

December 24, 2019

Judith Cash, Director  
State Demonstrations Group  
Centers for Medicare & Medicaid Services  
Centers for Medicaid and CHIP Services  
Mail Stop: S2-26-06  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Dear Ms. Cash:

We are writing in response to Tennessee's proposed amendment to the TennCare Demonstration, TennCare II Demonstration, Amendment 42. The waiver requests that CMS allow TennCare to adopt a commercial-style closed formulary, which may cover only one drug in each therapeutic area, and opens the door to the controversial method of evaluating the "value" of a treatment using cost-effectiveness analyses. The affordability of health care is a significant priority for patients and people with disabilities, and we applaud efforts to reduce the cost of care. Yet, we are concerned this proposal will lead to limited access and ultimately prevent patients and people with disabilities from receiving the care they need.

It is well documented that, in many cases, different patients react differently to the same drug. Some patients cannot tolerate or do not benefit from one drug in a therapeutic class, and therefore need an alternative that may be restricted under this new policy. Restricting access to one drug per class is especially dangerous for certain conditions where treatment failure could lead to serious consequences and costly adverse events.

The waiver would also allow TennCare to exclude drugs coming to market through the FDA's accelerated approval pathway until market prices are consistent or sufficient data exist regarding the "cost-effectiveness" of a drug. The waiver does not preclude the state from determining cost-effectiveness of drugs using existing value assessment practices, which rely on the discriminatory Quality-Adjusted Life Year (QALY) metric. As you know, the patient and disability communities have long had concerns about the use of the discriminatory Quality-Adjusted Life Year (QALY) to determine cost effectiveness or "value" of treatments. QALYs and similar metrics are referenced in other countries and in studies by independent third parties, such as the Institute for Clinical Economic Review (ICER).

The National Council on Disability (NCD), an independent federal agency, recently concluded that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities. NCD recommended that policymakers and insurers reject QALYs as a method of measuring cost-effectiveness for medical care and avoid referencing international pricing due to its reliance on QALYs.<sup>1</sup> In fact, NCD recommends that the use of QALYs be barred from use in Medicaid programs.

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<sup>1</sup> [https://www.ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf)

Historically, the QALY has been opposed by the American public and policy makers. In fact, there is currently a ban on use of the QALY or similar metrics in Medicare.<sup>2</sup> In 1992, a Republican administration established that Oregon's efforts to utilize a cost-effectiveness standard in Medicaid would violate the Americans with Disabilities Act (ADA).<sup>3</sup> Therefore, we have concerns that this metric is creeping into our state's health system.

The ability to exclude new drugs coming to market through the FDA's accelerated approval pathway would primarily impact drugs for rare conditions and disabling conditions for which there are currently no or few approved treatments, which would leave some of Tennessee's most vulnerable without care. This model is very similar to how many other nations run their health care systems, including the U.K and Canada. We know that patients and people with disabilities in these countries frequently experience delayed or lack of access to medications they need. Only 39% of medicines launched globally between 2008 and 2012 were available in Canada in 2013, and 38% of medicines to treat orphan conditions were rejected for coverage in Canada.<sup>4</sup> Between 2007 and 2017, nearly 80% of cancer treatments reviewed by U.K. health officials had some form of access restriction.<sup>5</sup>

Our goal is for TennCare to be centered on the needs, outcomes, and priorities of patients and people with disabilities; therefore, we oppose opening the door in Tennessee to limited formularies and the use of cost-effectiveness analyses based on the QALY and similar metrics, which would lead to discrimination and restricted access to care. We urge you to review carefully the recent NCD report raising concerns about the potential implications of use of QALYs under the ADA.

Thank you for your consideration. Please feel free to reach out to Thayer Surette at [thayer@pipcpatients.org](mailto:thayer@pipcpatients.org) or 508-843-1688 with any questions or if you would like to discuss in more depth.

Sincerely,

ACCSES

Aimed Alliance

Alliance for Aging Research

American Association on Health and Disability

American Autoimmune Related Diseases Association (AARDA)

Asthma and Allergy Foundation of America

Autistic Self Advocacy Network

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<sup>2</sup> 111th Congress of the United States of America. (2010). H.R. 3590 The Patient Protection and Affordable Care Act. *Section 1182*. Washington, DC.

<sup>3</sup> <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

<sup>4</sup> [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc\\_canada.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_canada.pdf)

<sup>5</sup> [http://www.pipcpatients.org/uploads/1/2/9/0/12902828/united\\_kingdom.pdf](http://www.pipcpatients.org/uploads/1/2/9/0/12902828/united_kingdom.pdf)

Rosie Bartel, Patient Advocate and Advisor

Beyond Type 1

The Bonnell Foundation: Living with cystic fibrosis

Diabetes Patient Advocacy Coalition (DPAC)

Epilepsy Foundation

Go2 Foundation for Lung Cancer

The Hepatitis C Mentor & Support Group, Inc.

Lakeshore Foundation

Lupus and Allied Diseases Association, Inc.

National Diabetes Volunteer Leadership Council

The National Minority Quality Forum

Partnership to Improve Patient Care

Preventive Cardiovascular Nurses Association