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EVALUATION FRAMEWORK FOR CRISIS STANDARD OF CARE PLANS

Many states and hospitals are relying on the use of Crisis Standard of Care plans to inform providers how to make decisions on the allocation and re-allocation of scarce medical resources. These plans should be carefully scrutinized to ensure that people with disabilities are not subject to discrimination. This guide, which accompanies guidance from disability and healthcare organizations that expands on a Bulletin from the Department of Health and Human Services' Office of Civil Rights, is designed to help advocates and policymakers ensure that Crisis Standard of Care plans and other documents providing criteria for the allocation or re-allocation of scarce medical resources comply with federal disability rights laws.

We identify six questions to ask when evaluating Crisis Standards of Care plans and other allocation criteria, and how particular allocation criteria amount to discrimination or risk being discriminatory.

1) **Does the plan include categorical exclusions on the basis of diagnosis or functional impairment?**

    a) Many Crisis Standard of Care plans include criteria excluding certain people from accessing critical care resources, such as ventilators. These criteria may reflect impermissible disability discrimination if they are based on disability diagnoses or on broad functional impairments (such as the need for support in activities of daily living or chronic use of a ventilator) rather than an individualized assessment that a person is unlikely to benefit from treatment.[i]

    b) Plans cannot make categorical exclusions on the basis of disability, as doing so precludes the possibility of a truly individualized assessment of a patient's ability to benefit from treatment.[ii]

        i) Some plans have identified certain conditions as exclusion criteria based on the following rationales: a) those with these conditions are too ill to likely survive the acute illness; b) those with these conditions have a one-year mortality probability so high that it is not reasonable to allocate

critical care resources to them in a crisis situation, and; c) those with these conditions require such a large amount of resources that it is not feasible to accommodate their hospitalization in a prolonged mass-casualty situation.

Each of these rationales poses disability discrimination concerns. The first rationale (that a patient is too ill to likely survive the acute illness) may be acceptable in the context of an individualized assessment of a particular patient, but the use of a categorical exclusion denies a patient the opportunity to receive the individualized assessment required under the law. It is well accepted that the ability to survive in the short term, with aggressive treatment for an acute illness, is a valid qualification for providing such treatment. However, the use of a categorical exclusion associating this determination with a diagnosis rather than an individualized assessment of a particular patient may erroneously exclude those within a diagnosis for which this is not an accurate judgment.

The second rationale (that a patient has a one-year mortality that is so high as to make it unreasonable to allocate critical care resources to that patient in a crisis) raises concerns if the evidence does not support a mortality expectation high enough to justify such an exclusion. Even if high one-year mortality is accepted as a permissible basis to exclude from critical care, medical advances may render categorical exclusion criteria arrived at on that basis obsolete even as institutional inertia maintains the categorical exclusion within guidance provided to providers.[iii]

The third rationale - the assumption that patients with the particular conditions will require too large an amount of resources - is not an acceptable rationale to justify an exclusion criteria. Not only does it not reflect an individualized judgment, but the need for additional resources may in many instances be mandated as a reasonable accommodation under Section 504 and the Americans with Disabilities Act. Treatment allocation decisions may not be made based on the perception that a person's disability will require the use of greater treatment resources, either in the short or long term. Reasonable modifications must be made where they are needed in order for a person with a disability to have equal opportunity to benefit from the treatment.

c) Given the lack of adequate research on the impact of COVID-19 on survival probabilities and the need for individualized assessment, plans must avoid the use of diagnosis or functional impairment-based categorical exclusion criteria in Crisis Standards of Care plans.[iv]

2) **Does the plan include implicit or explicit quality of life assessments as an allocation criteria?**

   a) Many plans may reference quality of life indirectly, by indicating that providers should consider underlying disabilities that play no role in survival probability, either by virtue of their existence prior to the receipt of treatment or the likelihood of individuals acquiring such disabilities after the receipt of treatment.[v]

   b) Assessments of the quality of life of patients with particular disabilities should never be used to deny treatment.[vi]

3) **Does the plan include long-term survival beyond the acute care episode as an allocation criteria?**

   a) Some Crisis Standard of Care plans permit the use of long-term survival beyond the acute care episode, permitting the prioritization of individuals with longer anticipated lifespans than those with shorter lifespans. This places individuals with chronic illnesses and disabilities that shorten long-term lifespan at a disadvantage for accessing treatment and fails to account for the significant uncertainty surrounding long-term survival probabilities.[vii]

   b) Long-term survival projections are significantly less certain than the assessment of short-term survival. Medical innovations such as new pharmaceuticals, surgical techniques and other interventions can shift the long-term prognosis for many conditions. Incorporating comorbidities that do not reduce a patient's short-term survival prospects into an assessment of whether or not they will receive care risks incorporating concerning value judgments that will systemically disadvantage people with disabilities and chronic health conditions and reduce the likelihood that they will receive medically indicated care.

   c) Any consideration of long-term survival in plans or allocation criteria, whether it comes in the form of explicit consideration of long-term survival or implicit consideration through prioritization of number of "life-years" saved rather than the number of "lives" saved, is inconsistent with disability rights laws.[viii]

   d) Careful scrutiny should be given to the instruments utilized to assess survival probabilities to evaluate the extent to which they are designed for the assessment of long-term survival probability, rather than survival from the acute episode in question.

