

WHY REFERENCING ICER'S UNSUPPORTED PRICE INCREASES (UPI) REPORT IS DANGEROUS

The Legislation Codifies Reference to an Independent Entity Lacking Accountability and Oversight:

The Institute for Clinical and Economic Review (ICER) is an independent non-profit entity. ICER is not a federal government agency and not affiliated with the FDA, nor does it have any authority to approve or deny drug access. The legislation developed by the National Association of State Health Policy (NASHP) is unusual in that it would codify referencing a report from a non-governmental entity as the sole source of information, thereby sidestepping usual state contracting processes that would allow for public comment and state government oversight of the report's methods and conclusions. It would also preclude reference to evidence from other, more appropriate, entities, stating, "the state shall utilize and rely upon the analyses of Prescription Drugs prepared annually by the Institute for Clinical and Economic Review (ICER) and published in its annual Unsupported Price Increase Report."

ICER is Not an Appropriate Source of Information: Many stakeholders have expressed concerns that ICER's UPI report suffers from many of the same weaknesses as its value assessments, including lack of transparency, disregard for outcomes that matter to patients and their families, cherry-picked data, and fundamental issues with the underlying information. Under its current methods, ICER solely determines the studies that will be used in its analyses. Only information provided by manufacturers would be considered to justify an exception to ICER's usual methods, and only ICER would determine how to use that additional information in its report's conclusions that would trigger state action. Alternatively, there are several other entities, including the Patient-Centered Outcomes Research Institute (PCORI) whose methodologies for comparative effectiveness research are more transparent and patient-centered than ICER. PCORI was created by Congress in 2010 as an independent agency whose work is evaluated by the Government Accountability Office every 5 years.

ICER Ignores Key Real-World Evidence: A key critique of the ICER UPI report, as with ICER's value assessment reports, is their reliance on randomized clinical trials (RCTs). ICER consistently argues that certain real-world evidence does not meet their "high quality" standards. This outdated and restrictive view of real-world data means many important benefits of a medicine observed in real patient populations could be completely disregarded. Additionally, as RCTs often do not reflect the true diversity of patient populations, ICER's assessments may also fail to capture important added value to underrepresented populations.

NASHP's Template Legislation Lacked Input from Patients and People with Disabilities: The template legislation being considered in various states to reference ICER's UPI report was developed by NASHP without input from patient stakeholders. Organizations representing patients and people with disabilities should have a seat at the table when discussing policies that could directly impact the access and availability of their medicines. Yet, these key voices were excluded from the NASHP model legislation development. ICER did not advise stakeholders of its plans for the UPI report to be a sole source of information for state policymakers and did not get significant input from patients and people with disabilities that operate with scarce resources. Legislation with such potential to impact access and innovation should not be advanced without robust engagement from those that have most to lose from its unintended consequences.

The UPI Does Not Preclude Use of Discriminatory Quality-Adjusted Life Years: While use of QALY's may not be front and center in ICER's UPI report, the protocol clearly indicates that QALYs can play an important supporting role. The 2020 UPI protocol considers "any new information that alters prior beliefs about the clinical effectiveness or cost effectiveness of a therapy." This means that the UPI report could include evidence that relied on discriminatory QALYs as a measure of value to determine whether price increases are "supported." ICER has the power to change its methodology in future years, after the report is enshrined into law, with significant implications for patients and people with disabilities.