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MEMORANDUM May 3, 2021

To: House Energy & Commerce Committee
[redacted]

From: [redacted]

Subject: **Use of QALYs for Domestic Drug Pricing and Potential Legal Issues Under the ADA and Rehabilitation Act**

This memorandum, provided on an expedited basis in response to your request, addresses the following questions:

- Could the use of Quality-Adjusted Life Years (QALYs) by the Department of Health & Human Services (HHS) and other federal agencies violate the American with Disabilities Act (ADA) or the Rehabilitation Act?
- If the U.S. government were to set prices for health care goods and services vital to the life and wellbeing of those with disabilities based on prices in countries that rely primarily or exclusively on QALYs to determine cost effectiveness, could this pricing mechanism violate the ADA or the Rehabilitation Act?

This memorandum begins with a background on QALYs and the relevant law pertaining to use of QALYs in certain federally funded health care programs, and it describes two examples of prior attempts to incorporate QALYs in federally funded health care programs. The memorandum then describes the relevant legal framework under the ADA and the Rehabilitation Act, before addressing the questions above. The limited case law on these issues suggests that whether the federal government's use of QALYs would violate the Rehabilitation Act or the ADA may depend on the specific manner of a QALY's use, including whether a disability-based QALY is used to make coverage or pricing decisions, whether its use results in harm to people with disabilities, and whether that harm is sufficiently direct.

Background

Quality-Adjusted Life Years (QALYs)

The QALY is a measure developed by health economists to measure and compare the value of health outcomes.[1] Based on the premise that health is a function of length and quality of life, the QALY was

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[1] *See* NAT'L COUNCIL ON DISABILITY, QUALITY-ADJUSTED LIFE YEARS AND THE DEVALUATION OF LIFE WITH DISABILITY 24

developed as an attempt to combine the value of these attributes into a single index number.[2] The QALY calculation assumes that certain health states (e.g., perfect health, represented by "1") are more desirable than others (e.g., death, represented by "0").[3] Researchers typically use preference surveys or questionnaires to measure how much patients may prefer one health state over another, and then assign a value to those different health states using a decimal number between 0 and 1.[4] The basic formula for calculating QALY multiplies that decimal number (representing a person's health-related quality of life, often called the "health utility") by a number representing a person's quantity of life, such as the number of years by which a particular medical treatment might extend life.[5]

Although the formula for calculating QALY is defined, there is no single standard method of determining health utility.[6] Researchers use several different survey instruments that are designed to assess how much patients value different health conditions or states.[7] Traditionally, QALY surveys typically measure the preferences of the general population.[8] Some researchers, however, advocate for measuring the preferences of patients with a particular disability or condition because members of the general public do not accurately understand the experience of life lived with disability and may systematically underestimate the value of disabled quality of life.[9] According to the National Council on Disability, the "overwhelming majority" of studies continue to use the preferences of members of the general population as the baseline for determining health utility.[10]

In the context of health care policies, QALYs are used in cost-utility analyses (CUAs) designed to compare various health care treatments to each other and determine whether the benefits of a treatment are worth its cost.[11] In a CUA, the number of QALYs gained from treatment is a measure of the overall benefit of the treatment.[12] QALY-based CUAs are used to inform various health care policies, such as decisions by insurers and government agencies regarding whether to provide coverage for certain drugs and treatments.[13] In England and Wales, for instance, the National Institute for Health and Care Excellence (NICE) undertakes a QALY-based CUA analysis to determine what drugs and treatments will be covered by the United Kingdom's National Health Service.[14] In addition to the CUAs, NICE uses other methodologies—such as the cost-consequences analysis—to determine whether certain

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(2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

[2] *See id.*

[3] P'SHIP TO IMPROVE PATIENT CARE, MEASURING VALUE IN MEDICINE: USES AND MISUSES OF THE QALY 7 (2017), http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_white_paper_-_measuring_value_in_medicine_-_uses_and_misuses_of_the_qaly.pdf. [hereinafter PIPC].

[4] *See* NAT'L COUNCIL ON DISABILITY, *supra* note 1, at 24.

[5] *See id.*

[6] *Id.* at 25.

[7] Commonly used survey instruments include the Euro-QOL 5-item scale (EQ-5D), 7-item Health Utilities Index 2 scale, and 6-item SF-6D scale. PIPC, *supra* note 3, at 8.

[8] NAT'L COUNCIL ON DISABILITY, *supra* note 1, at 29.

[9] *Id.*

[10] *Id.*

[11] *Id.* at 25.

[12] *See id.*

[13] *See id.*

[14] *See* NAT'L INST. FOR HEALTH & CARE EXCELLENCE (NICE), *How NICE Measures Value for Money in Relation to Public Health Interventions* (Sept. 1, 2013), https://www.nice.org.uk/Media/Default/guidance/LGB10-Briefing-20150126.pdf; George Gillett, *NHS Drugs, Aristotle and Health Economics: the Problem of Quantifying the Value of Life*, NEWSTATESMAN (Aug. 18, 2014), https://www.newstatesman.com/health/2014/08/nhs-drugs-aristotle-and-health-economics-problem-quantifying-value-life.

interventions, even though they might be costly and could reduce the health gain achieved in the population as a whole, should nevertheless be covered for specific disadvantaged groups to address, for instance, health inequalities.[15]

Relevant Federal Health Care Programs

In the United States, HHS administers several federally funded health care programs that directly or indirectly provide health care coverage for specified populations. Below is a brief summary of two key health programs and existing law pertaining to the use of QALYs vis-à-vis these programs.

