



December 4, 2018

Representative Tom Oliverson
Texas House of Representatives
Room E2.720
Austin, TX 78768

Senator Dan "Blade" Morrish
Louisiana Senate
119 W. Nezpique Street
Jennings, LA 70546

RE: National Council of Insurance Legislators Model Act Concerning Prescription Drug Costs

Dear Representative Oliverson and Senator Morrish:

I write today on behalf of America's Health Insurance Plans (AHIP) to provide comments on the National Council of Insurance Legislators (NCOIL) Model Act Concerning Prescription Drug Costs ("Model").

We appreciate your desire to act on one of the most critical issues impacting consumers: the soaring cost of prescription drugs and the lack of meaningful and transparent information about what goes into those costs. We offer the following thoughts regarding the proposed Model and ask that they be addressed by the Health, Long Term Care, and Health Retirement Issues Committee before proceeding with the Model:

- The proposed Model will not provide consumers and policymakers with actionable and meaningful information about the true cost of pharmaceuticals and what factors go into determining that cost;
- The price increase reporting requirement for drug manufacturers is weakened by limiting the required notice for drugs to those with a price increase of 50 percent or greater. Existing state laws use much lower thresholds for triggering a price increase report;
- The elements proposed for the required drug price increase reports are too limited to be of value to consumers and policymakers. In its current iteration, the Model fails to require basic and critical information such as the rationale for the price increase, a determination of whether the increase is due to a significant improvement in the drug's formula, and the accrued and projected costs for developing, marketing, and selling the drug;
- The proposed standards for manufacturers reporting price increase data are overly broad, requiring only data that is already available to the public. It is the failure of the existing public documentation that necessitates this Model;
- The utilization management disclosure requirements for health insurers would introduce an administrative burden that offers little to no value to consumers or policymakers; and

- Additional confidentiality protections are necessary to ensure that confidential information and trade secrets are protected from public disclosure.

AHIP is the national association whose members provide coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers. Our members are committed to providing consumers with affordable products that offer a broad range of robust provider networks of quality, cost-efficient providers.

The rise in the use and cost of prescription drugs has gained attention in recent years. While pharmaceutical advances have created life-saving medications that revolutionized the treatment of many diseases, the rising price of prescription drugs threatens the long-term sustainability of treatment innovation and patient access to the medications they need. The disturbing trend of dramatic price increases impacts the entire health care system, including state and local budgets, while also placing a substantial burden on employers, individuals, and families who purchase health coverage in the private market.

AHIP supports well-crafted efforts to shed light on prescription drug pricing because these costs account for a disproportionate and increasing share of health care spending. Prescription drugs are the largest segment of health spending and account for more than 23 percent of commercial premiums.¹ Drug spending is also a critical concern for the Medicare program. Recent data provided by the Medicare Payment Advisory Commission shows drug spending of \$137.4 billion for Part D in 2015 and drug spending of \$29.1 billion on Part B in 2016.² This data is not an isolated example, as spending on prescription drugs is projected to grow faster than any other component of health care services over the next decade.³ Unfortunately, consumers and policymakers have very little information regarding how drug manufacturers set the prices that are driving these cost increases, limiting the ability of policymakers to address this crisis.

How manufacturers calculate these increases is critical information for many reasons. Prescription drug manufacturers attribute rising drug costs to the need to invest and pay for research and development. However, there is very little data available publicly to validate that claim. Limited data culled from SEC filings shows that research and development constitute very little of actual drug costs – between 3-10 percent of total revenue. For nine of the country's top 10 drug makers, a greater proportion was spent on marketing and administration than on research and development.⁴ AHIP believes that greater transparency regarding drug pricing will make

¹ *Where Does Your Premium Dollar Go?* America's Health Insurance Plans. May 22, 2018. Available at <https://ahip.org/health-care-dollar/>

² *Health Care Spending and the Medicare Program: A Data Book*. Medicare Payment Advisory Commission. June 2018. Available at http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0.

³ Johnson, Carolyn Y. "U.S. Spending on Drugs Will Grow Faster than on Other Health-care Services over the next Decade." *The Washington Post*. February 14, 2018. Available at https://www.washingtonpost.com/news/wonk/wp/2018/02/14/u-s-spending-on-drugs-will-grow-faster-than-other-health-care-services-over-the-next-decade/?utm_term=.7dced87ba195.

