Chairman Grassley, Ranking Member Wyden and members of the Senate Committee on Finance, thank you for the opportunity to submit a statement for the record on the large employers’ perspective on drug pricing.

The National Business Group on Health (NBGH or the “Business Group”), whose members include 437 of the nation’s largest employers. We commend the Committee’s effort to take a holistic look at the root causes of high and escalating drug prices. In addition to these, we anticipate submitting comments on subsequent hearings within the Committee’s series on drug pricing.

Along with the government, taxpayers and families, employers have a vested interest in improving the efficiency and effectiveness of health care delivery, which includes the delivery of pharmaceuticals. According to NBGH’s 2019 Large Employers’ Health Care Strategy and Plan Design Survey, almost half, 49% of respondents are taking an activist role in driving delivery system change1. As part of this, more employers are scrutinizing the role of the pharmaceutical supply chain, as specialty pharmacy costs remain one of the top drivers of overall health care trend. Particularly as the growth of high-deductible plans over the past decade has put a spotlight on drug prices, employers have become increasingly frustrated by complexity within the supply chain, which could be described as a “rebate-driven” contracting model.

Nearly all employers believe the pharmaceutical supply chain model needs to change:
- 14% Believe it needs to be more transparent
- 35% Believe rebates need to be reduced
- 49% Believe the model needs to be overhauled and simplified

Regarding the use of rebates as a mechanism to control drug costs:
- 75% Do not believe drug manufacturer rebates are an effective tool for helping to drive down pharmaceutical costs
- 91% Would welcome an alternative to the rebate-driven approach to managing drug costs

The rapid pace at which reforms are being considered within the marketplace and by both legislative and regulatory bodies at the federal and state levels is encouraging. A focus of the hearing, the Administration’s proposals to implement changes to how pharmaceutical reimbursement and contracting is administered within Medicare Part B and Part D illuminates the need and possibility that there are likely to be multiple solutions that improve upon the current model within the private and public sector. *NBGH supports a model marked by transparency, and one that removes incentives to consistently increase prescription drug*

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1 2019 Large Employers’ Health Care Strategy and Plan Design Survey, National Business Group on Health
prices. However, we also urge cautious, thoughtful, and analytical approaches that comprehensively evaluate the impact to market dynamics for all supply chain stakeholders.

Below, we highlight NBGH’s perspectives on two of the widely discussed proposals. Our full comments on the International Pricing Index (IPI) model can be found here. Additionally, we intend to provide full comments on the rebate proposal by the April 8th deadline.

**International Pricing Index (IPI) Model**

- **We must take a broad perspective to assure that public policy decisions contribute to overall cost control and quality improvement for all Americans.** We commend the Administration’s commitment to lowering the cost of prescription drugs and encourage it to seek solutions. However, we strongly recommend that whatever CMS adopts, part of the consideration and criteria for evaluating the results must be the impact on the private market and the 170 plus million people covered by employers and insurers and not limited to the impact on Medicare alone. If we as a nation are to succeed in controlling health care costs, we must ensure that public policy decisions do not merely “squeeze the cost balloon” in one area only for it to expand and exacerbate the problem in another area.

- **Our chief concern centers on the ANPRM’s proposal to link reimbursement rates to other nations’ prices.** Apart from the fact that these nations determine prices differently, have different patent and exclusivity models, and often vastly different incentives for biosimilar utilization, we are concerned that the impact on prices for the same pharmaceuticals in the US may rise in the private sector and the market for biosimilars may be adversely impacted if Medicare adopts this approach.

**Rebate Reform Proposal**

Many large employers have already begun evaluating the utility of point-of-sale rebates as part of their benefit design and a subset (29 percent) have them in place today. Thus, HHS’s proposal picks up on the momentum from large employers and, more importantly, underscores the inefficiency of the pharmaceutical supply chain. Given the market momentum on this issue, to both lower out-of-pocket costs for patients and evaluate ways to simplify a complex system, the Business Group is in favor of market-based solutions relative to point-of-sale rebates. NBGH has the following serious concerns about proposals around rebates.

