law is also, arguably, shallow in design, ignoring, for instance, negotiated rebates and discounts. In addition, the statute risks signaling wholesalers in advance of a price increase, allowing them to stockpile many drugs slated to increase for resale later at the higher price.

Alternately, Nevada's legislation is narrow in scope, focusing only on diabetes-related drugs, but broad in design, requiring transparency not only from manufacturers but also from pharmacy benefits managers, sales representatives and nonprofit patient advocacy organizations. That legislation is now being challenged in the courts and the legal arguments strike at the root of many transparency initiatives: from the authority to establish patent policy, to the federal Defend Trade Secrets Act, to the Fifth Amendment's Taking Clause, to the Commerce Clause. How well this bill fares under judicial review may have profound effects on current and future transparency laws.

Last, while noteworthy for being the first successfully enacted drug transparency law in the nation, Vermont's statute may, nonetheless, be best known for its lack of impact. As required, the report mandated in this statute focuses on 10 drugs whose WAC had increased by 50 percent or more over the previous five years or by 15 percent or more over the last year. Manufacturers are required to justify these increases in a confidential report to the Office of the Attorney General. That office, in turn, summarizes those justifications in a publicly released report. The broad and vague details in the first final report — with its lack of any real impact — make it a cautionary tale of trying to legislate transparency without risking challenges from manufacturers.

In addition to examining these states' transparency legislation, because the budget proviso also expressed interest in Canadian prescription drug pricing, a summary overview of that country's health care system is provided in this report. Perhaps surprisingly, outside an inpatient setting, prescription drugs are not covered under Canada's universal health care system. (Most Canadians are insured for that component of

their health care through their employer or on their own.) Moreover, even with price-regulated and universally covered patented drugs for inpatients, Canada still has higher drug prices than all the other countries it uses for indexing prices, except for the United States — and for generic drugs, Canadians actually pay more than U.S. citizens. In short, while Canada may model some approaches worth adopting, its system struggles with rising prescription drug costs, too.

In taking such a broad view of the Canadian system, it seems worthwhile reiterating, briefly, the description of Washington’s current prescription drug purchasing strategies, which mirror some aspects of the Canadian system. As outlined in a report submitted to the Legislature last year, [Review of Prescription Drug Costs and Summary of Potential Purchasing Strategies](#), by allying itself with other major purchasers — including Oregon — the state’s process mirrors Canada’s exercising of market forces to better negotiate prescription drug prices.

Transparency has value, but it appears limited in other states under review. Both Nevada and California are now facing legal challenges to their prescription drug price transparency laws; the resolution of those suits is in the courts’ hands. Federal law prohibits states from directly negotiating drug prices and, instead, limits such negotiations to rebates, further affecting states’ opportunities.

Finally, in reviewing transparency of the four states highlighted here as well as others across the country, none has used its APCD (or the program directly responsible for its day-to-day operation) as its transparency reporting entity. Instead, such responsibilities have typically fallen to the state attorney general’s office, the state insurance office, the state health and human services program or the state health planning office. In Washington, consideration could be given to the first three locations, but perhaps the best fit might be in the Office of Financial Management, where the WA-APCD is housed as well as where the health care research and planning functions are conducted.

Introduction

In 2017, the Washington State Legislature passed the state operating budget, Substitute Senate Bill 5883 (Chapter 1, Laws of 2017, 3rd Special Session) that, in part, states:

(5) The office of financial management must perform a legal and policy review of whether the lead organization of the statewide health claims database established in chapter 43.371 RCW may collect certain data from drug manufacturers and use this data to bring greater public transparency to prescription drug prices. Specifically, the review must analyze whether the organization may collect and use manufacturer's pricing data on high-cost new and existing prescription drugs, including itemized production and sales data and Canadian pricing. The office of financial management must report by December 15, 2017, to the health care committees of the legislature the results of the study and any necessary legislation to authorize the collection of pricing data and to produce public analysis and reports that help promote prescription drug transparency.

This report is in response to that request.

As currently written, Chapter 43.371 of the Revised Code of Washington (RCW) would allow for:

- Reporting of consumer out-of-pocket expenditures for prescription drugs;
- Identification of the most commonly prescribed drugs;
- Annual charges for prescription drugs; and
- Identification of those drugs with charges that are increasing at a higher-than-average rate.

The current law would not, however, allow for the collection of pricing, itemized production or sales data from prescription drug manufacturers. Furthermore, prescription drug pricing in Canada is more complex — and decentralized — than perhaps implied by this directive. Canadian pricing lists, as well as price controls, vary by the medicines' patent or generic status, whether the prescription is for a patient in an inpatient or outpatient setting, and the province in which the patient resides.

In fact, chapter 43.371 RCW grants the lead organization the authority to collect claims data only. This authority is, initially, limited to claims data from the state Medicaid program, Public Employees' Benefits Board programs, all health carriers operating in the state, all third-party administrators paying claims on behalf of health plans in this state, and the state Labor and Industries program. However, the director of the Office of Financial Management may expand that authority, by rule, to include the following:

- a. Long-term care insurance governed by chapter 48.84 or 48.83 RCW;
- b. Medicare supplemental health insurance governed by chapter 48.66 RCW;
- c. Coverage supplemental to the coverage provided under chapter 55, Title 10, United States Code;
- d. Limited health care services offered by limited health care service contractors in accordance with RCW 48.44.035;
- e. Disability income;
- f. Coverage incidental to a property/casualty liability insurance policy such as automobile personal injury protection coverage and homeowner guest medical;

- g. Workers' compensation coverage;
- h. Accident-only coverage;
- i. Specified disease or illness-triggered fixed payment insurance, hospital confinement fixed payment insurance or other fixed payment insurance offered as an independent, noncoordinated benefit.

