

The Legality of QALY under the ADA

By *Jim McKenna and William Smith*

I. Question Presented

Does a state government violate the Americans with Disabilities Act when they use “quality of life” standards as a factor in determining which medical treatments are available to patients through their Medicaid programs?

II. Short Answer

The quality adjusted life year (QALY) methodology used to rate the cost-effectiveness of medical treatments would be extremely vulnerable to challenge under the Americans with Disabilities Act if it were utilized to determine treatments available to Medicaid patients. At this time, it cannot be said with certainty that the quality-of-life methodology, used most prominently by the Institute for Clinical and Economic Review (“ICER”) for rating the cost-effectiveness of medical treatments and therapies, violates or complies with the Americans with Disabilities Act (“ADA”). There has yet to be a decision issued by the Supreme Court that would govern such a case. In addition, no cases currently pending before the Supreme Court from the previous term or the upcoming term will address this issue.

That said, QALY would be extremely vulnerable to challenge under the ADA if it is utilized to determine treatments available to Medicaid patients because the use of QALYs has the potential to cause state governments to administer Medicaid to disabled persons in a discriminatory manner by providing them lesser benefits by prioritizing the achievement of “asymptomatic” status, rather than “medical effectiveness.” This outcome, which would have a disparate impact on individuals with both physical and mental disabilities, would be a clear violation of the ADA.

III. Definitions

The term “qualified individual with a disability” means an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity. 42 U.S.C. § 12131(2).

The term “public entity” means: (a) any State or local government; (b) any department, agency, special purpose district or other instrumentality of a State or local government; and (c) the National Railroad Passenger Corporation, and any commuter authority as defined in Title 49 of the United States Code. 42 U.S.C. § 12131(1).



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IV. Background

Enacted in 1965 as Title XIX of the Social Security Act, the Medicaid Act is a cooperative federal-state program designed to provide medical assistance to persons whose resources are insufficient to meet the costs of their necessary medical care. 42 U.S.C. §§ 1396 – 1396w-5; *Hines v. Shalala*, 999 F.2d 684, 686 (2d. Cir. 1993). Although a state is not required to participate in the Medicaid program, once it chooses to do so it must develop a plan that complies with the Medicaid statute and the regulations promulgated by the Secretary of the Department of Health and Human Services (USHHS). See *Hines*, 999 F.2d at 686 citing *New York v. Sullivan*, 894 F.2d 20, 21-22 (2d. Cir. 1990). State Medicaid plans must also comply with other federal law, such as the ADA and the United States Constitution.

The ADA was passed by the Federal Government in 1990 and addresses broadly discrimination against persons with disabilities. In the introductory provision of the ADA, Congress shared its findings applicable to all forms of discrimination that the ADA was meant to prohibit. Findings most relevant to this analysis are the following:

“(1) physical or mental disabilities in no way diminish a person’s right to fully participate in all aspects of society, yet many people with physical or mental disabilities have been precluded from doing so because of discrimination; others who have a record of a disability or are regarded as having a disability also have been subjected to discrimination;”

“(2) historically, society has tended to isolate and segregate individuals with disabilities, and, despite some improvements, such forms of discrimination against individuals with disabilities continue to be a serious and pervasive social problem;”

“(3) discrimination against individuals with disabilities persists in such critical areas as . . . institutionalization, health services . . . and access to public services;”

...

“(5) individuals with disabilities continually encounter various forms of discrimination, including outright intentional exclusion . . . exclusionary qualification standards and criteria, segregation, and relegation to lesser services, programs, activities, benefits, jobs, or other opportunities.”

42 U.S.C. §§ 12101(a)(1), (2), (3), (5). The ADA prohibits discrimination in employment practices (Title I, §§ 12111-12117), public services furnished by “public entities” (Title II, §§ 12131-12165), and public accommodations provided by private entities (Title III, §§ 12181-12189). The Rehabilitation Act provided the foundation for the ADA, and courts frequently find support in cases brought under the Rehabilitation Act, when interpreting the ADA. *DuBois v. Alderson-Broadbuss College, Inc.*, 950 F. Supp. 754, 760 (N.D.W. Va. 1997).

With healthcare spending steadily rising each year in the United States, there is a need for methods that identify treatments with the highest value. Covering the high-value treatments and dispensing of those with low-value, theoretically, will lower overall healthcare spending. One such method is the QALY, which attempts to assign relative value among the vast array of medical treatments using a single metric, quality-of-life.