While the stated goal of these proposals is to lower prescription drug prices and out-of-pocket costs for consumers by encouraging PBMs to pass discounts from drug manufacturers directly on to consumers and bring transparency to prescription drug market, we have various concerns with the proposals including but not limited to the following:

- **The proposals focus on out-of-pocket costs only.** The intent of the proposed rule and companion legislation is to lower out-of-pocket costs at the pharmacy counter and add needed pricing transparency to the market. While we support the proposed increased transparency and pricing relief for patients, we urge policy makers to avoid “quick fixes” that focus only on out-of-pocket costs, as opposed to total cost to the system. Focusing on

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out-of-pocket costs only has the potential to mask root causes of price increases, potentially lead to even higher increases over time, and drive the escalating trend on drug expenditures.

- **Any changes in supply-chain contracting should not result in a net increase in drug costs to any payor, nor windfall to any supply chain stakeholder.** Medicaid and CHIP Payment and Access, the Congressional Budget Office Commission (MACPAC) staff have noted that the CMS Office of the Actuary (OACT) estimated a net increase in Medicaid drug spending of $200 million over 10 years if the proposed rebate rule is finalized. A large chunk, if not the largest chunk, of this expected increase would come from the decline in inflation-based rebates. Further, manufacturer claim liabilities through the coverage gap discount program (CGDP) would be lower, which would produce an overall substantial savings for manufacturers. While savings is expected, that savings should be realized comprehensively across both the supply and demand sides of the pharmaceutical supply chain.

- **The proposals do nothing to address list prices.** The proposed rule “intends” and speculates that manufacturers might lower list prices, but there is little assurance that manufacturers will offset rebates with price reductions. In fact, at the hearing, not all CEOs in attendance would affirmatively state this would be the case at all, due to antitrust case law.

- **The proposed timeline within the HHS proposal is arguably too aggressive.** PBMs have largely already concluded negotiations on price concessions for plan year 2020 and are in the middle of actuarial analysis to prepare bids. There is no way to renegotiate in time to know the associated costs in order to bid properly, and it would be impossible to retool the supply chain in such a short period of time.

- **Premiums will increase.** The proposals are projected to increase the cost of healthcare for those who don’t use drugs having rebates, through premium increases, while disproportionately decreasing costs for those who do use drugs with discounts.

*Thus, while we agree that the rebate-driven model is ripe for reform and ineffective at controlling drug prices, we are concerned about the unintended consequences associated with the proposals as written.*

In addition to contracting concerns within the rebate-driven model, there remains substantial opportunity for policy change relative to prescription drug prices, most of which would encourage a more competitive and dynamic market with correspondingly more affordable prices.

**Advance Policies to Promote More Affordable, Financially Sustainable Prescription Drug Pricing**

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4 “Proposed Safe Harbor Regulation Impact” (Office of the Actuary, August 30, 2018).

5 “Manufacturer payments through the CGDP are expected to be about $2 billion per year lower on average. When POS costs are lower, it takes longer for the costs to accumulate toward the initial coverage limit (ICL) and the TrOOP threshold. CGDP payments would be lower as fewer members would be calculated as a percentage of a lower POS cost, but the impact would vary by manufacturer and by plan sponsor.”

6 “Impact of Potential Changes to the Treatment of Manufacturer Rebates” (Milliman, Inc., January 31, 2019).

7 “Foley Hoag Llp Whitepaper - Antitrust Implications of a Proposed HHS Rule to Limit Manufacturer Rebates,” accessed March 11, 2019
While many of the recommendations below are directed toward various agencies in the Administration, several of them require Congressional action. All of these policy recommendations are highlighted in the National Business Group on Health’s Issue Brief on Policy Recommendations to Promote Sustainable, Affordable Pricing for Specialty Pharmaceuticals

- **Remove Uncertainties Surrounding Risk-based and Value-Oriented Contracting and Implement Indication Specific Pricing and Reference Pricing in Public Programs**
  - Consider exemptions for value-based contracts from Medicaid best price requirements and clarify how drug makers and payers can conceive of value-based contracts without triggering broader Medicaid best price program implications.
  - Allow for variable pricing, where the price better reflects the evidence for benefit.
  - Evaluate the usefulness and application of the existing developed value frameworks and their potential to impact drug pricing in public programs, as well as their overall utility to the health care system.
  - Directly link reimbursement and improved patient outcomes.
  - Consider how drug makers and payers can enter into other types of innovative VBP arrangements, such as indication-specific pricing.
  - Implement reference pricing policies supported by clinical evidence consistently across public programs, where possible.

