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*Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow*

December 31, 2018

The Honorable Seema Verma  
Administrator, Centers for Medicare & Medicaid Services  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services  
Attention: CMS-5528-ANPRM  
P.O. Box 8013  
Baltimore, MD 21244-8013

Submitted electronically via: <https://www.regulations.gov>

**RE: Medicare Program; International Pricing Index Model for Medicare Part B Drugs**

Dear Administrator Verma:

The National Business Group on Health (NBGH or the “Business Group”) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services’ (CMS’s) advanced notice of proposed rulemaking (ANPRM), which will consider tying reimbursement rates of certain prescription drugs payable by Medicare Part B to an International Pricing Index (IPI), eliminating “buy and bill” practices under the program, and disaggregating the product reimbursement from the Medicare administration fee paid to providers. We provide comments and recommendations below on all three aspects of the proposal.

The Business Group represents 435 primarily large employers, including 74 of the Fortune 100, who voluntarily provide group health and other employee benefits to over 55 million American employees, retirees, and their families.

For the last two years, specialty pharmacy expenses have been the number one cost driver for large employers, according to the Business Group’s annual Health Care Strategy and Plan Design Survey.<sup>1</sup> Thus, we share CMS’s concerns about the high prices of prescription drugs, particularly those classified as specialty products, which are often biologics and biosimilars. **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 take a broad perspective to assure that public**

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<sup>1</sup> “2019 Large Employers’ Health Care Strategy and Plan Design Survey,” Survey (The National Business Group on Health, September 2018), <https://www.businessgrouphealth.org/pub/?id=B7F87411-A59D-D212-CA59-2A79A7683DF2>.

**policy decisions contribute to overall cost control and quality improvement for all Americans. Otherwise, public policy decisions may merely be “squeezing the cost balloon” in one area only for it to expand and exacerbate the problem in another area.**

### **IPI Model**

In the description of the new model, the agency describes that the new rates paid to Model Participants and Model Vendors would “more closely [align] Medicare payment with international prices, which would be about a 30 percent reduction in Medicare spending for included Part B drugs over time...”<sup>2</sup>

**While we recognize this is an ANPRM and that full details are pending release in the spring of 2019, 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.**

Given that Medicare is a major purchaser of medicines, as such it may influence prices to such an extent that prices may rise for private payers like employer plans if manufacturers seek to recoup lost revenue by raising prices outside of Medicare. Additionally, it is unclear whether the impact of adoption of such a model for payment in Medicare will serve to foster or inhibit the nascent biosimilars market. Therefore, we strongly urge CMS to consider both of these factors before going forward with a final rule.

We do not mean to imply that we are satisfied with the status quo with respect to pharmaceutical pricing, particularly specialty pharmaceuticals. We recognize that deficiencies in manufacturer pricing models, the pharmaceutical supply chain and abuses of patent and exclusivity policies must be addressed in order to bring down the high prices of specialty medicines. In this vein, we feel strongly that initial pricing of prescription drugs, further exacerbated by complicated and little-understood supply chain economics, should be a more central focus.

**Specifically, we encourage the Administration to stay the course on evaluating means to shore up an equitable playing field for biosimilar and generic products by 1) evaluating patent and exclusivity abuses that have led to anticompetitive practices within the pharmaceutical market, 2) continuing scrutiny of the rebate-driven supply chain model, 3) increasing monitoring of pay-for-delay deals, 4) analyzing the impact of market consolidation, 5) considering meaningful incentives for biosimilar utilization and 6) by assessing the potential impacts of and barriers to alternative payment models for prescription drugs, such as outcomes-based contracting and indication-specific reimbursement models.**

### **“Buy and Bill”**

The Business Group has long been outspoken about the need to reform payment and reimbursement policies within Medicare Part B. Generally, we believe that financial incentives to providers should play no role in clinicians’ determination of which medication to prescribe. Specifically, we have noted that the “buy and bill” model creates a two-part and cyclical incentive for prices to continuously inflate, under the existing average sales price (ASP)+6% reimbursement model. First, it encourages

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<sup>2</sup> “Medicare Program; International Pricing Index Model for Medicare Part B Drugs,” Federal Register, October 30, 2018, <https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs>. (herein, the “ANPRM”).

manufacturers to set prices high, as this may incent providers to choose those products linked to a higher reimbursement. It also creates an incentive for providers to continuously select higher-priced drugs, even when lower cost alternatives might be available. With that in mind, we have also noted that this policy inherently disadvantages the uptake of biosimilars in the marketplace and needlessly raises prices for payers and patients.

However, we have also historically expressed concerns about the wholesale elimination of the buy and bill policy. In previous comments to the agency, we expressed concerns that elimination of buy and bill could have the unintended consequence of accelerating market consolidation and more vertical integration, particularly in oncology and rheumatology. Although the ANPRM potentially buffers these concerns with the disaggregated administrative fee, it also contemplates that Model Vendors could be permitted to charge Model Participant delivery and/or distribution fees. Thus, we urge thoughtful consideration be given to the ability of non-hospital affiliated, independent clinical oncologists and other practitioners to absorb the financial impact, to avoid accelerated consolidation. Although the ANPRM proposes to expressly prohibit rebates and volume discounts, it still relies on Model Participant negotiation of rates. We have a concern that the negotiating position of larger entities would disadvantage vulnerable providers who help to assure competition in the marketplace.

Thank you for considering our comments and recommendations regarding the ANPRM. We look forward to better understanding the full mechanics of the IPI model when it is released next year and providing further comments at that time. Please contact me or 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.

Sincerely,

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

Brian Marcotte  
President and CEO