There has been no shortage of criticism however over the potential of QALYs to discriminate against the disabled. Most notably, in the late 1980’s and early 1990’s, the state of Oregon attempted to provide universal basic healthcare coverage to their low-income citizens. To do so, cost-saving techniques were proposed to ration the limited Medicaid funds available, including the prioritization of medical treatments based on ability to return a patient to an asymptomatic state. While the QALY methodology is allegedly facially-neutral, its measure of an individual’s restoration to a certain quality of life is inherently discriminatory when applied to persons with physical or mental disabilities, who may seek treatment but never experience a quality of life recognized by this narrow methodology.

The Bush Administration explicitly rejected the Oregon plan, based on concerns that its use of QALY to measure allocation of Medicaid funds was discriminatory and in violation of the ADA. In July 1992, twenty disability advocacy organizations publicly urged President Bush to reject the waiver request required to enforce the Oregon plan. On August 3, 1992, then-HHS Secretary Louis Sullivan informed Oregon Governor Barbara Roberts that he would not grant the waiver, and argued that the survey informing research for the plan was “based in substantial part on the premise that the value of life of a person with a disability is less than the value of life of a person without a disability.”

On January 19, 1993, the day before President Clinton’s inauguration, a Bush Administration political appointee in the Justice Department wrote to HHS that the revised plan continued to have “features that violate ADA,” as priority was accorded to treatments that would “return the patient to an asymptomatic state of health” after saving his or her life. The letter argued that the designation “asymptomatic” denigrated the quality of life of persons with disabilities.

Despite intense opposition by over seventy advocacy groups grounded in the newly enacted Americans with Disabilities Act, the Clinton Administration approved the “Oregon Reform Demonstration.” The plan was put into operation after all twenty-nine terms and conditions required by the Department of Health and Human Services were satisfied. Included in these conditions was assurance that qualified disabled persons would not be denied accommodating care and treatments. Although declared a success, it is unclear whether Oregon’s rationing plan has actually produced any savings at all.

V. Analysis

A. Title II Governs Public Programs Furnished by State Governments

The application of QALY to patients in public programs such as Medicaid is governed by Title II of the ADA as public services furnished by a “public entity.” 42 U.S.C. § 12131(1). Title II provides that:

“Subject to the provisions of this subchapter, no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.”

42 U.S.C. § 12132. In enacting the ADA, Congress abrogated the Eleventh Amendment, thus affording no immunity to states that violate its provisions. U.S. Const. amend. XI; *United States v. Georgia*, 546 U.S. 151, 158-59 (2006); *Goonewardena v. New York*, 475 F. Supp.2d 310, 322-23 (S.D.N.Y. 2007)

Three factors must be shown to establish discrimination through services or programs furnished by a public entity under the ADA. First, the individual must show that they are a qualified individual with a disability. Second, the qualified individual must show that they were excluded from participation in a public entity’s services, programs or activities or were otherwise discriminated against by a public entity. Third, such exclusion or discrimination must be shown to be due to their disability. 42 U.S.C. § 12132; *Fulton v. Goord*, 591 F.3d 37, 43 (2d Cir. 2009).

Whether an individual is a qualified disabled person may only be determined on a case-by-case basis, but would be easily proven assuming a qualified individual brings a lawsuit. As for the second factor, a state government is a “public entity” and Medicaid is a “service” or “program.” See *Taylor v. Colorado Dept. of Health Care Policy and Financing*, 811 F.3d 1230, 1233-35 (3d Cir. 2016); *Cohon ex rel. Bass v. New Mexico Dept. of Health*, 646 F.3d 717, 724-25 (10th Cir. 2011); *Arc of California v. Douglas*, 956 F. Supp.2d 1113, 1121-22 (E.D. Cal. 2013), *rev’d in part* 757 F.3d 975. With these items established, QALY’s legality under the ADA is left to one question: does QALY treat qualified disabled persons differently *because of* their disability?