Medicare

Medicare is a health program for persons age 65 and older, as well as certain other qualified beneficiaries.[16] The program largely consists of four main parts: A, B, C, and D.[17] Medicare Part A primarily covers inpatient hospital and post-acute care services, and Medicare Part B mainly covers physicians' and other outpatient items and services.[18] Part C (Medicare Advantage or MA) establishes a private plan option for providing Part A and B benefits (except hospice), and Medicare Part D provides federally subsidized outpatient prescription drug coverage to Medicare beneficiaries who choose to enroll in this benefit.[19] All parts of the Medicare statute are codified within the Social Security Act (SSA).[20]

The Affordable Care Act (ACA) created a nonprofit organization, the Patient-Centered Outcomes Research Institute (PCORI), to support comparative clinical effectiveness research (CER), which refers to a field of research that compares the effectiveness of two or more interventions or approaches to health care, examining their risks and benefits.[21] In contrast to CUA—which, as discussed above, quantifies the economics associated with treatment comparisons taking into account the cost of an intervention with its benefits—CER typically focuses on clinical or patient-centric issues.[22] The ACA specifically prohibits PCORI from developing a dollars-per-QALY "or similar measure that discounts the value of a life because of an individual's disability" as a threshold to establish what type of health care is cost effective or recommended.[23] The law further prohibits the HHS Secretary from using QALY or similar measures as a threshold to determine coverage, reimbursement, or incentive programs in Medicare.[24]

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[15] *See* NICE, *supra* note 14.

[16] 42 U.S.C. §§ 1395–1395*lll*. The HHS Secretary has delegated authority to administer the Medicare program to the Centers for Medicare & Medicaid Services (CMS). *See* 66 Fed. Reg. 35,437 (July 5, 2001) (transferring functions of the Health Care Financing Administration (HCFA) to CMS); 42 Fed. Reg. 13,262 (Mar. 9, 1977) (delegating responsibility for the administration of Medicare to HCFA).

[17] For discussion of the Medicare program and how its different parts (A, B, C and D) provide covered benefits, see CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis. Medicare also contains a fifth part, Part E, which contains miscellaneous provisions. 42 U.S.C. §§ 1395x–1395*lll*.

[18] *See* 42 U.S.C. §§ 1395c–1395i-5 (Medicare Part A); *id*. §§ 1395j–1395w-6 (Medicare Part B).

[19] *See id.* §§ 1395w-21–1395w-29 (Medicare Part C); *id.* §§ 1395w-101–1395w-154 (Medicare Part D). Discussion of Medicare Part D is beyond the scope of this memorandum.

[20] *Id.* §§ 1301–1397mm.

[21] PATIENT-CENTERED OUTCOMES RSCH. INST., *Research We Support* (Mar. 22, 2021), https://www.pcori.org/research-results/about-our-research/research-we-support.

[22] *See id.*

[23] 42 U.S.C. § 1320e-1(e).

[24] *Id.*

Medicaid

The Medicaid program is a collaborative effort between the federal government and states to provide medical assistance to a diverse group of low-income and medically needy individuals.[25] To participate in the Medicaid program and receive federal funding, a state must have a plan for medical assistance approved by the HHS Secretary; this plan must comply with a wide array of federal standards.[26] Among these standards, states must cover specified groups of individuals and provide particular types of health benefits to these groups.[27] The program also allows states to opt to cover certain additional populations and/or benefits, subject to federal conditions.[28] Failure to meet these federal requirements places federal Medicaid funds received by the state in jeopardy of being withheld.[29] At the same time, however, SSA Section 1115 authorizes the HHS Secretary to approve experimental, pilot, or demonstration projects that the Secretary finds likely to promote the Medicaid program's objectives.[30] Over the past few decades, the Secretary has approved a broad range of Section 1115 demonstrations, which give the states additional flexibility to design and improve their programs and test potential innovations in the provision of Medicaid coverage.[31]

No existing Medicaid provisions specifically address QALYs. However, federal regulations generally prohibit state Medicaid agencies from arbitrarily denying or reducing the amount, duration, or scope of a required Medicaid service to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.[32]

Past QALY-Related Proposals in Federally Funded Health Care Programs

There are at least two prior proposals that sought to incorporate some degree of QALY-based analysis, either directly or indirectly, into federally funded health care programs. In the first example, the state of Oregon sought to use QALYs to determine what treatments to cover in its Medicaid program. In the second example, a federal legislative proposal would direct the HHS Secretary to negotiate the prices of certain selected drugs and to consider for negotiation the prices of those drugs in certain specified countries, some of which may use QALYs to some degree in setting prices.

Oregon's Proposed Medicaid Demonstration

In the early 1990s, Oregon unsuccessfully sought a Section 1115 waiver from HHS to utilize QALYs in its Medicaid program to make coverage decisions. In 1989, the Oregon legislature passed a bill that sought to expand Medicaid eligibility to include all residents below the federal poverty line.[33] The bill

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[25] For an overview of the Medicaid program, see CRS IF10322, *Medicaid Primer*, by Alison Mitchell.

[26] *See* 42 U.S.C. § 1396a. *See also* Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650 (2003) (noting that a state Medicaid plan must be approved by the HHS Secretary).

[27] *See* 42 U.S.C. § 1396a.

[28] *See generally* MEDICAID & CHIP PAYMENT & ACCESS COMM'N, FEDERAL REQUIREMENTS AND STATE OPTIONS: HOW STATES EXERCISE FLEXIBILITY UNDER A MEDICAID STATE PLAN, https://www.macpac.gov/publication/federal-requirements-and-state-options/.

[29] *See* 42 U.S.C. § 1396c.

[30] *See id.* § 1315(a).

