

October 3, 2022

The Honorable Xavier Becerra  
Secretary, U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Becerra:

As organizations representing patients, people with disabilities and chronic conditions and older adults, we appreciate the Administration's commitment to nondiscrimination and this comprehensive proposed rule seeking to strengthen civil rights protections in federally funded health programs and HHS programs. We agree that the ability to access needed health care fully and free from discrimination is critical and requires action to support and strengthen existing nondiscrimination laws.

As you move forward with the rulemaking process, we ask you to consider the following related to the agency's request for comments on the extent, scope and nature of value assessment methods that discriminate on the basis of race, color, national origin, sex, age, or disability; the use of clinical algorithms in health care decision-making; and nondiscrimination requirements and enforcement.

**Nondiscrimination in health insurance coverage and other health-related coverage (§ 92.207):  
Use of Value Assessments**

We appreciate this opportunity to provide comments on value assessment methods and the extent to which certain methodologies discriminate. Having worked for many years to raise awareness of our growing concerns regarding impermissible discrimination in the application of value assessment methodologies to set valuations for health care goods and services, we were pleased to see those concerns described in the proposed rule. We firmly believe that the examples provided in the proposed rule highlighting the potential risk posed by value assessments that place a lower value on life-extension for a group of individuals based on a protected basis or via inappropriate adjustment of clinical end points on a protected basis under Section 1557 are violations of existing nondiscrimination laws.

First, patients and people with disabilities have long-held deep concerns about reliance on cost-effectiveness assessments based on the Quality-Adjusted Life Year (QALY) to determine what treatments will be covered benefits for patients. QALYs and similar metrics relying on averages are referenced in other countries and in studies by third parties, such as the Institute for Clinical and Economic Review (ICER) to determine whether treatments are "cost-effective." The QALY metric puts a lower value on the life of an individual living with a disability, and, as such, value assessments using this metric devalue treatments for people with disabilities.

In a 2019 report, the National Council on Disability (NCD), an independent federal agency advising Congress and the administration on disability policy, concluded that QALYs place a lower value on treatments which extend the lives of people with chronic illnesses and disabilities and indicated that the use of QALYs in public programs would be contrary to United States disability policy and civil rights laws.

#### Recommendations:

- We urge the Office for Civil Rights to advance a rulemaking that codifies a ban on the use of methods for calculating value that penalize individuals or groups of individuals on the basis of race, color, national origin, sex, age, or disability as part of utilization management, formulary design, price negotiations, alternative payment models and other incentive-based programs impacting access to care and affordability of care.
- We support the NCD’s recommendation that the HHS Office for Civil Rights issue guidance stating that Section 504 and Section 1557 also apply to Medicaid programs and discuss how these authorities apply to benefits and reimbursement decisions, as well as their recommendation that payment decisions should not rely on cost-effectiveness research or reports that are developed using QALYs.
- More broadly, we also support the NCD recommendation that federal programs, including Medicaid, should not rely on cost-effectiveness research or reports that gather input from the public on health preferences that do not include the input of people with disabilities and chronic illnesses.<sup>1</sup>

#### ***The Precedent Against Use of QALYs and Similar Metrics***

The United States has a thirty-year, bipartisan track record of opposing the use of the QALY and similar discriminatory metrics and establishing appropriate legal safeguards to mitigate their use. Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by any Executive Agency, including Medicare.<sup>2</sup> Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.<sup>3</sup> Based on the ADA’s passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.<sup>4</sup>

The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services (HHS) has no authority to deny coverage of items or services “solely on the basis of comparative effectiveness research” nor to use such research “in

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

<sup>2</sup> 29 USC Sec 794, 2017.

<sup>3</sup> 42 USC Sec 12131, 2017.

<sup>4</sup> Sullivan, Louis. (September 1, 1992). Oregon Health Plan is Unfair to the Disabled. The New York Times.

a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”<sup>5</sup> Additionally, the ACA specifically prohibits the development or use of a “dollars-per-quality adjusted life year (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.” The ACA also states, “The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII” (Medicare).”<sup>6</sup> The rationale for the ACA’s provisions barring the use of QALYs was articulated by a bipartisan group of Senators in 2009 early in the debate over creation of what became the Patient-Centered Outcomes Research Institute (PCORI), expressing support for comparative clinical effectiveness research, not comparative cost effectiveness, as well as seeking reassurance that such work would be used to improve health decisions and not restrict coverage.<sup>7</sup>

More recently, the U.S. Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age when designing or participating in value-based purchasing (VBP) arrangements.<sup>8</sup> Also, the recently-passed Inflation Reduction Act included language barring discriminatory evidence from being a factor in the negotiation process for determining a fair price for prescription drugs, stating, “In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”<sup>9</sup>