B. The QALY Methodology Likely Violates the ADA When Applied to Medicaid Patients with Disabilities

The use of broad population-based cost and cost-effectiveness analyses with a lack of patient-specific metrics in coverage decisions is damaging and discriminatory

against individuals with disabilities. People with disabilities and patients with chronic conditions often seek access to treatments and health interventions that improve their quality of life, even in the absence of a cure. Further, many people with disabilities may enjoy a quality of life comparable to non-disabled individuals, but may face a shorter life expectancy compared to someone without their condition. QALYs are determined by both quality as well as quantity of life, and thus, providing treatment to a non-disabled person with a longer life expectancy would be prioritized over a person with a disability or a life-shortening chronic condition.

QALY has the potential to unlawfully discriminate against disabled or chronically ill persons who may never experience full restoration to a certain quality of life defined by QALY. Consequently, the QALY methodology may cause Medicaid programs to have a disparate impact, or discriminatory effect, on disabled persons. Disparate impact could stem from QALY assigning lower values to treatments for disabilities; thus, rendering them less available to those whom they benefit. That treatments for disabilities may significantly improve one’s quality-of-life, but never restore them to a “perfect” quality, renders such treatments subject to lower QALY values.

i. QALY Could Readily Have a Disparate Impact on Treatments Available to Disabled Persons

Violations of the ADA may be found on three theories of liability: (1) disparate treatment; (2) failure to make a reasonable accommodation; or (3) disparate impact. *Goord*, 591 F.3d at 43. So long as QALY does not explicitly evaluate treatments differently based on abilities or disabilities, a disparate treatment claim cannot succeed. Furthermore, an alleged failure to make a reasonable accommodation is extremely fact-specific, based on the circumstances surrounding the plaintiff’s alleged discrimination. Therefore, determining whether a measure taken by a public entity was a reasonable accommodation of a disabled person’s needs may only be made on a case-by-case basis. *Dean v. Univ. at Buffalo Sch. of Med.*, 804 F.3d 178, 189 (2d Cir. 2015).

Disparate impact, however, is measured differently. A facially-neutral program, benefit, or service provided by a public entity creates a disparate impact when it has an actual or predictable discriminatory effect. *Gamble v. City of Escondido*, 104 F.3d 300, 306 (9th Cir. 1997). Disparate impact could manifest in numerous forms when applying QALY to patients under Medicaid.

The QALY's preference for treatments that restore patients to a 100 percent quality of life will disparately impact patients with disabilities who will find treatments that do not meet this threshold, but may nonetheless be extremely valued by patients with disabilities, as rated lower than treatments for non-disabled patients.

ii. The Mental Health Parity and Addiction Equity Act ("MHPAEA") Requires Equal Treatment of Physical and Mental Disabilities

On September 5, 2019, the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury jointly issued the final rule on the Mental Health Parity and Addiction Equity Act ("MHPAEA"). The MHPAEA requires that financial requirements, including coinsurance and copays, and treatment limitations, such as visit limits, imposed on mental health or substance use disorder ("MH/SUD") benefits cannot be more restrictive than measures applied to substantially similar medical or surgical benefits. The MHPAEA narrows the permissible insurance coverage gap between treatments afforded to individuals with physical disabilities and those with mental disabilities. These requirements are applied across six classifications of benefits: (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs.

Further, restrictions under the MHPAEA also apply to non-quantitative treatment limitations ("NQTL"), which are non-numerical limits on the scope or duration of benefits for treatment. As per the MHPAEA, a plan or issuer may not impose an NQTL on MH/SUD benefits unless all factors used in applying the NQTL are comparable to those used in assessing medical or surgical benefits. Federal MHPAEA regulations contain a non-exhaustive list of NQTLs which include medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative (including standards for concurrent review); exclusions based on failure to complete a course of treatment; and restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

The MHPAEA has been substantially amended since its initial enactment as the Mental Health Parity Act in September 1996. The Patient Protection and

Affordable Care Act in 2010 allowed for application of the regulation to many health insurance plans that had previously been outside its scope. Notably, the Mental Health Parity Act has been expanded to cover substance use disorders. However, despite efforts to allow for equal access to treatments for mental and physical disabilities, processes that evaluate annual and lifetime dollar limits, financial requirements and treatment limitations for MH/SUD continue to fall short. MHPAEA does not apply directly to small group health plans, and the act applies only to large group health plans and health insurance issuers that opt-in to policies that include MH/SUD benefits.