⁴ Lopez, German. "9 of 10 Top Drugmakers Spend More on Marketing Than Research." *Vox*. February 11, 2015. Available at <https://www.vox.com/2015/2/11/8018691/big-pharma-research-advertising>.

drug manufacturers more accountable to market forces, as well as provide policymakers with the data needed to craft policies that ensure consumers continue to have access to affordable prescription drugs.

Given its importance to consumers and state budgets, the current lack of transparency that drug manufacturers enjoy concerning pricing is unique. Insurers and providers are all subject to disclosure requirements regarding what they bill consumers. Health plans must report premium rates, including financial information related to administrative costs and clinical costs, for all products so that regulators may review requested increases. Nationally, the Centers for Medicare and Medicaid Services publish data regarding what physicians charge and several states publish what hospitals charge for services. There is no comparable information available regarding prescription drug pricing. Permitting the public access to additional pricing information, while minimizing administrative burdens and protecting bona fide trade secrets, would bring disclosure standards for drug manufacturers to the same level as other sectors of the health care market.

Consumers, businesses, and other sectors of the health care market support efforts to increase transparency around prescription drug pricing. Nearly nine out of 10 Americans support policies that require manufacturers to report information about how they set their prices.⁵ States have passed similar transparency bills with bipartisan support, backed by a coalition of organizations concerned about unexpected and unexplained price increases. This includes large and small businesses, labor unions, patient groups, and nearly every sector of health care (except one).

The price increase reporting requirement is weakened by high reporting threshold.

Cost and spending data for prescription drug pricing is critical to fully understanding and appreciating the factors that lead drug manufacturers to establish prescription drug list prices. This is particularly true for high-cost drugs where the magnitude of pricing changes has a substantial impact on patients. We appreciate that the Model takes steps to address this and the challenge of obtaining reliable information on drug prices. The quarterly wholesale acquisition cost (WAC) reporting requirement contained in Section 4 of the Model and the requirement for that information to be provided to the public are important steps.

In order to have a meaningful impact, however, the WAC reporting obligation must be accompanied by a requirement to report price increases for specific drugs that clear a minimum threshold. Consumers are significantly impacted by dramatic price increases for prescription drugs and deserve to be provided with an explanation when the manufacturer price for a current course of treatment increases by thousands of dollars. We support NCOIL's decision to include a price increase reporting requirement in Section 4(b) of the Model, but we are concerned that the requirement is severely weakened by the reporting threshold in Section 4(b)(1), which specifies that manufacturers are required to report a price increase if it exceeds 50 percent for a drug with a WAC of 100 dollars or more for a 30-day supply.

For this requirement to provide actionable information, the threshold should be at a reasonable level to ensure robust data submissions from manufacturers while avoiding unnecessary burdens

⁵ *Public Opinion on Prescription Drugs and Their Prices*. Kaiser Family Foundation. November 28, 2018. Available at <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>.

for slight increases in prices or changes to the most affordable drugs. A 50 percent reporting threshold will substantially reduce the number of drugs that are subject to the requirement. Manufacturers would be allowed under this language to raise the cost of their most expensive drugs by 49.9 percent without ever providing any explanation or justification for the change. For a specialty drug, this increase could often be in the thousands of dollars. Additionally, the Model does not include a timeframe or an aggregation standard for the 50 percent threshold, which is critical to determining whether the threshold has been met.

States passing similar legislation included much lower thresholds to trigger the price increase reporting requirement.⁶ **We ask that NCOIL amend Section 4(b)(1) to include a ten percent increase as the reporting threshold.** This more reasonable reporting threshold will create collective downward pressure on pricing, incenting drug manufacturers to self-police their pricing habits to avoid reporting requirements and reserve justified increases for those medications where manufacturers demonstrate product improvement, value, or other reasonable explanations. Consumers deserve access to prescription drug information and the 50 percent threshold proposed in the Model will deprive many patients of that information.

Manufacturer reporting elements and standards diminish the value of a price increase reporting requirement.