Nevertheless, while no authority is granted for the collection of data pertaining to the manufacturers' prescription drug production or sales data, the claims records in the all payers claims database (WA-APCD) do show the amounts charged and the amount ostensibly paid by the insurer for prescribed drugs. The amount reported as "paid" in the claims data is, however, qualified because it does not take into account rebates, coupons or other cost-related negotiations that may have occurred among manufacturers, pharmacy benefits management entities and insurers. In fact, such challenges in determining true costs and true reimbursements broadly underlie all attempts at bringing transparency to drug costs.

There are, of course, compelling reasons to seek transparency in drug prices. Between 2001 and 2017, prescription drug costs grew from being 13 percent of the health care costs for a typical American family of four to 17 percent. Moreover, although the year-to-year upward trend in prescription drug costs has somewhat abated, the increase in prescription drugs in 2017 — 8.0 percent — is more than twice the overall medical increase of 3.6 percent.ⁱⁱ Of course, widespread reports of skyrocketing prices by pharmaceutical manufacturers, best exemplified by Mylan's EpiPen, have added to the public outcry. Seeking a better understanding of the justifications, or lack thereof, for such price increases is an understandable response.

With that context in mind, this report will first provide definitions of some of the benchmarks used in defining costs, as well as an overview of the flow of drugs from manufacturers to patients and the flow of money back to manufacturers. Next, legislation pertaining to transparency developed by other states will be reviewed. These are Oregon, California, Nevada and Vermont. Canada's health care system will be briefly described and its approach in prescription drug pricing and price controls will be considered. Finally, Washington's current strategy in addressing rising prescription drug prices will be outlined.

Metrics and participants

The Legislature’s interest in collecting and using manufacturer’s pricing data on high-cost new and existing prescription drugs requires a definition of “pricing data.” The common starting point for a prescription drug pricing data is the average wholesale price (AWP). Created in the 1970 for the California Medicaid Drug Program,ⁱⁱⁱ the AWP became, by default, the industry standard. It can be thought of as a close equivalent to the sticker price on a car — essentially the starting point of negotiations between manufacturers and wholesalers or pharmacy benefit managers (PBM) (third-party administrators of prescription drug programs who contract with commercial, self-funded, federal and state health plans) or nonretail providers (hospitals, nursing homes, etc.). AWP has been referred to as “ain’t what’s paid”^{iv} but, in fact, is often the cash price uninsured consumers do pay.^v

While a number of proprietary third-party entities publish the AWP for purchasers’ use, First Data Bank, the original publishers of AWP, and Medi-Span were the two largest. In 2005, private health plan payers filed a class action suit against these publishing entities, contending they had conspired to artificially inflate prices. In 2009, a federal court found in favor of the plaintiffs and essentially called for the rollback in AWP prices for the 1,442 drugs specified in the case. This list eventually expanded to more than 50,000 pharmaceuticals.^{vi} First Data Bank subsequently ceased publishing the AWP in 2011;^{vii} others, however, continue to do so.

With the diminishment of the AWP, the most commonly used benchmark in pharmacy purchasing today is the wholesale acquisition cost (WAC). The two, however, are closely related. If the AWP is the *sticker* price on a car, the WAC approximates the *invoice* price the dealership pays. In fact, a general rule is that the AWP equals the WAC plus a 20 percent increase. What makes the WAC, and the subsequently derived AWP the generally preferable benchmark is that the WAC is defined in federal statute and thus, arguably, is not as easily manipulated as the AWP had been prior to 2009. However, the WAC is still quite limited in specificity and transparency:

The term ‘wholesale acquisition cost’ means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

- Section 1847A(c)(6)(B) of the Social Security Act

In short, since the WAC is established by the manufacturer — and is neither a transactional price nor transparent in its derivation — it is arguably as susceptible to artificial price increases as the AWP.

Such concerns underlie the recommendations of the American Medicaid Pharmacy Administrators Association and the National Association of Medicaid Directors’ (AMPAA-NASMD) 2009 white paper “Post AWP Pharmacy Pricing and Reimbursement.”^{viii} Instead of the WAC as a replacement pricing benchmark for the AWP, the AMPAA-NASMD recommended the “establishment of a single national benchmark for pharmacy reimbursement “*based on actual acquisition cost data*” (emphasis added). Such a measure, the report notes, would not be the same as the average sales price that is already reported by manufacturers to the Centers for Medicare and Medicaid Services (CMS) and is

essentially limited to injectable or inhalant products. Instead, the report envisions an average acquisition cost (AAC) that could be based upon surveys of invoices from independent and chain retail pharmacies.

Some states, in fact, had already implemented such AAC-like survey systems — although not universal in design — to calculate their maximum allowable costs (MAC), that is, the maximum price to be paid for a multi-source generic drug. However, most states PBMs used different methods for calculating their MACs, and those methods were often confidential or proprietary.

From the perspective of the AMPAA-NASMD, until the establishment of a national AAC-based system, the WAC, together with a more universally defined MAC, could serve as an interim benchmark, notwithstanding the WAC's susceptibility to manipulation and its lack of transparency. Further, the AMPAA-NASMD emphasized the interim nature of this approach and urged CMS to act quickly in developing an AAC-based benchmark.

In 2010, one year after the release of the AMPAA-NASMD white paper, the Journal of Managed Care Pharmacy (JMCP) published an in-depth assessment of potential pricing benchmarks to replace the AWP.^{ix} In doing so, it laid out the 12 criteria, listed below, that such benchmarks should meet:

1. accessible – readily available
2. timely
3. administratively simple and efficient
4. comprehensive
5. durable (not an interim solution)
6. stable (won't produce more litigation)
7. easily understood
8. transparent and unambiguous
9. auditable
10. trustworthy
11. not anticompetitive
12. acknowledges complexity of drug distribution system

The JMCP assessment noted the recommendation of the AMPAA-NASMD but dismissed an AAC-based benchmark for a host of reasons but primarily because, at that time, such a system was not readily available, and initiating one would be complex as well as challenging to maintain with timely, up-to-date data.