[31] *See* MEDICAID.GOV, *State Waivers List*, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html (last visited Apr. 28, 2021).

[32] 42 C.F.R. § 440.230(c).

[33] *See ADA Analysis of the Oregon Health Care Plan*, 9 ISSUES L. & MED. 397, 397 (1994) [hereinafter *ADA Analyses*]; Philip G. Peters, Jr., *Health Care Rationing and Disability Rights*, 70 IND. L.J. 491, 502 (1995).

sought to reduce the cost of this expansion by limiting the services Medicaid would cover.[34] To determine the scope of coverage, the bill created the Oregon Health Services Commission and directed the Commission to prioritize individual health services "from the most important to the least important."[35]

The Commission ranked the services by first dividing all treatments into 1 of 17 different categories and then ranked these categories, taking into account cost-effectiveness as one of many factors used to create and rank the categories.[36] The Commission then used QALYs to rank treatments within the 17 categories. The relevant health utility was measured using a random telephone poll of 1001 Oregon households in which respondents were asked to rank 23 symptoms and 6 levels of functional impairment.[37] Based on the poll results, the Commission assigned a value to various health states, such as requiring a wheelchair or having severe burns.[38] The Commissioners also reviewed the resulting list and adjusted some of the rankings using their "professional judgments and their interpretation of the community values."[39] The process resulted in a ranking of 709 treatments of which the legislature determined it could cover the first 587 treatments.[40] Because the prioritized benefits package would have excluded certain procedures, it would deny some required Medicaid services to individuals with particular conditions, potentially in violation of existing federal requirements.[41]

In August 1991, Oregon filed an application for a Section 1115 waiver, seeking HHS approval of its plan. On August 3, 1992, HHS denied Oregon's request for a waiver, concluding that the manner in which the rankings were determined indicated they were based "in substantial part on the premise that the value of the life of a person with disability is less than the value of the life of a person without a disability," a premise the Agency concluded is inconsistent with the ADA.[42] Specifically, HHS took issue with three aspects of the rankings. First, the telephone survey could not serve as a starting point for the rankings given the survey "quantifies stereotypic assumptions about persons with disabilities."[43] Second, the rankings should not have considered certain "community values"—including "quality of life" and "ability to function"—which place importance on "restored" health and functional "independence," and thus expressly value a person without a disability more highly than a person with a disability.[44] Finally, with regard to specific exclusions, the rankings should not have precluded coverage for liver transplants for alcoholic cirrhosis and life support for extremely low birth weight babies under 23 weeks' gestation when other liver transplants and life support for low birth weight babies would be covered.[45]

On November 13, 1992, Oregon submitted a revised plan that no longer incorporated quality of life data from the telephone surveys. Under the revised methodology, the services were ordered first on their ability to prevent death. Services considered equal in that regard were then ordered according to their ability to "return the patient to an asymptomatic state of health after saving the life." Services that were equal after those two factors were further ordered on the treatment's ability to take the patient from a

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[34] *See ADA Analyses*, *supra* note 33, at 397.

[35] *Id.*

[36] Peters, *supra* note 33, at 502–53.

[37] *Id.* at 503 n.51.

[38] *Id.*

[39] *Id.* at 503.

[40] *Id.* at 503 & n.54.

[41] *See supra* 32 and accompanying text.

[42] Letter from Louis W. Sullivan to Barbara Roberts, Governor of Oregon, *reprinted in ADA Analyses*, *supra* note 33, at 410.

[43] *Id.*

[44] *Id.* at 411.

[45] *Id.* at 411–12.

symptomatic to an asymptomatic state of health.[46] Thus, the revised plan would downrank treatments that left individuals in a "symptomatic" state. In a January 19, 1993 letter, the Department of Justice's Office of Legal Counsel (OLC) advised HHS that the use of such "tie breakers" raised serious concerns under the ADA, given that "symptoms" as defined under the revised plan was, in many cases, equivalent to disability. Thus, a discrimination in favor of "asymptomatic" individuals incorporated a bias against individuals with disability.[47]

On March 19, 1993, HHS approved the revised plan but required Oregon to re-rank the priority list again without taking into account "whether treatment returned an individual to an asymptomatic state."[48] The Oregon Commission eventually approved a new list that was based first on mortality and then, as a tie-breaker, on cost considerations. The Commission then adjusted the list to reflect community values, such as a preference for preventive services and medically effective care.[49] The plan took effect on February 1, 1994.[50]

The Lower Drug Costs Now Act of 2019

The Lower Drug Costs Now Act of 2019, which passed the House in December 2019 and was not taken up by the Senate, would have created a "Fair Price Negotiation Program" under which the HHS Secretary would negotiate, on behalf of Medicare and participating commercial health plans, the prices of certain selected drugs.[51] In negotiating the prices, the Secretary would have been directed to consider a series of factors, including certain manufacturer specific information (such as the drug's research and development and the drug's market data), information about alternative products (including information about the drug's comparative effectiveness and the costs of therapeutic alternatives), and the drugs' Average International Market (AIM) price.[52] A drug's AIM is the average price from six specified countries (Australia, Canada, France, Germany, Japan, and the United Kingdom).[53] The bill would have also placed a cap on negotiated prices; any negotiated price could not exceed 120% of the drug's AIM price for the relevant period.[54] Accordingly, to the extent AIM price indexed countries rely on a QALY-based analysis to determine prices, at least to some degree,[55] the program would indirectly utilize some degree of QALY in the negotiation process.