The law and regulations governing federal health care programs have established clear precedent that QALY-based assessments of cost and clinical effectiveness are discriminatory against people with disabilities and contrary to federal nondiscrimination laws. The Disability Rights Education and Defense Fund (DREDF) published a report in 2021 discussing the elements of QALYs that rely on a set of discriminatory assumptions that devalue life with a disability, thereby disadvantaging people with disabilities seeking to access care based on subjective assessments of quality of life. DREDF concluded that, under disability nondiscrimination law, health care programs cannot use measures to determine the drugs worth covering that are based on discriminatory assumptions about the quality of life with a disability, nor can reliance on the measure produce a disproportionately negative impact on the health care services and treatments that people with disabilities uniquely rely on. DREDF stated, “The lives of all

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<sup>5</sup> 42 USC Sec 1320e, 2017.

<sup>6</sup> 42 USC Sec 1320e, 2017.

<sup>7</sup> 155 Cong. Rec. 1796, Feb 6, 2009.

<sup>8</sup> <https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>

<sup>9</sup> Public Law No: 117-169.

individuals regardless of disability are equally valuable; this fundamental principle cannot be ignored for the sake of cost savings.”<sup>10</sup>

**Recommendation:** Therefore, we encourage HHS to build on this precedent and make very clear across federal programs that QALYs discriminate and value assessments relying on them cannot be used in benefit design, including in designing utilization management and incentive program strategies.

***Clinical Endpoints Should Represent Outcomes that Matter to Patients and People with Disabilities***

We are similarly concerned about the clinical endpoints that define whether a studied treatment or service represents a therapeutic advance as compared to existing therapeutic alternatives, which provide the basis for determining its clinical or cost effectiveness. We strongly supported provisions in PCORI’s statute emphasizing its duty to achieve preferred outcomes that matter to patients and to study the heterogeneity of impact of a studied treatment or service on subpopulations. Since its creation, PCORI has been at the forefront of efforts to improve the methods used to compare treatments and services to assure that the measured outcomes, including clinical endpoints, are defined by people with lived experience to improve their quality of life.

By contrast, we are concerned that studies comparing health care treatments and services using historic methods have strong potential to devalue outcomes that matter to people needing care. It is essential that the value assessments driving care decisions reflect the burdens experienced by people with lived experience, and place value on the outcomes that they determine to represent improved quality of life. For example, a child’s ability to sit up independently in bed on treatment may seem small in academic terms, but significant to the child seeking independence and the family members that provide caregiving. ISPOR, the professional society for health economics and outcomes research, acknowledges this data gap and has stated that accurate measures of patient-centered outcomes are critical, and that there is a need for research to improve methodology for translating outcomes related to a disease or condition into utilities for use in value assessment, particularly for people with disabilities.<sup>11</sup>

**Recommendation:** HHS OCR should advance standards for nondiscriminatory value assessment that includes using clinical endpoints that indicate whether a studied treatment or service represents a therapeutic advance from the perspective of its end user, patients and people with disabilities.

***To Avoid Discriminatory Impact, Value Assessments Must Consider Health Equity***

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<sup>10</sup> DREDF, ICER Analyses Based on the QALY Violate Disability Nondiscrimination Law, September 21, 2021 at <https://dredf.org/wp-content/uploads/2021/09/ICER-Analyses-Based-on-the-QALY-Violate-Disability-Nondiscrimination-Law-9-17-2021.pdf>

<sup>11</sup> <https://www.ispor.org/strategic-initiatives/science-strategy>

We also are concerned that these comparisons have historically relied on health care data that excludes information on subpopulations, especially for people already experiencing health disparities, as well as excluding consideration of the social and structural determinants of health that are drivers of health inequity. Truly representative and non-discriminatory value assessments require high-quality data that includes the experiences of all affected patients and people with disabilities, including people historically excluded from clinical trials and other sources of patient experience data. Any value assessment will only be as strong as the data that underlies the model. High quality data provides information about the different responses to treatment among patient subpopulations, their preferred outcomes and health equity considerations, all of which are essential components of value assessment if it is to accurately capture treatment value to everyone and result in equitable care for everyone.