However, in 2011, two years after the release of the AMPAA-NASMD white paper, a survey by CMS found that most state Medicaid agencies indicated they wanted a national pricing benchmark using an AAC-based metric. Thus, in the following year, CMS contracted with a public accounting firm to perform a survey of invoices from independent and chain retail pharmacies.^x By the end of that year, CMS posted a set of draft data on its website, and by 2013, the National Average Drug Acquisition Cost was available online.^{xi} These data are updated weekly and monthly, and available at data.medicaid.gov under “drug pricing and payment.”

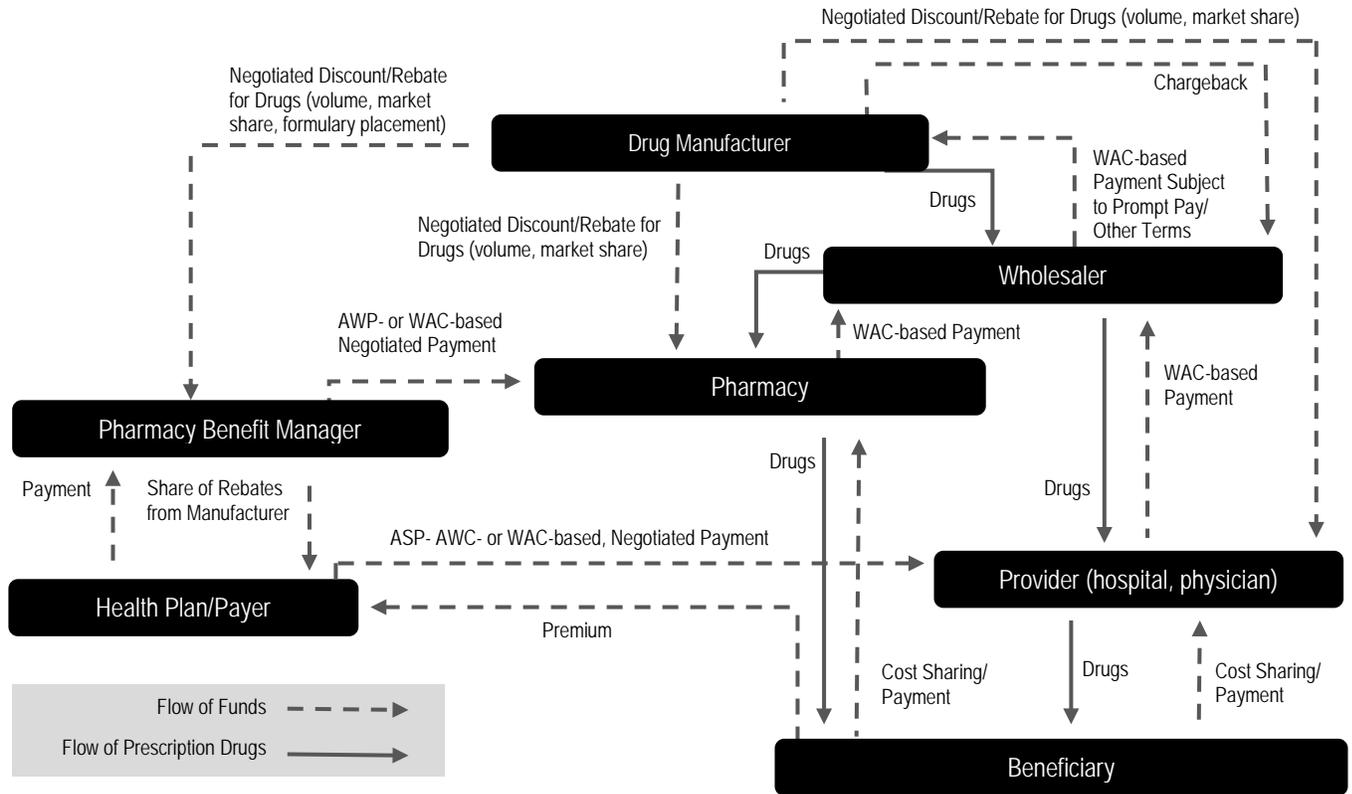
It is worth noting, though, that although the data listed appear comprehensive in scope, they are not. While including brand and generic prescription drugs, as well as over-the-counter ones, the list is limited to only those pharmaceuticals currently covered by CMS. Furthermore, because the prices shown are for the drug ingredients only, the cost for the pharmacy to dispense the medications must be added. Such fees can be as high as \$21 per prescription for rural Alaskan pharmacies, but are generally around \$10 or \$11 for the ACC-based state systems. In AWP- or WAC-based systems, the dispensing fees average around \$5 or less; however, costs for dispensing are offset by the higher reimbursement rates set for the drugs themselves.^{xiii}

It should be further noted that notwithstanding the efforts that have been expended in the development of an AAC-based metric, as of June 2017, 25 states — including Washington — still use either AWP or WAC in benchmarking their Medicaid prescription drug payments. An additional 10 states use AWP, WAC or an AAC-based metric, depending on which are available and/or cost less.^{xiii}

Beyond state and national pricing benchmarks used by each state’s Medicaid program, there are proprietary pricing benchmarks that PBMs, chain or major retail pharmacies, drug wholesalers and commercial health plans may use. The Predictive Acquisition Cost^{xiv} is one such pricing benchmark and describes itself as being transparent, accessible, comprehensive, timely, unable to be manipulated and administratively simple. However, because of its proprietary nature, we could not verify those claims.