Much like QALY evaluation standards, the MHPAEA also considers likelihood of improvement of a medical condition. For instance, in the context of residential treatment of MH/SUD, MHPAEA requires the likelihood that inpatient treatment will result in improvement, and policies under this act cover only services that result in measurable and substantial improvement in mental health status within 90 days. The MHPAEA also does not recognize certain experimental and investigative treatments that tend in practice to affect more adversely availability of treatments for MH/SUD. Autism Spectrum Disorder is categorized as a mental disability, and Applied Behavior Analysis (ABA) therapy has been professionally recognized as a method of treatment for children with the disorder. However, the NQTL is applied more stringently to MH/SUD, excluding these benefits under the MHPAEA. Although both the ADA and MHPAEA facially prohibit discrimination on the basis of disability, the standards used to assess financial requirements and treatment limitations oftentimes have a disparate impact on chronic life-shortening and mental disabilities. Misapplication of the ADA and MHPAEA, and discrimination against certain individuals with disabilities may lead to even more severe consequences, particularly in the case of mental disabilities.

iii. QALY Creates a Risk of Institutionalization of Mentally Disabled Persons Which is Prohibited by the ADA through the Integration Mandate

The Attorney General, in issuing regulations implementing Title II of the ADA as directed by Congress, created the integration mandate. *See* 28 C.F.R. § 35.130(d). The integration mandate states that:

"A public entity shall administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities."

Id. The integration mandate reflects the need for heightened protection in preventing discrimination against mentally disabled persons in the form of segregation from others in receiving relevant treatment opportunities. Although the integration mandate is significant for all individuals with disabilities, it may simply be more difficult to fully measure the effectiveness of a mental treatment on the quality-of-life of a person with such a disability, and thus, there must be further consideration for individuals with mental disabilities. Likewise, a QALY-based ADA violation may be found if the reduced availability of treatments increases the risk of certain mentally disabled people requiring institutionalization.

In particular, QALY's assignment of lower values for treatments of mental conditions may deny mentally ill persons Medicaid coverage and thereby render effective treatments unaffordable to them. As a result, their conditions may worsen, requiring them to reside in a specialized mental institution or otherwise be isolated from the community. The standard for a mentally disabled person's full quality-of-life may be especially difficult to measure or for them to achieve. If QALY's ratings result in greater Medicaid-funded availability of treatments for physical injuries, diseases, or disabilities, it could be seen to permit lesser medical benefits to mentally disabled persons, because of their disability. This is precisely the type of discrimination the ADA prohibits. The administration of a service or program furnished by a public entity in a manner that increases the risk of institutionalization for mentally disabled persons violates the ADA. In one of the most influential cases interpreting the ADA, the Supreme Court found this to be a clear violation due to the disparate impact on mentally disabled persons. *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581 (1999). There is a significant likelihood that application of QALY would make treatments unavailable that would improve a mentally disabled person's condition, but not return them to an unattainable full quality of life. Without these treatments, some mentally disabled persons would be at a higher risk of being institutionalized.

Likewise, a public program or service that causes mentally disabled persons to receive care in a segregated institutionalized setting, while allowing the

physically disabled to receive services in a community setting, is itself a violation of the ADA. See *Davis v. Shah*, 821 F.3d 231, 260 (2d. Cir. 2016). However, undue institutionalization of the mentally disabled is discrimination under the ADA regardless of how everyone else is treated. *Amundson ex rel. Amundson v. Wisconsin Dept. of Health Servs.*, 721 F.3d 871, 874 (7th Cir. 2013), citing *Olmstead*, 527 U.S. at 597-603.

The reasoning underpinning the *Olmstead* decision has been expanded beyond just the institutionalization of mentally disabled persons. This presents a significant problem for the legality of QALY, compounded by the ADA's animating policy that empowers courts to construe its provisions broadly in order to effectuate its purpose. *Helen L.*, 46 F.3d at 331-33; *Soto v. City of Newark*, 72 F. Supp.2d 489, 493 (D.N.J. 1999); *Darian v. Univ. of Mass. Bos.*, 980 F. Supp. 77, 89 (D. Mass. 1997); *Niece v. Fitzner*, 922 F. Supp. 1208, 1217 (E.D. Mich. 1996); *Lincoln CERCPAC v. Health and Hosps. Corp.*, 920 F. Supp. 488, 497 (S.D.N.Y. 1996).