Analysis

Federal law prohibits discrimination in government services based on disability. Accordingly, it seems likely that determining the scope of covered benefits based on QALYs—at least those systems which, as is common, rely on impairments to quantify value—could potentially violate antidiscrimination laws. There is limited case law on these issues. Available precedent shows that whether government use of QALYs violates the Rehabilitation Act or the ADA would depend on (1) whether the QALYs take disability into account (i.e., whether some QALY factors are disability neutral); (2) whether they are used to make decisions that negatively affect people with disabilities (i.e., whether the use of some QALY may

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[46] *Id.* at 421.

[47] *Id.* at 421–22.

[48] *Id.* at 423.

[49] Peters, *supra* note 33, at 504.

[50] *See id.*

[51] *See* H.R. 3, § 101(a), 116th Cong. (2019) (creating SSA §§ 1191(c)(1), 1194, 1197).

[52] *See id.* § 101(a) (creating SSA §§ 1194(b)(1), 1194(d)).

[53] *See id.*

[54] *See id.* (creating SSA § 1194(c)).

[55] *See supra* notes 14–15 and accompanying text.

not reduce benefits); and (3) whether those negative effects are sufficiently direct (i.e., whether disability laws reach harms that are causally connected to discriminatory acts).

This memorandum applies these considerations to the potential use of QALYs in (1) determining the scope of covered benefits and (2) setting the price of covered drugs. It describes some of the ways QALYs may improperly take disability into account. Analysis of Oregon's system illustrates how a substantially similar system would likely fare under relevant law in its use of disability. Whether a QALY system ultimately imposes negative effects and denies benefits, however, likely depends on a system's specific parameters—a full analysis would require more information about the system's function. Causation, or considering whether discrimination qualifies as a proximate cause of harm, may also come into play. This element, however, may be more relevant in analyzing whether the use of a QALY-based approach to set drug pricing than would be the case for a QALY care-allocation system if (as was the case with Oregon's proposed Medicaid demonstration) the care-allocation system closely affects access to certain benefits.

The Rehabilitation Act and the Americans with Disabilities Act

Two federal statutes, the Rehabilitation Act of 1973, 29 U.S.C. § 794, and the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. § 12132, bar government service providers from discriminating against people with disabilities. The Rehabilitation Act governs federal funding recipients and federal programs, including Medicare and Medicaid.[56] The ADA reaches private and state actors,[57] Federally funded medical programs or providers may fall under one or both statutes; a federal funding recipient, covered by the Rehabilitation Act, may also be a state public service provider (under ADA's Title II) or a public accommodation (under ADA's Title III).[58] In the ADA, Congress recognized that people with disabilities face persistent discrimination in, among other areas, "health services."[59]

The statutes largely overlap and courts routinely rely on precedent construing one when applying the other[60]—the principal meaningful difference is in their causation standards.[61] In prohibiting discrimination, the Rehabilitation Act provides that "[n]o otherwise qualified individual with a disability . . . shall, *solely* by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency."[62] The ADA, in turn, prohibits disabled individuals from being "excluded from participation or be denied the benefits" of a public entity service or program "*by reason* of such disability."[63] While the Rehabilitation Act requires that disability be the sole cause of the discrimination, caselaw interpreting the ADA recognizes that disability need not be the sole factor behind the discriminatory decision.[64]

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[56] 29 U.S.C. § 794; Alexander v. Choate, 469 U.S. 287, 290 (1985) (applying the Rehabilitation Act, prior to the enactment of the ADA, to Tennessee's Medicaid program). *See also* U.S. DEP'T OF JUSTICE, *A Guide to Disability Rights Laws*, https://www.ada.gov/cguide.htm#anchor65610.

[57] 42 U.S.C. § 12131.

[58] 29 U.S.C. § 794; 42 U.S.C. §§ 12132, 12182.

[59] 42 U.S.C. § 12101(a)(3).

[60] Henrietta D. v. Bloomberg, 331 F.3d 261, 272 (2d Cir. 2003) ("[T]he standards adopted by Title II of the ADA for State and local government services are generally the same as those required under section 504 [of the Rehabilitation Act for] federally assisted programs and activities." (internal quotation marks omitted)).

[61] Bennett-Nelson v. La. Bd. of Regents, 431 F.3d 448, 454 (5th Cir. 2005) ("[T]he rights and remedies afforded plaintiffs under Title II of the ADA are almost entirely duplicative of those provided under § 504 of the Rehabilitation Act" and the "only material difference between the two provisions lies in their respective causation requirements.").

[62] 29 U.S.C. § 794 (emphasis added).

[63] 42 U.S.C. § 12132 (emphasis added).

[64] Halpern v. Wake Forest Univ. Health Scis., 669 F.3d 454, 461-62 (4th Cir. 2012)("To succeed on a claim under the

Thus, to prove that a public program violates these statutes, plaintiffs generally must establish the following elements: (1) that they are qualified individuals with a disability; (2) they were excluded from the benefits or services of a relevant public program, or otherwise were discriminated against by the public program; and (3) such exclusion or denial or benefits was caused by their disability.[65]

On the first element, the ADA and Rehabilitation Act define disability as "a physical or mental impairment that substantially limits one or more of the major life activities," a "record of such an impairment," or "being regarded as having such an impairment."[66] In 2008, Congress amended the definition applicable to both the Rehabilitation Act and the ADA to expand impairments that qualify as a disability.[67] Temporary conditions, for example, now more easily qualify as a disability under the statutes.[68]