In short, “manufacturer’s pricing data” is a somewhat elusive construct that appears to be evolving. Moreover, the complexities and nuances of the various pricing benchmarks arguably constitute only the tip of the iceberg, as may be suggested from the flowchart in Exhibit 1 of the drug distribution and payment model.^{xv}

Exhibit 1 Drug Distribution and Payment Model



AMCP Guide to Pharmaceutical Payment Methods | 2013 Update

While the flow of drugs is straightforward — from manufacturer to wholesaler to pharmacy or provider and then on to the beneficiary or patient — the flow of funds is not. In addition to whichever metric one chooses for establishing a “price,” the true cost may also need to take into account markups added by wholesalers; fees charged by PBMs as well as the discounts, rebates and chargebacks negotiated in return for adding drugs to their formulary and preferred tiers; overhead charges of health plans; and cost-sharing or full payments by beneficiaries plus any premiums they may have paid.

A brief CNBC report, [The Pharma Money Chain](#), provides an overview of this flow of funds using Mylan’s EpiPen as an example. Broadly, for an EpiPen with a list price (AWP) of \$610, Mylan would receive about \$290 in payment, resulting in a substantial profit on what’s estimated to cost, at most, \$30 to manufacture, but still leaving \$320 unaccounted for. Part of that remainder would go to the local pharmacy, the distributor and the PBM — somewhere around \$20 to \$30 each. The majority of the remaining funds would be in the form of a rebate from Mylan to the insurer.

In short, beyond the complexity of establishing a price, there is another layer of complexity pertaining to who profits and by how much.

Transparency legislation in Oregon, California, Nevada and Vermont

Oregon

During the 2017 legislative session, the Oregon Legislature introduced a bill that addressed rising drug costs and transparency. As subsequently amended, [House Bill 2387A](#) made it through the legislative process up to the Ways and Means Committee but was never voted out.

The bill called for the creation of the Oregon Premium Protection Program in the state's consumer protection and business regulatory agency, the Department of Consumer and Business Services. That program would create a price cap limiting prescription drugs charges to the highest price charged to countries in the Organisation for Economic Co-operation and Development. The bill would also require 60-days' notice for any WAC price increase exceeding 3.4 percent over a 12-month period and limit copayment to between \$250 and \$500 per year. If the WAC exceeded the 3.4 percent threshold or if the introductory WAC for a newly FDA-approved drug exceeded \$12,000 per year for a course of treatment, the manufacturer would be required to provide information on the costs for research on the drug's development, including clinical trials, and for research on the drug's safety and effectiveness. Manufacturers would also be required to provide information on costs for manufacturing and marketing as well as for information on projected profit margins and 10-year return on investment). If justification for such prices were not sufficient, manufacturers would be required to refund insurers the difference between the state's cap and their WAC.

Opposition to the bill from Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group representing the pharmaceutical industry, was not surprising. Neither, perhaps, was the opposition from large — and small start-up — biotech companies. But opposition also came from the NAACP, HIV/AIDS advocates and organizations representing individuals with rare or chronic diseases.

PhRMA's concerns included (1) using WAC as an index because it does not capture discounts and rebates; (2) the 60-day advance signaling of a price increase incentivizing stockpiling before an increase and thus allowing subsequent resale at the higher price; (3) the ability of insurers to drop high-price drugs from their formularies without adequate patient notification; and (4) the refunding to insurers without any subsequent refunding to patients.^{xvi}

The biotech industry concerns also included the WAC indexing and the price cap's potential in reducing return on investment and thus discouraging new drug development. Yet the focus appears to be mostly on the "vague, yet complex reporting and compliance requirements" that could lead to civil penalties and further divert resources from development.^{xvii}

Patient advocacy groups argued that the bill protects only insurers, not the patients, and would allow expensive drugs to be dropped from formularies without adequate notice — or viable alternatives — to those in need. They also argued the bill would dampen innovation.^{xviii}

California

One of the largest purchasers of prescription drugs in the nation, California recently enacted [Senate Bill 17](#), which has garnered much attention and differs from other legislation in that it requires reporting from both the health care payers/insurers and the drug manufacturers.

Under the legislation, payers would annually provide a list to the Department of Managed Health Care or the Department of Insurance of the 25 most commonly prescribed drugs, the 25 most-costly drugs in terms of annual spending and the top 25 drugs in terms of increase in year-over-year spending. Using weighted and actuarially adjusted rates, the payers would also report on the impacts prescription drug costs have on each year's premium rates. This information would be made publicly available.^{xxix}

For those drugs with a WAC of more than \$40 per course of therapy and a price increase of more than 16 percent over the course of two years, drug manufacturers would be required to provide a description to the Office of Statewide Health Planning and Development (OSHPD) of the specific financial and nonfinancial factors used to make the decision to increase the WAC of the drug and the amount of the increase including, but not limited to, an explanation of how these factors explain the increase in the WAC. In addition, manufacturers would be required to provide 60-days' advance notice of the planned 16 percent or higher price increase. This information, too, would be made publicly available.

Finally, the law requires manufacturers to report to the OSHPD within three days after release of any new specialty drug that exceeds Medicare's specialty drug price threshold.^{xxx}

Proponents of the legislation contend there is a public need-to-know in rising prescription drug prices, and while no direct mechanisms for limiting costs are included in the statute, the mere act of having to justify such increases may dampen the rising price trend.