By contrast, the data that informs value assessments from entities such as ICER generally reflects population-level averages, omitting specific data on subpopulations such as people with disabilities and people of color. In a study of cost-effectiveness analyses published through 2016, only 19% reported patient subgroup results and only 4.4% reported on race or ethnicity specifically.<sup>12</sup> Relying on this type of data, value assessments are powered to show results for a patient population that is largely white, middle-aged, non-disabled, and male. This can lead to inherent discrimination by devaluing treatments that may have increased value specifically for people who do not fit that archetype, including people with disabilities or people of color. Inclusive data is essential to ensure that value assessments accurately represent treatment needs of people historically excluded from the data and therefore do not discriminate by deferring to data representative of white, non-disabled populations.<sup>13</sup>

Recommendation: We urge the HHS Office for Civil Rights to require that any use of value assessment in decisions related to utilization management, formulary design, price negotiations, alternative payment models and other incentives driving access to health care consider health equity and be built on high-quality, representative, patient-centered data.

### ***Standardization is Needed to Advance Improved Methods for Valuing Health Care***

PCORI is the standard-bearer in conducting high-quality research on outcomes that matter to patients. In 2019, PCORI was reauthorized by Congress and explicitly given authority to capture “the full range of clinical and patient centered outcomes” including “the potential burdens and economic impacts of healthcare services.”<sup>14</sup> As part of this work, PCORI has published principles that define key factors demonstrating that their research has considered the potential burdens and economic impacts of healthcare utilization on “different stakeholders and decision-makers.” Their principles are relevant to the value assessment enterprise and could inform standards that a value assessment should meet to demonstrate its quality and representation

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<sup>12</sup> Lavelle TA, Kent DM, Lundquist CM, Thorat T, Cohen JT, Wong JB, Olchanski N, Neumann PJ. Patient variability seldom assessed in cost-effectiveness studies. *Medical Decision Making* 2018;38(4):487–94

<sup>13</sup> <https://www.nmqf.org/nmqf-media/traditional-value-assessment-methods>

<sup>14</sup> *Further Consolidated Appropriations Act, 2020*, Pub L. No. 116-94 § 104 (e) (2019).

of diverse stakeholders with lived experience. For example, PCORI calls for consideration of the full range of outcomes important to patients and caregivers, including potential burdens and economic impacts. PCORI also calls for the collection of data on potential burdens and economic impacts of intervention options to be appropriate and relevant to the clinical aims of the study. PCORI describes its process as follows:

PCORI requires applicants to engage relevant stakeholders in the formulation of the research question and the development of the study design, as well as the identification of outcomes to measure. This approach is intended to ensure that PCORI-funded research will provide evidence that is ultimately relevant and applicable for the end user; it also seeks to avoid the unnecessary capture of data that are not relevant to the aims of the study and may not be beneficial to the goals of the research. This same expectation should apply when considering whether and which potential burden and other economic impact data a research study should capture.

Similarly, the Innovation and Value Initiative (IVI) has developed consensus-based principles on the most effective methods for value assessment, seeking to define best practices in the applied use of value assessment and applying those principles to disease-specific models. IVI is working to cultivate modernized methods, including complementary approaches that address societal perspectives and broader cost parameters, as well as reduce discrimination and disparities based on patient heterogeneity or disability. We appreciate that IVI recognizes the need for improved clinical and real-world data, investment in it and standards for its generation. IVI is also working toward a value assessment process that supports health equity, which requires sub-group and distributional impact analyses, improved research methods reflecting diverse communities and experiences, and a policy dialogue about improving access and equity.<sup>15</sup>

The NCD report published in 2019 discussed alternative metrics that are less likely to be discriminatory. The NCD recommended use of well-established alternatives to QALYs, such as multi-criteria decision analysis (MCDA), a method capable of capturing the complexity of healthcare coverage decisions, or cost-benefit analysis.<sup>16</sup> NCD raised serious concerns about methods using health utilities relying on EQ-5D surveys, which take an extremely limited approach to measuring “quality of life” and fail to measure the wide variety of impacts a disability or illness could have on quality of life.

We are concerned that cultural barriers exist within the health economics and research establishment related to the incorporation and consideration of patient preferences into comparative research and value assessment. Research has shown that high-quality patient preference information can be collected in a manner that is systemic and scientifically

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<sup>15</sup> [https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA\\_FINAL.pdf](https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf)

<sup>16</sup> [https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA\\_FINAL.pdf](https://www.thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf)

rigorous,<sup>17</sup> and that it can be integrated into value assessments.<sup>18</sup> Many entities, including PCORI, have funded research on patient-preferences. By advancing a consistent policy throughout federal health care programs identifying safeguards against the use of discriminatory metrics in value assessment, the HHS Office for Civil Rights would be supporting culture change in the process of value assessment, similar to the efforts of PCORI to change the culture of comparative clinical effectiveness research to be patient centered.