While we are pleased that the Model seeks to address price increases through new reporting requirements, the data elements proposed in Section 4(b)(1) have little value for consumers or those researching new ways to approach prescription drug costs. Of the six proposed elements, three are so limited that they could be contained together in a single sentence. Further, the use of reporting elements such as “aggregate, company-level research and development costs” has no value to a discussion about a price increase for a specific drug. Aggregate reporting of research and development costs avoids the very relevant question of how those costs apply to the drug that is the subject of the price increase. Additionally, aggregate reporting would include pharmaceuticals that are meant for animals, agricultural business products, and other purposes, and not solely for the prescription drugs that are subject to the reporting. Consumers derive little valuable information when their prescription drug spending data is based on irrelevant products.

The price increase reporting elements also ignore many of the most significant elements already enacted in some states and that were previously proposed by AHIP. Our earlier proposal called for specific elements to be contained in a price increase report as part of the PBM Licensure and Regulation Model Act (“PBM Model”) currently under development. We believe that these previously submitted data elements provide real and actionable value to policymakers and patients, as compared to the very limited set proposed in this Model. Those elements are included as an appendix to this letter and include:

- the factors that contributed to the price increase;
- research and development costs associated with the drug that were paid using public funds, giving taxpayers a view into how public research dollars are spent;
- direct costs for manufacturing, marketing, and distributing the drug;

⁶ See California SB 17 (2017) and Oregon HB 4005 (2018).

- total sales revenue for the drug; and
- profit attributable to the drug in the previous year.

Despite NCOIL’s best efforts to address drug prices, it is unlikely that any reporting requirement will hold significant value if it does not contain such basic information as the factors that led to the increase. **We ask that NCOIL revisit AHIP’s recommendations for price increase reporting elements as submitted during the PBM Model deliberations.**

We are also concerned that the data standard identified in Section 4(b)(2) further degrades the reporting requirement. For data reporting to have value, it must result in the dissemination of reliable and meaningful data. Requiring nothing more than a high-level overview similar to a Securities and Exchange Commission Form 10-K or “any other public disclosure” will eliminate much of the benefit that can be derived from transparency. The impetus for this Model is the lack of information currently being provided, which limits the beneficial impact of a reporting requirement that uses currently available information as the standard. **We ask that Section 4(b)(2) be eliminated in its entirety.**

Transparency model should ensure that submitted reports are studied for future policymaking.

The Model should take steps to ensure that costs and burdens associated with reporting drug cost information are not incurred without benefit to the public. The Model’s approach of having a regulator collect and post that information online does not ensure that adequate consideration will be given to the information that is reported. While transparency holds a tremendous amount of value for consumers grappling with substantial price increases, it also has the potential to inform policymaking. However, that potential will not be realized if the reports submitted pursuant to the Model are posted online with no further action.

In the past, AHIP has supported efforts in the states and at NCOIL to pursue prescription drug transparency. Specifically, we were strong proponents of the approach taken in Oregon, which was included in our June 5 comments to the Committee on the proposed PBM Model. The Oregon law that AHIP has supported in the past contains the following language as an example of ways to amend the Model to ensure that the submitted reports have value to policymakers:

No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees’ Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.⁷

Such a provision will ensure that the NCOIL Model results in information that is valuable to legislators as they seek to address one of the most important issues facing their constituents.

⁷ Oregon HB 4005 (2018)

Without further studying the information collected pursuant to this Model, legislators will continue to face a dearth of meaningful information. **We ask that NCOIL amend the Model by creating an additional section that mandates the study of reported data.**

Utilization management disclosure requirements are difficult, costly to satisfy.

As responsible stewards of taxpayer dollars, our member health plans support reporting their own prescription drug spending and trends among generic, brand, and specialty drugs, as well as identifying the most costly, commonly prescribed, and most marked-up medications. In our June 5, 2018, comments to NCOIL in response to the PBM Model, AHIP proposed reporting requirements very similar to those contained in Section 6(a)(1) of the Model. We believe that transparency is a critical tool in addressing prescription drug costs and acknowledge that this requires transparency across all stakeholders in order to be effective.