Opponents contend that the statute may serve as a stalking-horse for future legislation on price controls.^{xxxi} Some proponents of the law agree.^{xxxii}

But in their opposition to the statute, drug manufacturers point mostly to three shortcomings in the law: (1) The WAC is not representative of the true cost paid by purchasers; (2) As in Oregon, the 60-day notification of a price increase would simply allow wholesalers to stockpile purchases prior to the increase date and resell at higher prices afterwards with no net savings to consumers; and (3) The reporting requirements, as written in law, are vague and, depending upon how they are implemented, may be subject to challenge.^{xxxiii}

Having just been signed into law in October 2017, the potential benefits of, as well as the potential challenges to this law are evolving. In fact, on Dec. 8, 2017, PhRMA filed a suit challenging the constitutionality of this new law.^{xxxiv}

Nevada

To address the rising cost of diabetes-related drugs through price transparency legislation, Nevada enacted [Senate Bill 539](#) in June 2017. Although narrow in its focus, the law is broad in scope. It not only requires transparency from pharmaceutical companies, it also requires transparency from PBMs, sales representatives and nonprofit patient advocacy organizations, with each reporting on financial information pertaining to manufacturing, rebates, sales or donations.^{xxv} However, in September 2017, two pharmaceutical lobbying groups, PhRMA and Biotechnology Innovation Organization (BIO), filed suit in federal court alleging that federal law preempts Nevada's law, which they contend violates the U.S. Constitution.^{xxvi} That suit is pending.

SB 539 requires the Nevada Department of Health and Human Services (NDHHS) to compile a list of prescription drugs considered essential for treating diabetes and prediabetes, such as insulin and biguanidines. For drugs on that list, manufacturers are required to report to NDHHS the following information:

- Costs of producing the drug;
- Total administrative expenditures relating to the drug, including marketing and advertising costs;
- Profit earned by the manufacturer from the drug and the percentage of total profit for the period attributable to the drug;
- Total amount of financial assistance provided by the manufacturer through any patient assistance program;
- Cost associated with coupons provided directly to consumers and for copayment assistance programs, along with the cost to the manufacturer attributable to the coupons and copay programs;
- The drug's WAC;
- History of WAC increases over the preceding five years, including the amount of each such increase expressed as a percentage of the total WAC, the month and year in which each increase became effective and any explanation for the increase;
- Aggregate amount of all PBM rebates provided by the manufacturer for sales of the drug in Nevada; and
- Any additional information prescribed by NDHHS regulation.^{xxvii}

From that list NDHHS will identify a second list of drugs whose WAC has increased by a percentage equal to or greater than either (1) the Consumer Price Index, Medical Care Component (CPI Medical) during the previous calendar year or (2) by twice the CPI Medical during the previous two years. For drugs meeting those criteria, manufacturers will be required to report on each of the factors that contributed to the WAC increase, the percentage of the WAC increase those factors represented and any other information required under rules.

For all the drugs on the first list, PBMs will be required to report on the rebates they negotiated with the manufacturers, including how much of the rebate they passed on to their clients and how much they kept for themselves. Those reports will be broken down by payer type, including Medicare, Medicaid, other government payers, third-party plans and plans subject to ERISA, the Employee Retirement Income Security Act.

Sales representatives will be required to register with the state, and only registered sales representatives will be allowed to market prescription drugs. Sales representatives must then subsequently report to NDHHS

all instances where they had compensated — in any way — a health care provider with anything valued at \$10 or more per instance or \$100 or more over the course of the year. This provision includes all drugs, not just those for diabetes.

Finally, spurred in part by a report in the *New England Journal of Medicine*, [Conflicts of Interest for Patient-Advocacy Organizations](#), nonprofits will have to disclose any funding they receive from drug companies, PBMs and health insurers.

In their lawsuit, PhRMA’s and BIO’s arguments against SB 539 fall into four categories: the authority to establish patent policy, the federal Uniform Trade Secrets Act, the Fifth Amendment’s Takings Clause and the Commerce Clause.^{xxviii}

Authority to establish patent policy – Article I of the U.S. Constitution, they argue, grants Congress the power “to promote the process of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings,” and Congress, in the 1984 Hatch-Waxman Act, created market and patent exclusivity periods for branded and generic drugs. PhRMA and BIO further note that drug development is an expensive process, citing a finding that 95 percent of experimental medicines fail to be safe and effective.^{xxix} Hence, they argue, although price controls are not explicitly enacted in the Nevada statute, the requirement that manufacturers provide detailed information on why price increases are necessary “in purpose and effect ... punishes manufacturers ... thus restrain[ing] patent holders from setting list prices in a manner that the federal patent laws secure in order to incentivize innovation.”^{xxx}

Uniform Trade Secrets Act – The plaintiffs next argue that the Uniform Trade Secrets Act, which most states (including Nevada and Washington) have adopted, together with the 2016 U.S. Defend Trade Secrets Act (DTSA), would be violated by SB 539 once the NDHHS publishes all the information manufacturers are required to submit. “SB 539 alters the operation of the DTSA — and the laws of every other jurisdiction in the nation — to eliminate trade-secret protection for confidential advertising, cost, marketing, pricing, and production information associated with diabetes drugs.”^{xxxi}

Fifth Amendment’s Takings Clause – Here the plaintiffs argue that SB 539 denies all economically beneficial or productive use of property because it eliminates the trade-secret protections held by manufacturers, a “categorical” taking of property rights. Moreover, even if not deemed categorical per se, it still constitutes a “taking” because of the economic impacts and the reasonable expectations that the company information would remain secret.^{xxxii}

Commerce Clause – Finally, the plaintiffs argue that SB 539 violates the Interstate Commerce Clause that gives the federal government the authority to regulate interstate commerce. By removing the trade-secret protections for manufacturers, none of whom are located in Nevada, SB 539 nullifies the trade-secret laws of every other state and the federal government. Eli Lilly, they cite as an example, is located in Indiana. By exposing that company’s trade secrets, Nevada undermines that company’s ability to promote growth, create local jobs and fuel the local economy in Indiana.

Legislators supporting SB 539 counter that these concerns have either been addressed or assessed and found to be unwarranted, and see the suit as simply a delay tactic. The decision will be the court’s.

