



# National Health Council

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February 13, 2019

Steven D. Pearson, MD, MSc  
Founder and President, Institute for Clinical and Economic Review  
Institute for Clinical and Economic Review  
Two Liberty Square, Ninth Floor, Boston, MA 02109

## Re: Unsupported Price Increase Assessment

Dear Dr. Pearson:

The National Health Council (NHC) is pleased to provide comments on the Institute for Clinical and Economic Review's (ICER) solicitation for feedback on the Unsupported Price Increase Assessment draft protocol.<sup>1</sup>

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people in the United States with chronic diseases and disabilities, and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include professional and membership associations; nonprofit organizations with an interest in health; and representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries.

This work is very much aligned with our 2017 report *Policy Recommendations for Reducing Health Care Costs*.<sup>2</sup> One of the recommendations included in that report was that the National Academy of Medicine could commission reports on price increases on selected drugs of significant interest to patients. Selection criteria would be based on lack of competition, shortages, and significant price increases. We suggested that manufacturers would submit any relevant information to provide justification for the price increase, and the National Academy would retain any confidential and propriety information. The information to be collected would include but not be limited to:

- A narrative of factors contributing to the drug's pricing
- Existing therapeutic alternatives and any information demonstrating its comparative patient value, consistent with information contained in the FDA label
- Acquisition information if the drug was not developed by the current manufacturer

<sup>1</sup> Institute for Clinical and Economic Review (ICER). Unsupported Price Increase Assessment: Draft Protocol (January 17, 2019). [https://icer-review.org/wp-content/uploads/2019/01/ICER\\_UPI\\_Draft\\_Protocol\\_011719.pdf](https://icer-review.org/wp-content/uploads/2019/01/ICER_UPI_Draft_Protocol_011719.pdf)

<sup>2</sup> National Health Council. Policy Recommendations for Reducing Health Care Costs. Available from: <http://www.nationalhealthcouncil.org/sites/default/files/NHC%20Policy%20Proposals%20for%20Reducing%20Health%20Care%20Costs%20UpdatedFINAL052217.pdf>

- Aggregate research, development, and administrative expenditures
- Aggregate rebates, discounts, and other concessions that reduce the effective price

While the current draft protocol does not consider each of these factors, the outlined process is an important starting point. We encourage ICER to consider this additional, relevant information in future iterations of the unsupported price increase program.

We appreciate ICER's inclusion of a patient representative on the multi-stakeholder advisory committee. We encourage the consideration of additional patient representatives and engagement in the process. ICER should also outline a role for patient representatives within the individual reviews. For example, patient perspectives from those with experience in a particular disease area would provide useful insights within the scope of individual reviews. The draft protocol contains a detailed explanation of how manufacturers can submit information but is lacking in detail on how patients and patient organizations can contribute to the process in a similar fashion as ICER's therapeutic reviews.

For this initiative to be successful, processes must be rigorous, transparent and reproducible. Opportunities for stakeholder and public input will help facilitate the program's credibility. We are pleased that ICER will provide an opportunity for members of the public to identify additional drugs that do not necessarily meet the cost criteria, but nevertheless cause hardships among patients and their families. Additional details on how this input will be sought would be helpful. The NHC would be happy to disseminate calls for input.

Additionally, greater clarity on how ICER will identify "important affordability implications for individual patients even if not for the health system" is needed. Greater clarity on the intended meaning of "affordability implications" would be needed for operationalizing the program and improve transparency. The scoping document also does not describe whether or not the Advisory Committee will participate in the selection of the (up to) three additional drugs. If not, how will the drugs be selected? Since many patients struggle with the costs of drugs and only up to three public-identified drugs will be considered, transparent and detailed selection criteria would help facilitate the process.

Additional details on how the independent systematic reviews will be performed would also be useful. For example, the scoping document refers to "high quality comparative observational studies." We recommend that ICER provide a definition or characteristics of "high quality" in this context.

ICER's decision to categorize drug-price increases as either "price increase with new clinical evidence" (those with moderate/high quality new evidence of a substantial improvement in net benefit) or unsupported is a reasonable approach. However, it may be important to consider what is included under the "clinical evidence" umbrella. For example, we recommend consideration of other factors that typically fall into the "contextual considerations" category of ICER's therapeutic reviews, such as impact on adherence, social factors, productivity, quality of life, or other outcomes not typically considered "clinical." Determination of impacts to consider would be greatly benefitted by engaging with patients and patient organizations.

Finally, the NHC recommends greater clarity on the format of the public reports. We recommend that ICER publish a report that can be understood by individual patients and include information that explains what the potential impact may be for them. For example, our 2017 recommendation calls for a report that "offer[s] context around the selected drugs' pricing and attempt to characterize its health, economic, and societal benefits, measured through both short- and long-term patient outcomes, adherence, productivity, quality of life, and/or life expectancy."

## Conclusion

The NHC appreciates the opportunity to comment on this initiative and agrees that methodology will need to be updated as experience in this space grows. Future iterations of ICER's Unsupported Price Increase Assessment program could also consider medical devices, surgeries, and other non-drug medical products.

Please do not hesitate to contact Eric Gascho, our Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink, appearing to read "MBoutin", with a long horizontal flourish extending to the right.

Marc Boutin, JD  
Chief Executive Officer  
National Health Council