However, we believe that some of the specific data elements that would be disclosed under the proposed language will not provide consumers with valuable data, while imposing a costly administrative burden on health insurance carriers seeking to comply with the requirements. Specifically, the information mandated in Sections 6(a)(1)(D) and (E) is unnecessary and difficult to ascertain. Premium rates and reductions result from a highly complex calculation involving a multitude of factors and behaviors. It is unlikely that these two elements will provide any value to consumers. **We ask that Sections 6(a)(1)(D) and (E) be stricken.**

Section five reporting requirements do not provide valuable insight into drug pricing and could have anti-competitive implications.

The value of data to be reported pursuant to the Model is derived from gaining access to additional information that is not currently available to the public. However, the information should have utility to the regulator to use to better understand drug pricing. The disclosures outlined in Section 5 regarding rebates, fees and other payments collected by PBMs and passed on to health plans do not inform drug pricing. This is highly sensitive information that if disclosed publicly would threaten a PBMs ability to negotiate future discounts, raising the costs for health plans in future years. We object to this because it does not serve a purpose in helping policymakers understand why drug costs are increasing. These are *discounts* on drug prices – therefore, it is important to keep the focus on why drug prices are going up, not impeding those who are negotiating to get those prices lower. Health plans, PBMs, and drug manufacturers operate in highly competitive markets, and steps should be taken to ensure that the important goals of this Model are not hindered by the release of competitively sensitive information that could create serious problems in the market. This matter should be of concern to all entities required to submit information pursuant to the Model, as well as lawmakers.

Any data reported pursuant to this Model that includes sensitive information must remain proprietary, confidential, privileged, and not subject to other existing legal requirements (such as subpoena power, discovery in civil trials, etc.). Ensuring that sensitive data remains outside the public realm is critical, and all affected parties must know that the data they submit will be treated as highly sensitive and confidential. Disclosure of the information required by Section 5 would have serious competitive implications that would ultimately increase drug prices for

consumers, businesses, insurers, and taxpayers. This very real possibility of anti-competitive behavior is made more concerning by the minimal value provided by the information that would be reported.

AHIP supports greater transparency for prescription drug manufacturers as it encourages appropriate pricing behavior without relying on artificial price controls. It also allows policymakers a window into pricing challenges that could be addressed through further legislation. Armed with this knowledge, consumers will have better insight into the factors that are driving their prescription drug costs to unaffordable levels. Unfortunately, prescription drug prices remain in a black box, hidden from public view and unaccountable to the forces of the private market. In such a system, prices will continue to increase arbitrarily and without consideration of the burden borne by patients. That is why we support NCOIL's efforts to pursue meaningful transparency around prescription drug pricing practices and their impacts on consumers.

We look forward to working collaboratively in the coming months to reach consensus on an approach that maximizes the availability of quality data while balancing the administrative burdens associated with collecting and reporting that data. If you have any questions or would like to discuss the matter further, please do not hesitate to contact me at (202) 861-6365 or Lgassaway@ahip.org.

Sincerely,

A handwritten signature in black ink that reads "Leanne Gassaway". The signature is written in a cursive, flowing style.

Leanne Gassaway
Senior Vice President, State Affairs and Policy

Cc: Members of the NCOIL Health, LTC and Health Retirement Issues Committee
Tom Considine, NCOIL Executive Director

APPENDIX

AHIP Proposed Price Increase Reporting Elements for Manufacturers

- (1) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;
- (2) The length of time the prescription drug has been on the market;
- (3) The factors that contributed to the price increase, including a statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement;
- (4) The name of any generic version of the prescription drug available on the market;
- (5) The research and development costs associated with the prescription drug that were paid using public funds;
- (6) The direct costs incurred by the manufacturer:
 - (A) To manufacture the prescription drug;
 - (B) To market the prescription drug;
 - (C) To distribute the prescription drug; and
 - (D) For ongoing safety and effectiveness research associated with the prescription drug;
- (7) The total sales revenue for the prescription drug during the previous calendar year;
- (8) The manufacturer's profit attributable to the prescription drug during the previous calendar year;
- (9) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
- (10) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
- (11) Any other information that the manufacturer deems relevant to the price increase described in [subsection (b)(2)] of this section; and
- (12) The documentation necessary to support the information reported under this subsection.