Recommendation: As the HHS Office for Civil Rights seeks to define parameters for the use of value assessment in federal health care programs and policies, we urge collaboration with entities such as NCD and PCORI that are also invested in advancing nondiscriminatory research and methods for assessing value of health care. Entities engaged through contracts should not have a history of relying on QALYs or the equal value of life year gained that is based on the QALY for measuring value. Any third-party contributing data to HHS should have experience with alternative metrics unrelated to QALYs and a commitment to using representative data that captures outcomes that matter to people with lived experience. Regulations that call out the discriminatory implications of QALYs and similar average metrics failing to account for health equity will then drive investment in alternative metrics that do not rely on flawed data and surveys such as the EQ-5D. Ultimately, a combination of well-established metrics, as proposed by NCD, would be increasingly available for use.

### **Use of clinical algorithms in decision-making (§ 92.210): Potential to discriminate against people with disabilities**

We appreciate HHS recognized that the use of clinical algorithms can lead to discriminatory decision-making. Guidelines based on “objective” point systems or algorithms can function to discriminate against people with disabilities, as many of these systems were designed and validated based on populations without disabilities.<sup>19</sup> As HHS stated in its Notice of Proposed Rulemaking, many Crisis Standards of Care used during the COVID-19 pandemic relied on discriminatory decision tools and assumptions of the life worth of people with disabilities. Some of these algorithms and “objective” standards may misinterpret disability-related characteristics. For example, the Sequential Organ Failure Assessment (SOFA), which was used throughout the COVID-19 pandemic as a factor in Crisis Standards of Care, would give someone a higher SOFA score which indicates a higher risk of mortality if they are unable to give a verbal response, regardless of whether they are typically able to do so, thereby increasing their risk of being denied care in a shortage.<sup>20</sup> One study found that SOFA is associated with overestimated

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<sup>17</sup> Marsh K, Krucien N. Evaluating the Consistency of Patient Preference Estimates: Systematic Variation in Survival-Adverse Event Trade-Offs in Patients with Cancer or Cardiovascular Disease. *Patient*. 2022 Jan;15(1):69-75. doi: 10.1007/s40271-021-00513-3. Epub 2021 May 31. PMID: 34056700.

<sup>18</sup> Marsh, K., De Bekker-Grob, E., Cook, N., Collacott, H., & Danyliv, A. (2021). How to integrate evidence from patient preference studies into health technology assessment: A critical review and recommendations. *International Journal of Technology Assessment in Health Care*, 37(1), E75. doi:10.1017/S0266462321000490

<sup>19</sup> <https://dredf.org/disability-nondiscrimination-in-health-care-and-community-life-during-the-covid-19-pandemic/>

<sup>20</sup> <https://dredf.org/disability-nondiscrimination-in-health-care-and-community-life-during-the-covid-19-pandemic/>

mortality among Black patients compared with White patients, suggesting that Crisis Standards of Care are associated with systematic deprioritization of care to Black patients.<sup>21</sup>

Recommendation: We urge HHS to learn from the pandemic and codify regulations that health care providers may not rely on clinical algorithms that function to discriminate against providing care to people based on race, color, national origin, sex, age, and disability.

### **Nondiscrimination Requirements Should Ensure Accessible Access to Information Used to Make Health Care Decisions**

We appreciate that the HHS OCR outlined specific nondiscrimination requirements for health care programs and activities. Accessibility and effective communication are essential for people with disabilities and people with limited access to technology such as broadband. For example, it is difficult to hold health care decision-makers such as state Pharmacy and Therapeutic Committees and Drug Utilization Review Boards (DURB) accountable for decisions related to benefit design and coverage if their websites do not meet the accessibility requirements of the Americans with Disabilities Act (ADA) or clearly communicate to the public the information on which they have relied to make decisions. All people should be able to participate in P&T Committee or DURB meetings required to be public, with accessible teleconferencing capabilities and telephone capabilities, as well as sufficient notice to register to participate. The considerations being discussed at the meeting should be clearly stated to the participating public stakeholders, including copies of the evidence under discussion with the exception of legally protected material.

Recommendation: We urge the HHS OCR to provide guidance to state Medicaid program directors on the requirements of the ADA and their obligations to ensure their programs, including P&T Committees, DURBs and their outside contractors, are meeting the ADA's requirements for accessibility to the information on which they make decisions and communicating that information in a manner that does not disadvantage people with disabilities or people with limited access to technology.