Vermont

In June 2016, Vermont became the first state to pass legislation requiring transparency from drug manufacturers. That law, [18 V.S.A. § 4635](#), requires the Green Mountain Care Board, the state health care system's regulatory and planning entity, to each year identify up to 15 drugs on which "significant health care dollars" are spent and for which the WAC has increased by 50 percent or more over the previous five years or by 15 percent or more over the last 12 months. From that list, the Vermont Office of the Attorney General (VOAG) would contact the manufacturers of those drugs and require them to provide a justification for those increases in a "format that the Attorney General determines to be understandable and appropriate."^{xxxiii} That justification may include:

- All factors that have contributed to the WAC increase;
- The percentage of the total WAC increase attributable to each factor; and
- An explanation of the role of each factor in contributing to the WAC increase.

Each year, and in consultation with the Department of Vermont Health Access, the VOAG is required to submit a report to the state General Assembly based upon the information received from manufacturers and to post that report on the VOAG website.

However, in the state law, the information the VOAG receives from the manufacturers is deemed confidential and "exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information."^{xxxiv}

In December 2016, the VOAG issued its first report. For the 2016 fiscal year, the VOAG assessed 10 prescription drugs, ranging in total gross Medicaid spending from \$6.5 million for Abilify, a brand antipsychotic medication, to \$70,000 for permethrin, a generic insecticide used generally in treating head lice. The five-year average WAC increase for Abilify was 55 percent; the one-year average WAC increase for permethrin was 50 percent. The cost estimates included rebates provided by drug manufacturers to the state.^{xxxv}

Doxycycline hyclate, a generic antibiotic used to treat a wide range of conditions from acne to Lyme disease, had the greatest relative increase in WAC: 4,788 percent over the course of five years. Such a dramatic rise may, in part, be attributed to a temporary shortage brought on by the outbreak of Lyme disease in an area, and may also be mitigated by the relatively low initial price. "The retail price of doxycycline increased from about three cents per pill, to more than \$5 per pill over the past 18 months, according to local doctors and pharmacists,"² reported the Vineyard Gazette in September 2015.^{xxxvi} Medicaid's fiscal year spending for doxycycline was \$194,000. Below is the complete listing:

² It may be worth noting that as of August 2017, the price of doxycycline has fallen to \$0.60 per pill according to The New York Times. https://www.nytimes.com/2017/08/08/health/generic-drugs-prices-falling.html?_r=0

Exhibit 2
Identified Drug List per 18 V.S.A. § 4635

Type	Brand Name	Generic Name	Labeler	Therapeutic Class	1 year Avg. WAC % increase	5 year Avg. WAC % increase	SFY 2016 Gross Drug Spending
Brand	Abilify	Aripiprazole	Otsuka America	Quinolinone Derivatives		55.27%	\$6,500,094
Brand	Lantus	Insulin Glargine	Aventis Pharmaceuticals	Human Insulin		89.83%	\$5,445,451
Brand	Humira	Adalimumab	Abbott Laboratories	Anti-TNF-alpha-Monoclonal Antibodies	27.95%	113.79%	\$4,712,103
Brand	Enbrel	Etanercept	Amgen/Immunex	Soluble Tumor Necrosis Factor Receptor Agents	16.42%	92.73%	\$3,194,725
Brand	Crestor	Rosuvastatin Calcium	Astrazeneca	HMG CoA Reductase Inhibitors	20.75%	75.98%	\$1,759,834
Brand	Epipen	Epinephrine	Mylan Specialty	Anaphylaxis Therapy Agents	32.02%	205.45%	\$1,697,384
Brand	Latuda	Lurasidone HCl	Sunovion Pharmaceuticals, Inc.	Antipsychotics-Misc.	19.80%	99.68%	\$1,149,040
Brand	Prevacid	Lansoprazole	Takeda Pharmaceuticals America	Proton Pump Inhibitors	20.78%	103.32%	\$941,689
Generic	Doxycycline hyclate	Doxycycline Hyclate	Mutual Pharmaceuticals Company	Tetracyclines		4787.61%	\$194,044
Generic	Permethrin	Permethrin	Perrigo Pharmaceuticals	Scabicides & Pediculicides	50.00%		\$69,949

Although not lengthy, the VOAG report focuses in part on the limitations of the metric used — WAC — noting many of the limitations cited above in the section on metrics. Additionally, the report discusses negotiations on favorable positioning of drug formularies: how as WACs increase, the rebates often proportionately increase and how the manufacturer has no control over payers’ decision on patient out-of-pocket expenses under the various prescription pharmaceutical benefit plans.

Concluding with factors commonly mentioned by the manufacturers in making their pricing decisions, the VOAG listed these, in no particular order:

- Cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class).
- The size of the patient population for the drug.
- Investments made (including in research and development) and the risks undertaken.
- Creation and maintenance of manufacturing facilities and capabilities, including the ability to address drug shortages caused by production issues.
- Cost of ingredients.
- Competition, including for drugs in the same class.
- Return on investment and fiduciary responsibilities.
- The percentage of their sales in commercial, Medicare or other government channels.

Perhaps best summing up the response to this report was a statement by Vermont State Rep. Anne Donahue, who had voted for the bill: “Some of the information is probably more synthesized than what we might have envisioned, and in that sense is perhaps a little less helpful than we might have hoped.”^{xxxvii}

Prescription drug pricing in Canada

As noted in the introduction, prescription drug pricing — and, in fact, the whole Canadian health care system — is far more complex than what might be commonly perceived. To begin with, Canada does not have a national health care system. Instead, the Canadian Constitution charges the provinces with the responsibility of establishing, maintaining and managing hospitals, asylums, charities and charitable institutions.^{xxxviii} The federal government funds half the costs for provinces' health care systems provided they meet these five criteria:

1. portability (insurance continues when people move from province to province);
2. accessibility (people cannot be charged extra for any service that is covered);
3. universality (all Canadian citizens and permanent residents are automatically covered);
4. comprehensiveness (all necessary medical services are covered); and
5. public administration (the health care system is administered on a public, not-for-profit basis).^{xxxix}

In addition, while drugs administered to patients in hospitals are fully covered in each province, those same drugs, when administered to patients in an outpatient setting, are not. Instead, they are generally covered through an employer or private insurance plan. Furthermore, although the prices for all patented drugs are subject to national price control regulations, price controls for generic drugs are the responsibility of each province. Below is a brief description of Canada's drug pricing system.

