

HHS' Finalizes the Regulations on Section 504 of the Rehab Act Clarifying Rules for Nondiscrimination

Today, the U.S. Department of Health and Human Services (HHS) announced the [final rule governing Section 504 of the Rehabilitation Act](#), which protects the rights of people with disabilities in programs and activities receiving federal financial assistance. In response to the proposed rule, last year the Partnership to Improve Patient Care (PIPC) joined 100 organizations and individuals on a [letter](#) providing the agency with a series of recommendations. Our review of the rule below is limited to the provisions on which PIPC commented.

As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would likely include the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). HHS' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards used by payers in the U.S. and other countries. Although we look forward to increased clarity related to the standards set in the final rule as cases are reviewed by the Office for Civil Rights, we appreciate the agency's broad interpretation of what constitutes the discriminatory use of value assessment in its description of the rule.

To achieve increased clarity and stronger protections for patients and people with disabilities, PIPC continues to:

- Strongly support H.R. 485, the Protecting Health Care for All Patients Act, which would advance a consistent policy across federal programs barring the use of QALYs and similar measures as it already exists in Medicare law;
- Call on the Centers for Medicare and Medicaid Services (CMS) and the Innovation Center to explicitly recognize and follow, without exception, the existing Medicare statute barring use of QALYs and similar measures – as well as the new rules governing Section 504 – consistent with recommendations of the National Council on Disability against reliance on cost-effectiveness;
- Urge policymakers to ensure CMS does not override existing prohibitions against QALYs or similar measures by referencing decisions made in other countries that use these standards.

In summary, the final rule addressed comments from PIPC and [others](#) as follows:

- In response to our recommendation that the final rule model the language used in Section 1182(e) of the Affordable Care Act to achieve consistency across programs, the agency chose not to amend the rule as proposed but stated, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to

qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment.” This language implies that the final rule holistically is intended to be interpreted in a manner that is consistent with, and broader than, the law barring the use of QALYs and similar measures in Medicare.

- PIPC and others recommended that the final rule should explicitly include a ban on use of similar measures that discriminate based on quality of life and quality-of-life improvement. We are concerned that the agency chose not to amend the proposed rule’s narrow view of discriminatory value assessments in § 84.57 which only describes those using a measure that “discounts the value of life extension.” Yet, we appreciate the agency’s clarification that “discounting the value of quality of life on the basis of disability for purposes of denying or limiting medical treatment to a qualified individual with a disability would likely violate § 84.56.” The agency also stated, “Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56’s prohibition of discrimination based on biases or stereotypes about a patient’s disability, among others.”
- PIPC and others recommended that HHS be explicit in the final rule that recipient payers cannot categorically exclude or limit access to care that is not futile for individuals with disabilities or selectively deny or limit care to a person with a disability based on the determination the person’s quality of life is not worth the cost of treatment. The agency responded it will determine such discrimination on a case-by-case basis.