### **Enforcement is Crucial for Health Equity and Nondiscrimination**

We appreciate that the HHS OCR recognized the importance of enforcement of nondiscrimination laws. Because so much information is not publicly accessible to determine if a benefit design or coverage decision was based on evidence that itself discriminates, it is difficult to legally challenge coverage denials that may be discriminatory. We concur with the proposed rule that when a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate the appropriate enforcement procedure. We also would appreciate increased oversight from OCR of the activities of state-based Medicaid programs, particularly P&T Committees and

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<sup>21</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781190>



DURBs, to better understand how they make decisions about benefit design, coverage and preferred drugs and whether they are relying on discriminatory value assessments.

We are concerned that many states very explicitly reference QALY-based evidence to make decisions within their Medicaid programs. Currently, HHS is reviewing Oregon's Medicaid waiver which will determine if the state's Health Evidence Review Commission (HERC), which guides the Oregon Health Plan's benefit decisions, will be authorized to continue to use a QALY-driven data and analysis in the formula for the prioritized list of services. In New York, their DURB has referenced QALY-based studies from ICER to make reimbursement decisions related to treatments for cystic fibrosis, migraines and spinal muscular atrophy. Similarly, Washington State's Health Technology Clinical Committee routinely commissions QALY-based studies to make coverage determinations for selected health technologies which are followed by state purchased health care programs including Medicaid, Uniform Medical Plan and the Department of Labor and Industries.<sup>22 23</sup>

Recommendation: We urge HHS OCR to increase oversight and enforcement of state Medicaid programs to determine the extent to which they are relying on discriminatory value assessments to make decisions impacting coverage and access to care.

Thank you for your consideration of our comments. We appreciate your commitment to nondiscrimination and stand ready to work with you as you work towards these goals. Please don't hesitate to reach out to Sara van Geerturden, [sara@pipcpatients.org](mailto:sara@pipcpatients.org) if you have any questions or if we may provide additional information.

Sincerely,

ACMCRN Arachnoiditis and Chronic Meningitis Collaborative Research Network  
Allergy & Asthma Network  
Allfocus Technologies, Inc  
Alliance for Aging Research  
Allies for Independence  
Alstrom Syndrome International  
American Association of Kidney Patients (AAKP)  
American Association of People with Disabilities  
American Association on Health & Disability  
American Behcet's Disease Association  
Angelman Syndrome Foundation  
Asthma and Allergy Foundation of America  
Autistic Self Advocacy Network  
Autistic Women & Nonbinary Network  
Bone Health and Osteoporosis Foundation

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<sup>22</sup> <https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-clinical-committee>

<sup>23</sup> <https://www.patientaccessproject.org/#State-Tracker>

Cancer Support Community  
CancerCare  
Caring Ambassadors Program  
Center for Autism and Related Disorders  
Center for Independence of the Disabled, NY  
CFC International  
Coalition to Cure CHD2  
COMBINEDBrain, Inc.  
COPD Foundation  
Cure SMA  
Cystic Fibrosis Research Institute  
Davis Phinney Foundation  
Derma Care Access Network  
Disability Community Resource Center  
Disability Policy Consortium  
Disability Rights California  
Disability Rights Education and Defense Fund (DREDF)  
Disability Rights Oregon  
Dup15q Alliance  
Easterseals  
Epilepsy Alliance America  
Epilepsy Foundation  
Familia Unida Living with MS  
Genetic Alliance  
GO2 Foundation for Lung Cancer  
Haystack Project  
Health Hats  
HealthHIV  
Hermansky-Pudlak Syndrome Network  
Hope for HIE  
Hydrocephalus Association  
Hypertrophic Cardiomyopathy Association  
ICAN, International Cancer Advocacy Network  
International Pemphigus and Pemphigoid Foundation  
Lennox-Gastaut Syndrome (LGS) Foundation  
Lupus Foundation of America  
Men's Health Network  
Rosie Bartel  
National Disability Rights Network (NDRN)  
National Down Syndrome Society  
NBIA Disorders Association  
Not Dead Yet  
Partnership to Improve Patient Care  
Patient Partner

Pulmonary Hypertension Association  
PXE International  
Rare Epilepsy Network (REN) Coordinating Committee  
RASopathies Network  
SLC6A1 Connect  
Syngap1 Foundation  
The ALS Association  
The Arc of the United States  
The Assistance Fund  
The Bonnell Foundation: living with cystic fibrosis  
The Coelho Center for Disability Law, Policy and Innovation  
The Headache and Migraine Policy Forum  
The Hepatitis C Mentor and Support Group-HCMSG  
The Hepatitis C Mentor and Support Group-HCMSG  
The Partnership to Advance Cardiovascular Health  
TSC Alliance  
U.S. Pain Foundation  
United Spinal Association  
VHL Alliance  
Whistleblowers of America