The process for newly patented drugs begins with a review by the Canadian Patented Medicine Prices Review Board's (PMPRB) Human Drug Advisory Panel to determine if the drug is a new version of an existing drug or is a new active substance (NAS), i.e., a molecule never sold in Canada before. If it is a new version of an existing drug, the PMPRB compares the proposed price to similar drug prices in Canada, and allows the drug to go to market provided that price is in keeping with those other prices.

If the drug is a NAS, the PMPRB compares the proposed price to existing products in the same therapeutic class and the median price in France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States, and from that assessment establishes a maximum average potential price (MAPP). If the price of the new drug is at or below the MAPP, no further action is taken. If the price is above the MAPP, the PMPRB enters into negotiations with the manufacturer to reduce the price. At that point, consideration may be given to the cost of making and marketing the drug, as well as other factors considered relevant.^{xi}

For all patented drugs, the PMPRB limits the rate of price increase to the rate of increase in the Consumer Price Index over any three-year period.^{xii}

Figure 1
Patented Drugs
Average Foreign-to-Canadian Price Ratios
2015



Source: Protecting Canadians from Excessive Drug Prices, Health Canada, 2017

Even with this process, the prices for patented drugs in Canada remain higher than those in six of the seven countries it uses in setting its MAPP, with the United States as the clear outlier. (Consideration is currently being given to revising the list of comparison countries by adding new ones and excluding the United States.^{xlii}) See Figure 1.

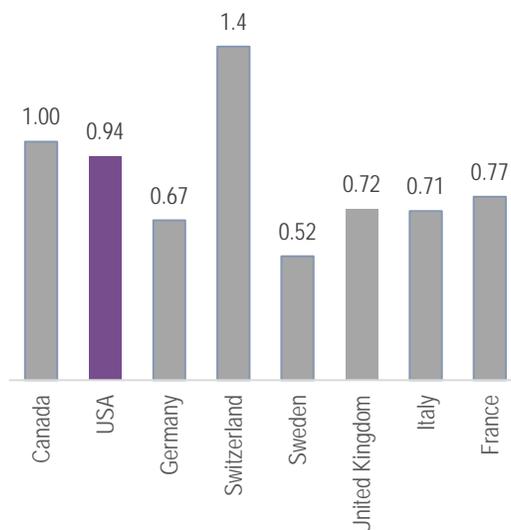
It is worth noting, though, that the prices used by PMPRB are the AWP, that is, the list (or the ain't what's paid) prices, and thus may overstate the variations shown depending upon the types of discounts and rebates built into other countries' drug pricing systems. Reforms in the PMPRB process may, therefore, also include consideration of a different metric or at least an accounting of such discounts and rebates.^{xliii}

While generic drugs accounted for more than 70 percent of the prescriptions dispensed in Canada in 2016, they accounted for only slightly more than 22 percent of the dollars spent on prescription drugs.^{xliv} This is similar to the United States, where in 2016, generics accounted for 89 percent of prescriptions dispensed but only 26 percent of the costs.^{xlv} Nevertheless, the higher prices seen for generics in Canada compared to other countries have raised concerns. See Figure 2.

Those higher prices are largely seen as a function of limited competition among pharmacy chains in combination with the capping of the formulary at a percentage of the brand name price and specifying a maximum reimbursement cost for a drug or drug group. The pharmacy chains are, in short, able to negotiate steep discounts on the AWP for generics while, concurrently, using the AWP on branded versions to set the cap. Private insurers, who cover prescription drug costs, are not incentivized to lower those costs because they are often paid as a percentage of the plan cost — hence the higher the cost, the more they profit.^{xlvi}

Each province is addressing these generic drug costs in differing ways. Perhaps the most innovative and well-established is British Columbia, which initiated a reference-based pricing (RBP) system beginning in 1995. This approach groups certain classes of drugs together that are deemed to be essentially equally safe and effective and can be interchanged, even if they are not bioequivalent. A referent price is set for each class, and the RBP will cover the cost of a prescription at or below that price. If a physician prescribes a higher-priced drug, and the patient chooses to use it, the patient pays the difference. Currently RBP is being used for five therapeutic classes of drugs in British Columbia. In 2002, the introduction of the RBP for drugs used in treating hypertension, congestive heart failure and coronary artery disease was found to have led to a 6 percent savings. Unfortunately, no more recent assessments have been published.^{xlvii}

Figure 2
Generic Drugs
Average Foreign-to-Canadian Price Ratios
2014



Source: Generics360 – Generic Drugs in Canada, 2014, Patented Medicine Prices Review Board, 2016

Washington's current drug purchasing strategy

In November 2016, the Washington State Health Care Authority (HCA), together with the Office of Financial Management, issued a report to the Washington State Legislature on prescription drug costs and potential purchasing strategies.^{xlviii}

As outlined in that report, four recommendations were issued by an inter-agency Prescription Drug Work Group convened in 2001:

1. Establish a statewide Pharmacy and Therapeutics Committee to develop, implement and maintain a Washington State Preferred Drug List. The committee will, where appropriate, seek additional expertise to address issues concerning special populations.
2. Establish a statewide Drug Utilization Review Board to develop treatment guidelines and criteria for appropriate drug use.
3. Explore the feasibility of consolidating claims processing, claims adjudication and other pharmacy management and information services.
4. For agencies and/or programs that directly purchase drugs, explore the feasibility of implementing and maintaining a consolidated rebate program.