As to the second element, there are generally two theories of discrimination relevant in this context: (1) intentional discrimination and (2) disparate impact. Intentional discrimination is singling out persons with disabilities for lesser treatment. It can include acting on "stereotypic assumptions not truly indicative of the individual ability of such individuals to participate in, and contribute to, society."[69] Disability laws also reach some claims that government action, while not intentionally singling out people with disabilities, has an unjustified disparate impact.[70] In the context of the Rehabilitation Act, the Supreme Court has observed that the law serves "two powerful but countervailing considerations": to address discrimination against people with disabilities that often results from "apathetic attitudes rather than affirmative animus" while keeping the protection process from becoming "a wholly unwieldy administrative and adjudicative burden."[71] Thus, the Court has stated that the law's protections reach beyond intentional discrimination, but do not necessarily "embrace all claims of disparate-impact discrimination," though the Court has not demarcated the law's specific parameters.[72]

In *Alexander v. Choate*, the Supreme Court held that, in the context of a state Medicaid program, the Rehabilitation Act requires the state program to provide "meaningful access to the benefit that the [program] offers," i.e., its Medicaid services, but does not require the program to guarantee that each recipient will receive the level of care precisely tailored to their needs.[73] Accordingly, the Court concluded a state rule that reduced from 20 to 14 the number of inpatient hospital days the state program would pay hospitals did not deny handicapped individuals "meaningful access" to the program's services even though handicapped individuals may have "greater need for prolonged inpatient care."[74]

Rehabilitation Act, the plaintiff must establish he was excluded 'solely by reason of' his disability; the ADA requires only that the disability was 'a motivating cause' of the exclusion."); Baird ex rel. Baird v. Rose, 192 F.3d 462, 470 (4th Cir. 1999) (concluding that while an ADA plaintiff may prevail by showing "disability played a motivating role," "[d]amages may not be awarded . . . if the defendant would have taken the same action in the absence of the impermissible motivating factor")(internal quotation marks omitted).

[65] Shotz v. Cates, 256 F.3d 1077, 1079 (11th Cir. 2001). Disability law aims to remedy both "outright intentional exclusion" and "relegation to lesser services." 42 U.S.C. § 12101(a)(5).

[66] 42 U.S.C. § 12102; 29 U.S.C. §§ 794, 705(20) (cross-referencing ADA's disability definition); 28 C.F.R. § 35.104.

[67] ADA Amendments Act of 2008, Pub. L. No. 110-325, § 4(a) (Sept. 25, 2008).

[68] Summers v. Altarum Inst., Corp., 740 F.3d 325, 331 (4th Cir. 2014).

[69] Tennessee v. Lane, 541 U.S. 509, 516 (2004) (quoting findings in a prior version of the ADA).

[70] While programs do not have to ensure that people with disabilities obtain the same results as others, they "must afford" people with disabilities "equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement." 45 C.F.R. § 84.4(b)(2) (emphasis added).

[71] Alexander v. Choate, 469 U.S. 287, 295–99 (1985).

[72] *See id.* at 299.

[73] *Id.* at 301–02.

[74] *See id.* The antidiscrimination rule, as applied to government health care providers, does not impose "a 'standard of care' for

Rehabilitation Act regulations bar covered entities from "directly or through contractual or other arrangements," using "criteria or methods of administration . . . that have the effect of subjecting qualified [people with disabilities] to discrimination" or "have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to . . . persons [with disabilities]."[75]

At the same time, under discrimination laws, covered entities may rely on administrative criteria *unrelated* to disability.[76] Furthermore, covered entities need not provide services to anyone, disabled or not, who fails to meet "the essential eligibility requirements for the receipt of such services."[77]

Lastly, a disability discrimination claimant under either the ADA or Rehabilitation Act must show that the discrimination at issue caused an alleged harm. That is, disability laws, like tort laws, reach only those harms that are causally connected to discriminatory acts.[78] The harm a plaintiff alleges must have "a sufficiently close connection to the conduct the statute prohibits."[79] This "requires some direct relation between the injury asserted and the injurious conduct alleged."[80] The more links in a causal chain between a discriminatory act and a plaintiff's harm, the more difficult it becomes to show causation.[81] As noted above, the Rehabilitation Act may impose a higher causation standard—reaching only harm attributable "solely" to one's disability—than the ADA.

(1) Use of QALY Metrics to Make Health Coverage Decisions

Federal entities' use of QALY to determine scope of covered benefits would likely raise the most concerns under the ADA and Rehabilitation Act (as compared to drug pricing determinations). Two aspects of QALYs may support intentional discrimination or disparate impact claims, assuming the use of QALY results in coverage decisions that affect disabled individuals by denying them access to benefits or providing lesser benefits than those to which they would otherwise be entitled. First, it could be argued that a system's use of symptoms or impairments could improperly allocate services based on disability. Second, it could be alleged that a system's use of subjective quality-of-life valuations may improperly categorize people with disabilities based on generalized assumptions, contravening disability laws' ultimate aim that governments not rely on stereotypes about disability.

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whatever medical services they render," but it does enact a "nondiscrimination requirement with regard to the services they in fact provide." Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581, 60 n.14 (1999); *see also* Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 641 (1986).

[75] 45 C.F.R. § 84.4(b)(4).

[76] *Bowen*, 476 U.S. at 630 (holding that denying health care to infants with severe impairments is permissible when based on parents' failure to consent, regardless of whether parents' motives include a child's disability status).

[77] 45 C.F.R. § 84.3(l)(4); *see also* 42 U.S.C. § 12131(2). In the context of health care, the Supreme Court has held that this requirement would allow states to deny community placement to patients with mental disabilities if they are "unable to handle or benefit from community settings" outside of an institution. *Olmstead*, 527 U.S. at 601-02. And, in applying the Rehabilitation Act to a recipient of Medicare funds, the D.C. Circuit has concluded that a hospital could discharge a child with disabilities when it concluded he was "no longer medically appropriate for hospitalization." Lunceford v. D.C. Bd. of Educ., 745 F.2d 1577, 1580 (D.C. Cir. 1984).