- **Limit Reach of Medicare Part D Protected Classes**
  - Following the MedPAC’s recommendations, the Congress and CMS should limit legislative and regulatory restrictions on formulary design within protected classes by modifying the Medicare Part D rules to remove those protected classes where enough generic competition exists, a change that would give private plans more freedom to control their formularies and negotiate for expanded manufacturer rebates.
  - Specifically, CMS should resubmit its proposal to remove antidepressants, antipsychotics, and immunosuppressants for transplant rejection from the list of protected classes because, in these classes, price reductions have been more closely linked with the availability of generics than to their status as “protected” and stand firm against industry-funded campaigns that seek to undermine the agency’s data-driven proposal to increase competitive pricing.
  - At a minimum, policy makers should evaluate the potential anticompetitive influence of protected classes on the commercial market, and specifically, evaluate the limitations imposed on private payers’ ability to negotiate competitive prices for drugs in the protected classes due to market spillover.

- **Eliminate Perverse Payment Incentives Under Medicare Part B**
  - Eliminate financial incentives for prescribing more expensive medicines, in more expensive settings.
  - Establish direct links between reimbursement and improved patient outcomes.
  - Encourage manufacturers to assume some financial risk for use of high-priced drugs.

- **Encourage the Uptake of Biosimilars**
  - Consider the utility of having an “interchangeability” distinction and potential alignment with the European biosimilars model, which has no such distinction.
  - Work with stakeholders to disseminate provider and patient education to firmly establish the safety and efficacy of biosimilar drugs to their reference products, recognizing that key successes to the uptake of biosimilar medicines in other countries
was predicated on the creation of trust and confidence among all the stakeholders involved, such as prescribers, pharmacists, and patients.
- Maintain payer autonomy to implement utilization management tools for specialty pharmaceuticals, including tools that pertain to biosimilar products.

- **Reform Permissive Patent and Exclusivity Protocols**
  - Reduce the market exclusivity period for biologics from 12 years to 7 years.
  - Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited, or no additional company investment or patient value produced.
  - Develop sound policy that would discourage patent abuses such as “evergreening” and “product hopping.” These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.
  - Refine the biosimilars patent dance to effectively incentivize the use of the section 351(l) patent dispute resolution provisions.

- **Reject anticompetitive “quick fixes”**
  - As consumers find themselves paying more of their drug costs, it’s tempting to be lured into new policies which may only further contribute to an anticompetitive climate. These policies may include specialty drug price caps, out-of-pocket payment caps, limitations on utilization management tools and mandated disclosure of propriety information.
  - Additionally, a federal law permitting importation nationwide could lead to some price reductions for both payors and patients in the short-term but, as markets adapt, it is unclear what the long-term effect on prices would be. It would also likely require a significant boost in resources for the Food and Drug Administration (FDA) to monitor imports and assure safety.

The National Business Group on Health, representing 437, primarily large, employers (including 70 of the Fortune 100) who voluntarily provide valued health benefits and other health programs to over 55 million American employees, retirees, and their families, looks forward to working with you on our shared goals for health care: lower costs, improved access, and higher quality – umbrella goals we consider inclusive of prescription drugs. Please contact Steven Wojcik, the National Business Group on Health’s Vice President of Public Policy, at (202) 558-3012, if you would like to discuss our comments in more detail or if we can provide additional information as the Committee continues its evaluation of drug pricing.

Sincerely,

Brian J. Marcotte
President and CEO