D. Adjusting QALY to Comply with the ADA Would Likely Undermine Its Cost-Saving Purpose

Unequal treatment *among* people with different disabilities is not per se discrimination under the ADA, so long as disabled individuals are not denied services provided to the able-bodied (or able-minded) on the basis of their disabilities. However, this unequal treatment is permissible only if a public entity administers a service or program to provide greater benefits to the disabled:

“Nothing in this part prohibits a public entity from providing benefits, services, or advantages to individuals with disabilities, or to a particular class of individuals with disabilities beyond those required by this part”

28 C.F.R. § 35.130. Any adjustment to the QALY methodology that distinguished among different types of disabilities would be scrutinized, likely being upheld only if it provides a greater benefit to a class of disabled persons. Hence, any cost-saving adjustment would likely be a violation in itself, if it was found to make any treatment less available or more expensive.

VI. Conclusion

A definitive determination of whether the QALY violates the ADA when applied to Medicaid patients cannot be obtained until it is implemented and challenged in court. There is nothing that can be done to prevent a lawsuit challenging QALY's compliance with the ADA, if it is incorporated into state Medicaid programs. A legal challenge on ADA grounds seems almost certain given the history of similar methodologies.

Nevertheless, it can be predicted with confidence that such use of QALY would violate the ADA on at least two separate, but related grounds. First, by decreasing the availability of effective treatments for disabled persons. Second, by increasing the risk of institutionalization of certain mentally disabled persons. Any cost-saving adjustment of QALY's methodology that makes certain treatments more expensive or less available would itself be a violation, even if done in an effort to comply with the ADA.

There are additional ADA grounds upon which QALY could be challenged that were not addressed. These include, but are not limited to: the participation rates of both physically and mentally disabled persons in the surveys imputed into QALY's valuations; the ability of mentally disabled persons to fully-comprehend and meaningfully participate in the surveys; and non-coverage of drugs that significantly improve the quality of life for individuals with conditions causing shortened life expectancy. These challenges may be brought by one qualified disabled individual that lost coverage for a treatment QALY deemed as "low value" or an entire class of similarly situated disabled persons.

In addition to ADA compliance issues, there is a possibility that QALY also does not comply with the Medicaid Act. A separate analysis would be necessary to predict QALY's threshold legality under the Medicaid Act.

Endnotes

- 1 Partnership to Improve Patient Care, *Measuring Value in Medicine: Uses and Misuses of the QALY* (2017)
- 2 Daniel M. Fox and Howard M. Leichter, *The Ups and Downs of Oregon's Rationing Plan*, project hope – the people-to-people health foundation, inc. (<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.12.2.66>)
- 3 Jonathan Oberlander, Theodore Marmor & Lawrence Jacobs, *Rationing Medical Care: Rhetoric and Reality in the Oregon Health Plan*, United States Nat'l Lib. of Med. Nat'l Inst. of Health (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC81116/>) (May 29, 2001)
- 4 Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury, *FAQs about Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39*. (<https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf>).
- 5 *The Mental Health Parity and Addiction Equity Act (MHPAEA)*, Centers for Medicare and Medicaid Services. (https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet.html).
- 6 Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury, *FAQs about Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39*. (<https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf>).
- 7 United States Dept. of Justice, Statement of the Dept. of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead v. L.C. ex rel. Zimring*, at Q.6 (last updated June 22, 2011); see also *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 599 (1999) (“[t]he ADA stepped up earlier measures to secure opportunities for people with developmental disabilities to enjoy the benefits of community living”) (Ginsburg, J.)
- 8 *Olmstead* was a plurality opinion, with Justice Ginsburg writing for the Court, Justice Stevens and Justice Kennedy both writing separately concurring in the judgment, and Justices Thomas, Rehnquist and Scalia filing a dissent. Following this decision, a number of federal circuit courts have applied *Olmstead's* recognition that an increased risk of institutionalization is unlawfully discriminatory under the ADA. *Davis v. Shah*, 821 F.3d 231 (2d. Cir. 2016); *Pashby v. Delia*, 709 F.3d 307 (4th Cir. 2013); *M.R. v. Dreyfus*, 697 F.3d 706 (9th Cir. 2012); *Radaszewski ex rel. Radaszewski v. Maram*, 383 F.3d 599 (7th Cir. 2004); *Fisher v. Oklahoma Health Care Auth.*, 335 F.3d 1175 (10th Cir. 2003).



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