[78] *See* Bank of Am. Corp. v. City of Miami, Fla., 137 S. Ct. 1296, 1305 (2017) (stating discrimination under the Fair Housing Act is "akin to a 'tort action'" in assessing causation); Univ. of Texas Sw. Med. Ctr. v. Nassar, 570 U.S. 338, 346 (2013) (applying tort causation standards to employment discrimination claim); Siefken v. Vill. of Arlington Heights, 65 F.3d 664, 666 (7th Cir. 1995) (denying ADA and Rehabilitation Act claims where disability was not the "immediate cause" for plaintiff's job loss).

[79] Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 139 (2014).

[80] Bank of Am. Corp., 137 S. Ct. at1306 (assessing proximate cause under the Fair Housing Act).

[81] *Lexmark Int'l, Inc.*, 572 U.S. at 139.

Reliance on Symptoms or Impairments

Because federal law defines disability as an "impairment that substantially limits one or more of the major life activities," a QALY-based system that relies on symptoms or functional limitations to allocate services or benefits could be deemed to amount to intentional discrimination, contradicting the ADA and Rehabilitation Acts' mandate that the government not act "on the basis of" disability.[82] QALY metrics commonly consider characteristics such as mobility, self-care, mood, and activity level.[83] These characteristics closely align with the law's definition of "major life activities," including functions like "caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, . . . learning, . . . communicating, and working."[84] As if to underscore that medical symptoms qualify as disabilities, the law also provides that "operation of a major bodily function" is a life activity.[85]

Oregon's initial QALY-based system provides an example of how such a system could violate discrimination laws. Specifically, the use of QALY resulted in a separate classification for alcoholic cirrhosis of the liver, as opposed to cirrhosis not caused by alcoholism, and the program would only cover the treatment of the latter but not the former condition.[86] Because disability law generally forbids reliance on impairment for denial of services, it precludes using a preexisting condition to allocate health care. Thus, Oregon's classification—by denying coverage for alcoholic cirrhosis but not other forms of cirrhosis—denied access to benefits to those with a preexisting condition or impairment, i.e., alcoholism. Conceivably as well, such a QALY-based system could also impermissibly result in the coverage of open-heart surgery for ambulatory patients while denying it to a wheelchair user, since the added years of life in a wheelchair would be valued less than added years of life with full mobility.

Disability laws would similarly disallow consideration of a treatment's degree of cure, to some extent. For instance, an ambulatory heart patient who will recover fully cannot be prioritized over one who will gain life years but will, after surgery, require a wheelchair.[87] Denial of surgery based on a less satisfactory outcome would not provide a person with a disability "equal *opportunity* to obtain the same result, to gain the same benefit."[88] A particularly problematic aspect of Oregon's revised plan in relation to federal disability law was the plan's reliance, as OLC recognized, on the "existence or nonexistence of post-treatment symptoms" in ranking the value of care.[89] This is because a symptom or impairment (which included, in the Oregon plan, such circumstances as relying on a wheelchair or learning difficulties) is a disability—the very characteristic the law bars the government from using when it allocates services.[90]

Insofar as a QALY-based scheme relies on an impairment to determine the scope benefits, and the reduced benefits negatively harms individuals with disability, OLC's Oregon analysis would likely apply. The more inclusive, current statutory definition of "major life activities" would include a greater array of

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[82] 45 C.F.R. § 84.4(a); *see also* 29 U.S.C. § 794, 705(20); 28 C.F.R. § 35.104.

[83] NAT'L COUNCIL ON DISABILITY, *supra* note 1, at 26.

[84] 42 U.S.C. § 12102(2)(A).

[85] *Id.* § 12102(2)(B). The statute lists some of those functions as "functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions."

[86] *ADA Analyses*, *supra* note 33, at 504.

[87] *Id.* at 404.

[88] 45 C.F.R. § 84.4(b)(2) (emphasis added).

[89] Letter from Timothy B. Flanagan, Assistant Attorney General, Office of Legal Counsel, to Susan K. Zagame, Acting General Counsel, Dep't of Health & Human Srvs. (Jan. 19, 1993), *reprinted in ADA Analyses*, *supra* note 33, at 421 [hereinafter AAG Flanagan Letter].

[90] *Id.*

symptoms or impairments as disabilities than analyzed by OLC, meaning that a QALY system would be more difficult to defend now than it would have been before the 2008 ADA amendments.[91]

That said, it is likely that a QALY-based system could deny services if a health condition, including a disability, renders a particular service medically inadvisable.[92] In that case, individuals are not likely "otherwise qualified" service recipients."[93]

Use of Generalizations and Stereotypes

A QALY system, if it uses symptoms of impairments to allocate care, may also violate disability law in its use of generalizations or stereotypes about disability. The Supreme Court and governing statutes describe disability law as aiming, among other things, to combat "prejudice,"[94] "unwarranted assumptions,"[95] and "society's accumulated myths and fears about disability and disease."[96] Federal law mandates individualized assessment of persons with disabilities. In applying the Rehabilitation Act to public school employment, for example, the Supreme Court disallowed generalizations about tuberculosis contagion, ordering an inquiry on remand into whether a fired teacher was, in fact, contagious and whether the school could make appropriate accommodations.[97]

The use of QALYs to determine the scope of covered benefits arguably could contravene this purpose and impose intentional discrimination. Use of patient surveys, community surveys, polls of health care workers, and other subjective metrics of "quality of life" require assumptions about disabilities.[98]

