



## MEDICARE PROPOSAL TO RELY ON OTHER COUNTRIES' FLAWED COST-EFFECTIVENESS STANDARDS DISCRIMINATES AGAINST PATIENTS AND PEOPLE WITH DISABILITIES

Misuse of cost-effectiveness thresholds by health insurance companies and policy-makers has reemerged as a major concern for U.S. patients and people with disabilities. The fact that several recent policies and proposals rely on quality-adjusted life-year (QALY) standards is particularly troubling, as this method ignores differences in individual patients and discriminates against people with disabilities and other vulnerable populations.

Most recently, a new threat emerged in a proposal released by the Administration to overhaul how Medicare reimburses providers for physician-administered medicines, in which the Centers for Medicare & Medicaid Services (CMS) proposed to set national coverage and payment policies based on decisions made in countries that use QALYs and cost-effectiveness thresholds. Similarly, this year a pharmacy benefit manager also planned to deny coverage of medicines that do not meet an arbitrary cost-per-QALY threshold, evoking significant opposition from patients.

We know the fate of patients and people with disabilities in these countries: denied access to care. We don't know how the U.S. could or would protect their own from a similar fate if we import their discriminatory policies.

### THE POLICY

In October, CMS announced a plan to reimburse prescription drugs covered under Medicare Part B based on an "International Pricing Index." The proposal would use reference countries—many of which use QALY-based cost-effectiveness thresholds—to reduce Medicare spending.

Patients and people with disabilities share the goal of improving affordability across the health care system, including for prescription drugs. However, attempting to do so by importing decisions made through use of deeply flawed cost-effectiveness standards is profoundly misguided. The QALY cost effectiveness formula applies greater "value" to the health gains a treatment achieves for a non-disabled individual than an individual with a disability. In effect, treatments for younger, healthier patients have much higher QALYs than for older patients or people with disabilities.<sup>1</sup> The result is discrimination.

### WHAT DOES REAL-WORLD DISCRIMINATION LOOK LIKE IN OTHER COUNTRIES?

Patients and people with disabilities living in countries that utilize QALY-based cost-effectiveness thresholds are frequently faced with barriers to accessing the treatments they need.<sup>2</sup> Patients with cancer, chronic conditions, rare diseases, and others are often victims of policies that fail to put patients and people with disabilities at the center of their health care decision-making. For many, one-size-fits-all policymaking has real life and death implications.

A patient with breast cancer in the U.K. said, "It's devastating to not even be able to try a drug that could work for you... I understand a line has to be drawn but it feels unfair that other people make decisions about your life and how much it's worth." (*Daily Mail*, Sept. 2018)

"By the way, Europe does pay more—in the form of reduced access. Of 74 cancer drugs launched between 2011 and 2018, 70 (95%) are available in the United States. Compare that with 74% in the U.K., 49% in Japan, and 8% in Greece." (*WSJ*, Oct. 2018)

<sup>1</sup> This was illustrated in stark terms in a cost-effectiveness analysis recently conducted by the Institute for Clinical and Economic Review (ICER) for two treatments for a rare, serious childhood disease, spinal muscular atrophy (SMA)

<sup>2</sup> The Editorial Board, "Why Are Drugs Cheaper in Europe?" Opinion, *The Wall Street Journal*, October 28, 2018. Accessed December 5, 2018. [Web](#).

Patients pay the price for delayed and restricted access to life-saving medication – five-year survival rates for breast, colon, lung, and prostate cancers are higher in the U.S. than in Canada, France, Germany, Italy, Japan, and the U.K. (WHO mortality database, May 2018)

An Australian confined to a wheelchair since childhood, was diagnosed with type 2 spinal muscular atrophy (SMA) as an infant and for the past 25 years, he and his family have been hoping for a cure.<sup>1</sup> Their hopes soared a treatment was developed, but Australia decided to restrict coverage to SMA patients age 18 and under. He said “I was quite depressed. I waited 25 years.” (*The Herald Sun*, Aug. 2018)

Parent of a child with spinal muscular atrophy in the U.K. - “It’s incredibly cruel to use the cost-effectiveness line and it makes me shake with rage... It has been approved in Scotland and the US and Europe but England is just lagging so far behind... It’s an abomination of human rights that the drug isn’t available. It feels like discrimination against his disability.” (*Daily Mail*, Oct. 2018)

The Tale of Two Friends – one covered in the U.S. and the other in Canada, both diagnosed with breast cancer as young women who underwent mastectomies and aggressive chemotherapy, only to have the cancer return in different parts of their bodies. One was covered in the U.S. and prescribed the drug that put her in remission, the other did not get coverage in Canada and pays \$8,000 a month for the same hope of recovery. (*Canadian Broadcasting Company*, Jan. 2018)

## IMPLICATIONS BEYOND MEDICARE PART B: DEMONSTRATIONS ARE CREATED WITH EXPANSION IN MIND

To justify such a far-reaching policy change, CMS points to authority it has under CMMI to “test” policy changes. Unfortunately, this extends far beyond the bounds of a test, and instead represents a profound policy change with unknown effects that would be imposed on Medicare patients in almost half the U.S. Additionally, despite continued pressure from patients and people with disabilities, CMMI has never established patient-centeredness criteria to guide their work as called for in statute.<sup>3</sup> These criteria are vital to ensure that a demonstration’s success is measured by achieving outcomes that matter to patients before being expanded program-wide.

## AREN’T MEDICARE PATIENTS PROTECTED AGAINST USE OF COST-PER-QALY STANDARDS?

Yes, the U.S. has repeatedly rejected the use of cost-effectiveness assessments and QALYs to make coverage decisions for treatments in our public programs, choosing instead to protect patients and people with disabilities from discrimination. As part of the Affordable Care Act, Congress included a critical safeguard with bipartisan support prohibiting Medicare from using cost-per-QALY standards or similar cost-effectiveness thresholds for making any coverage or payment decisions.<sup>4</sup> Unfortunately, Congress also gave CMMI broad “waiver” authority that enables CMS to ignore this safeguard.<sup>5</sup> Even prior, in 1992, the Administration concluded it was a violation of the Americans with Disabilities Act (ADA) to employ QALY-based cost-effectiveness standards in Medicaid due to resulting discrimination against people with disabilities. It’s time to reaffirm this stance - not undermine it.

## A BETTER WAY

Let’s learn from the experience of other countries rather than replicating their misguided policies. Efforts to reduce drug costs should put patients at the center and protect vulnerable Americans, not put their health in jeopardy. Urge CMS and the Trump Administration to heed calls for the development and use of patient-centered policies, rather than modeling American health care on countries that deem patients and disabilities as worth less.

<sup>3</sup> 42 USC Sec 1315a, 2011. Accessed December 3, 2018. [Web](#).

<sup>4</sup> 42 USC Sec 1320e, 2017. Accessed December 4, 2018. [Web](#).

<sup>5</sup> 42 USC Sec 1315a, 2011. Accessed December 3, 2018. [Web](#).