As follow-up to those recommendations, in 2003, the Uniform Medical Plan, Department of Labor and Industries and the state's Medicaid program created the Washington Prescription Drug Consortium and contracted with a PBM for negotiating prices and rebates. During that same year, the passage of Senate Bill 6088 established a prescription drug program to create and administer the Washington Preferred Drug List and the Therapeutic Interchange Program. Preferred drug lists, in general, provide an incentive to manufacturers to negotiate prices and provide rebates so their drug will be deemed "preferred." The Therapeutic Interchange Program identifies therapeutically equivalent drugs within a class, thus allowing pharmacists to automatically exchange a nonpreferred drug with an equally safe and effective preferred drug unless the prescription specifies "dispense as written."

In 2005, the Legislature passed Senate Bill 5471, requiring all state agencies to purchase their drugs through the consortium unless they could demonstrate they received greater discounts elsewhere. One year later, Washington joined with Oregon to create the Northwest Prescription Drug Purchasing Consortium. Key characteristics and benefits of that arrangement include:

- The contract for prescription drug purchasers is fully transparent.
- Access is provided to competitive retail pharmacy discounts.
- All drug manufacturer rebates are passed through in full.
- Contracts have a guaranteed ceiling price, putting the PBM at risk for excess costs.
- Consortium drug prices have consistently proven better than commercial rates now available to other large groups in either state.
- Both the annual market price assessment and the program benefit audits are performed by a third party but are paid by the PBM.

As noted in the report, “Total consortium drug spending is currently approaching \$1 billion annually for nearly one million members in Oregon and Washington, including programs for public employee benefits, K-12 educators, worker’s compensation, uninsured discount cards, corrections, and small-employers.”

Summary and conclusions

Transparency has value. However, transparency in prescription drug prices may face significant legal barriers, many of which are now being litigated in other states. And while transparency may intuitively seem to be an effective mechanism in reducing unnecessary price increases because it has been implemented in only one state, there is little evidence to date to show that such provisions alone drive down or keep down prices.

Although Washington's drug purchasing strategy does not currently use prescription drug price transparency to mitigate price increases, its market approach as an empowered large purchaser does provide an effective mechanism for some degree of control of prescription drug prices. If federal law were changed to allow states to negotiate price directly, a broad purchaser consortium — including both public and private purchasers — could have enough market power to fully negotiate prices. Such a public/private purchasing consortium would functionally mirror the purchasing power of the Canadian system.

Alternately, a regulatory approach like Canada's, enacted perhaps under a public utility model where prices would be regulated much in the same way electricity, natural gas and water rates are, could also theoretically control costs. This seems to be the fear underlying the drug manufacturers' opposition to price transparency, as explicitly stated by those opposing (and some supporting) California's drug transparency law. Public outcry over obvious price gouging practices, such as seen with EpiPen, may not be sufficient or sustainable and could quickly fade, having only short-term impacts, if any. However, building a sustained case for unwarranted price increases — which price transparency could do — lays a foundation for regulatory action. That fear of a potential case being made for a regulatory approach may, in fact, be the true “stick” of such legislation — and the threat alone may be sufficient to affect drug manufacturers' pricing practices. But while a threat could mitigate price increases, measuring and attributing such an effect may be difficult.

If price transparency legislation were to be enacted in Washington, careful consideration should be given to the following factors:

1. Price metrics – While WAC is readily available and widely used, manufacturers are correct in pointing out that those prices do not reflect the true purchasing price. The National Average Drug Acquisition Cost, though limited in scope, more closely captures such costs. An expansion of the surveys of independent and chain retail pharmacies would, however, be necessary to acquire those data. Even still, those prices would not reflect negotiated discounts.
2. Manufacturers' costs – Nevada's comprehensive approach in requiring manufacturers' cost data elicited the strongest response from the industry, and is certainly the most probing. The details outlined in that state's statute would clearly spell out all the costs involved in every step from manufacturing to marketing. The broad legal challenge against that legislation is pending, and the court's findings will help determine if such legislation can serve as a viable model.

3. Advance notice – California’s 60-day advance public notice of a WAC increase at or above 16 percent could dampen manufacturers’ willingness to quickly raise prices. They may, however, counter by initially introducing drugs at a higher price or offer few or lower rebates. Public interest may wane in such increases, especially for lower-cost drugs for which, for instance, an \$8 increase on a \$50 prescription over the course of two years would constitute a 16 percent price increase. Moreover, as noted for both Oregon and California, such advance notice would allow wholesalers to stockpile many drugs at the lower costs and resell them later at the higher prices.
4. Public reporting – As noted with Vermont, without careful consideration of what the end-product would be, public reports may ultimately be quite limited in their impact and fundamentally call into question the utility of such transparency requirements.

While the proviso in Substitute Senate Bill 5883 asks that the WA-APCD be considered as a mechanism for establishing a prescription drug price transparency program, this does not appear to be an optimal choice. Prescription drug transparency involves detailed information from drug manufacturers — and potentially others — on why a price increase is needed. The WA-APCD is not designed for collecting such information, and instead collects claims data submitted to payers. However, Second Substitute House Bill 1541, proposed in February 2017, provides a framework for prescription drug price transparency in Washington.

From the review of other states’ transparency legislation, in addition to those reported here, OFM would neither suggest specific language nor other language that would make the WA-APCD a natural entity for collecting and reporting detailed manufacturers’ cost data justifying prescription drug price increases. Such functions have typically fallen to the state attorney general’s office, the state insurance office or the state health planning office.

In Washington, consideration could be given to these entities, but a prescription drug transparency program might best fit in the Office of Financial Management, where the health care research and planning functions are located, as well as where the WA-APCD is housed. Moreover, the WA-APCD would be useful for numerous analyses augmenting the information collected through a price transparency program such as data on consumers’ out-of-pocket expenditures, identification of the most commonly prescribed drugs, the annual charges per brand name and generic drugs and percentage increases in drug prices over time.

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