Generalizations and qualitative assessments of QALY systems could be seen as incorporating the discriminatory animus of others. As the Supreme Court has noted, the Rehabilitation Act's "basic purpose" is to ensure people with disabilities are not denied benefits because of the "prejudiced attitudes or the ignorance of others."[99] Oregon's plan illustrates how some QALY systems might do this. OLC characterized Oregon's initial plan's telephone survey as having "merely quantified such stereotypical assumptions," resulting in the exclusion from coverage two treatments that affect individuals with disability.[100] Even with respect to Oregon's revised plan, which continued to employ certain "community values" in determining covered benefits, OLC observed that the state concluded "'that 'infertility services are not highly valued by Oregonians'; accordingly, these services were ranked near the bottom of the list'" of services for reimbursement. The state relied on "an intentional devaluation of treatment on account of disability," the disability of infertility.[101]

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[91] ADA Amendments Act of 2008, Pub. L. No. 110-325, § 4(a) (Sept. 25, 2008). The amendments also apply to the Rehabilitation Act. 29 U.S.C. §§ 794, 705(20).

[92] *Olmstead*, 527 U.S. at 601-02 (holding state mental health system need not deinstitutionalize patients who cannot function in a community setting); Lunceford v. D.C. Bd. of Educ., 745 F.2d 1577, 1580 (D.C. Cir. 1984) (denial of care appropriate where "no longer medically appropriate").

[93] 29 U.S.C. § 794; 45 C.F.R. § 84.3(l)(4) (noting beneficiaries must meet "the essential eligibility requirements for the receipt of such services").

[94] 42 U.S.C. § 12101(a)(8).

[95] *Zimring*, 527 U.S. at 600.

[96] Sch. Bd. of Nassau Cty., Fla. v. Arline, 480 U.S. 273, 284 (1987).

[97] *Id.* at 285, 287–88.

[98] NAT'L COUNCIL ON DISABILITY, *supra* note 1, at 26 (discussing use of surveys and quoting bioethicist Joseph Stromondo as stating that "while there is a relationship between disability and quality of life, it is extremely variable, and impossible to generalize").

[99] *Arline*, 480 U.S. at 284.

[100] AAG Flanagan Letter, *supra* note 87, at 419; *see also supra* note 45 and accompanying text.

[101] *Id.* at 422. Quality-of-life metrics are problematic even if based on extensive polling that accurately reflects widespread

(2) Use of QALY Metrics to Set Drug Prices

You also asked whether incorporating pricing models from other countries that rely on QALY schemes might violate federal antidiscrimination laws. In general, disability law would not require governments to equalize the prices of different drugs based on their use by people with disabilities. The Supreme Court has concluded that governments need not change Medicaid benefits to "meet the reality that the handicapped have greater medical needs."[102] Nor must the state "view certain illnesses, *i.e.*, those particularly affecting [people with disabilities], as more important than others and more worthy of cure through government subsidization."[103]

To the extent a QALY is used not to make coverage decisions, but to set drug prices paid by the federal government, it may raise fewer ADA and Rehabilitation Act concerns for at least two reasons. First, depending on how a QALY would be used to set prices, use of a QALY may or may not result in any negative effects on disabled individuals that would amount to discrimination. To the extent a QALY-based system is used to set prices for a select number of drugs and does not affect coverage of drugs, it would not change benefits offered by the public program. This is especially true if the drug setting scheme is intended to *lower* drug prices and pass through the discount to the beneficiaries in a neutral manner.

The analysis, however, may be different if the program in fact results in a negative impact on disabled beneficiaries. In the course of preparing this expedited memorandum, we have not found case law directly addressing drug pricing or similar circumstance under the Rehabilitation Act. The Supreme Court has stated, however, that governments need to provide "evenhanded treatment" in offering health care and "the opportunity . . . to participate in benefit from programs" even if they need not provide "equal results."[104] As the forgoing discussion explains, using QALY systems that rely on disability status to allocate services raises concerns about whether decisions would be judged "evenhanded treatment" or would constitute intentional discrimination. Although the law is less certain on this point, pricing drugs based at least in part on disability could qualify as discrimination.[105]

Although it is difficult to predict how courts would assess the matter, it could be argued that differential and higher pricing, if passed on to recipients, contravenes Rehabilitation Act regulations. Such regulations bar programs from giving people with disabilities an "aid, benefit, or service that is not equal to that afforded others" and is "not as effective as that provided to others."[106] Regulations also prohibit "direct[]" or "contractual arrangements" using "criteria or methods of administration . . . that have the effect of subjecting qualified [people with disabilities] to discrimination" or "have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to . . . persons [with disabilities]."[107] In the context of ADA accommodations, the law bars any "surcharge" for disabled people, even if disability accommodations impose costs on the provider.[108]

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professional judgment or social values. As one evaluator of Oregon's plan concluded: "A thousand arbitrary responses do not constitute a rational basis for rating the value or disvalue of life in a nursing home, wheelchair, or coma." *ADA Analyses*, *supra* note 33, at 404.

[102] Alexander v. Choate, 469 U.S. 287, 303 (1985).

[103] *Id.* at 303–04.

[104] *Id.* at 304.

[105] This assumes that pricing affects people with disabilities—that they pay a higher price because of disability. If the pricing scheme does not impact drug consumers in terms of pricing or availability, it likely would not violate disability law.

[106] 45 C.F.R. § 84.4(b).

[107] *Id.* § 84.4(b)(4).

[108] Dare v. California, 191 F.3d 1167, 1171 (9th Cir. 1999) (construing ADA and applicable regulations). The Ninth Circuit concluded that the statutory language barred a charge for disability parking placards, stating that "surcharges against disabled

As the regulations acknowledge, the government's *reasons* or "purpose" for price adoption affects the analysis. Absent discriminatory intent, federal disability law does not require that governments adjust neutral rules to afford people with disabilities equal results.[109] Drugs that happen to be higher-priced are not necessarily discriminatory, but intentional use of disability to adjust pricing likely would be.

Second, depending on the specific pricing scheme, use of QALY may not meet the causation element. That is to say, even if a QALY scheme takes disability into account, and so amounts to intentional discrimination, the QALY's impact on benefits the federal government provides to a person with a disability may be so attenuated that it does not support an ADA or Rehabilitation Act claim. This may be the case if a pricing scheme incorporates use of international prices, some of which are based to some degree on a QALY-based scheme that relies on disability. Accordingly, depending on the circumstances, federal entities might convince a court that the connection between its drug pricing scheme and a foreign government's use of QALY based on disability is too attenuated to amount to discrimination. Federal civil rights laws are generally understood to follow tort principles in considering causation.[110] At some point in the chain of events, a discriminatory action is no longer cognizable as the cause of harm.[111] For example, the Supreme Court has suggested that lending discrimination does not provide a cause of action for harm to cities injured by widespread disclosures merely because the harm was "forseeable."[112] Accordingly, even if intentional discrimination is part of a QALY system, and that system later affects prices paid by the beneficiaries, plaintiffs would find it difficult to succeed in a discrimination claim absent a fairly close causal connection. This is particularly true if foreign actors implemented a discriminatory QALY system to generate drug prices upon which U.S. decisionmakers later rely. Within the causation analysis, the differences between the Rehabilitation Act and the ADA may matter. The Rehabilitation Act bars discrimination "solely by reason of . . . disability."[113] And because federal entities are subject to the Rehabilitation Act and not the ADA, litigants might find it difficult to challenge pricing as discriminatory if QALY-based analyses, particularly developed by others, are one of many factors considered.[114]

How courts would assess various degrees of QALY application in drug pricing is difficult to predict. It would likely come down to several factors, including whether the government's selection of this scheme amounted to intentional discrimination—with a "purpose" of impairing disabled beneficiaries' access to health care; whether the use of this scheme in fact resulted in negative effects (e.g., higher prices) on disabled beneficiaries; and whether, under Rehabilitation Act standards, any such negative "effect[s]" are too attenuated to trace back to improper consideration of disability status.[115]

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people constitute facial discrimination." The rule also applies when entities seek to impose other extraneous costs—such as requiring a public school student to pay for liability insurance for his service dog. Alboniga v. Sch. Bd. of Broward Cty. Fla., 87 F. Supp. 3d 1319, 1339 (S.D. Fla. 2015). *See also* Disabled in Action of PA v. Nat'l Passenger R.R. Corp., 418 F. Supp. 2d 652, 655, 658 (E.D. Pa. 2005).

[109] Alexander v. Choate, 469 U.S. 287, 289–90, 301 (1985) (holding a 14-day limit on hospitalization coverage did not discriminate against people with disabilities, even though they tended, on average, to require longer hospital stays).

[110] *See* Bank of Am. Corp. v. City of Miami, Fla., 137 S. Ct. 1296, 1305 (2017) (stating discrimination under the Fair Housing Act is "akin to a 'tort action'" in assessing causation); Univ. of Texas Sw. Med. Ctr. v. Nassar, 570 U.S. 338, 346 (2013) (applying tort causation standards to employment discrimination claim); Siefken v. Vill. of Arlington Heights, 65 F.3d 664, 666 (7th Cir. 1995) (applying causation principles to disability discrimination in employment)

[111] *Bank of Am. Corp.*, 137 S. Ct. at 1306.

[112] *Id.* The Court held that more than foreseeability is required, but remanded for assessment of the appropriate standard).

[113] 29 U.S.C. § 794. Outside of the employment discrimination context, this difference in causation has not been clearly developed in legal precedent.

[114] While programs run by federal agencies need not comply with the ADA, many federal grant recipients *would* be covered.

[115] 45 C.F.R. § 84.4(b)(4).

Potentially Neutral QALY Factors

Not all QALY metrics incorporate disability. Accordingly, some potential uses of QALY, either in drug pricing or care allocation, could likely avoid disability discrimination. In its ultimately negative assessment of Oregon's QALY scheme, for example, the OLC pointed to several factors the state *could* use in pricing and allocating care. "These factors include, but are not limited to, the cost of medical procedures, the length of hospital stays, prevention of death, and prevention of contagious diseases."[116] In OLC's view, these were "content neutral factor[s] that do[] not take disability into account or . . . have a particular exclusionary effect on individuals with disabilities."[117]

Use of survival rates would likely not violate the ADA or Rehabilitation Act, even if they are used to ration care. Accordingly, when allocating a heart transplant, programs could likely refuse to provide one to a patient with diabetes on the grounds that the probability of survival is lower.[118] The decision does not rely on subjective assessments about quality of life or stereotypes about people with diabetes' capabilities or characteristics. Thus, they would likely satisfy courts' directives that governments provide "evenhanded treatment" even though they need not provide "equal results."[119]

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[116] AAG Flanagan Letter, *supra* note 87, at 420 (citing Alexander v. Choate, 469 U.S. 287, 302 (1985) (construing the Rehabilitation Act)).

[117] *Id*.

[118] Peters, *supra* note 33, at 527.

[119] *Alexander*, 469 U.S. at 304.