4) **Does the plan permit allocation or re-allocation on the basis of anticipated or documented duration of need?**

a) Many plans permit prioritization on the basis of anticipated or documented duration of need, either in the initial decision to allocate a scarce medical resource or in a subsequent decision to re-allocate the resource in the event that a patient makes use of it for a greater than typical time period.[ix]

b) Treatment allocation decisions may not be made based on the perception that a person's disability will require the use of greater treatment resources, either in the short or long term. This should preclude the denial of initial access to a scarce medical resource, such as a ventilator, based on the assessment that the person will require its use for a longer period of time.[x]

c) In the context of re-allocation decisions, reasonable modifications must be made where needed by a person with a disability to have equal opportunity to benefit from the treatment. These may include interpreter services or other modifications or additional services needed due to a disability. They may also include permitting a person to continue using a ventilator for additional time where an underlying disability means that additional time is necessary for recovery.

5) Where the plan incorporates short-term survival probabilities, does it do so in an individualized fashion consistent with available standards of evidence?

a) Many Crisis Standard of Care plans reference likelihood of short-term survival as a criterion for the allocation of scarce medical resources. Though some consideration of short-term survival probability is permissible, it must be based on an individualized assessment of the patient's particular circumstances rather than a broad-based conclusion on the basis of a diagnosis.

b) To avoid discrimination, doctors or triage teams must perform a thorough individualized review of each patient and not assume that any specific diagnosis is determinative of prognosis or near-term survival without an analysis of current and best available objective medical evidence and the individual's ability to respond to treatment.

c) Many plans rely on the use of the Sequential Organ Failure Assessment (SOFA), a measure designed to predict short-term mortality, to assess relative survival probabilities. The SOFA may disadvantage specific disability categories, such as chronic ventilator users, that start at a higher SOFA score as their "baseline" condition.

d) While the use of the SOFA is not unacceptable, plans must include provisions for ensuring that reasonable modifications to the SOFA and other instruments are

made for those whose underlying impairments result in the SOFA penalizing them for their baseline level of impairment prior to the acute care episode.

6) Special Consideration for Chronic Ventilator Users

a) Several plans appear to limit the ability of chronic ventilator users to bring their personal ventilators with them into the hospital or other acute care setting, raising the concern that their personal ventilators may be subject to re-allocation should they need to seek acute care.[xi]

b) Doctors and triage teams must not reallocate ventilators of individuals with disabilities who use ventilators in their daily lives and come to the hospital with symptoms of COVID-19.

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[i] For example:

- Florida excludes from hospital admissions individuals with "complex disorders with significant neurological component and prognosis for imminent expected lifelong assistance with most basic activities

of daily living (i.e., toileting, dressing, feeding, respiration)." *See* Florida Department of Health. "Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines," by the Pandemic Influenza Technical Advisory Committee, April 5, 2011, 27. http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/_documents/acs-guide.pdf.

- Tennes2see excludes from hospital admission those with "advanced untreatable neuromuscular disease (such as ALS, end-stage MS, spinal muscular atrophy) requiring assistance with activities of daily living or requiring chronic ventilatory support." *See* Tennessee Altered Standards of Care Workgroup, "Guidance for the Ethical Allocation of Scarce Resources during a Community-Wide Public Health Emergency as Declared by the Governor of Tennessee," July 2016, 21. https://www.tn.gov/content/dam/tn/health/documents/2016_Guidance_for_the_Ethical_Allocation_of_Scarce_Resources.pdf.

- Utah excludes from hospital admission individuals with "known severe dementia medically treated and requiring assistance with activities of daily living." *See* Utah Department of Health, "Utah Pandemic Influenza Hospital and ICU Triage Guidelines," by the Utah Hospitals and Health Systems Association, August 11, 2009, 5. http://pandemicflu.utah.gov/plan/med_triage081109.pdf.

- Colorado, among other states, lists as an exclusion criteria from admission or transfer to critical care "cystic fibrosis with post-bronchodilator FEV1 <30% or baseline Pa02 <55 mm Hg." *See* Colorado Department of Public Health and the Environment, "CDPHE All Hazards Internal Emergency Response and Recovery Plan, ANNEX B: Colorado Crisis Standards of Care Plan," May 10, 2018, 78. https://cha.com/wp-content/uploads/2018/10/Crisis-Standards-of-Care-05102018-FINAL.pdf.

[ii] In an April 8, 2020 announcement of the results of a compliance review in Alabama, the HHS Office of Civil Rights raised concerns that the state's use of categorical exclusion criteria may violate federal law. To resolve the compliance review, Alabama agreed "that it will not, in future CSC guidelines, include similar provisions singling out certain disabilities for unfavorable treatment or use categorical age cutoffs; and that it will also not interpret the current Guidelines in such a manner." *See* HHS Office of Civil Rights., "OCR Reaches Early Case Resolution With Alabama After It Removes Discriminatory Ventilator Triaging Guidelines," April 8, 2020. https://www.hhs.gov/about/news/2020/04/08/ocr-reaches-early-case-resolution-alabama-after-it-removes-discriminatory-ventilator-triaging.html?fbclid=IwAR0JlMVCu0goRGzW6oEaRmw-oJqqA9yy0-_LNp89SDChIB-i3F2Vt-8l_VU

[iii] For example:

- Tennessee lists "Cystic fibrosis with post-bronchodilator FEV1 <30%" as an exclusion criteria for hospital admission, as do several other states. However, research on the life expectancy of people with cystic fibrosis whose FEV1 is less than 30% shows the median survival prior to transplant at >6.5 years. Recent advances in pharmaceutical interventions may have further extended the life-expectancy of people with CF. As a result, the use of cystic fibrosis as an exclusion criteria, even with this caveat, cannot be justified on the basis of the rationale articulated within the Crisis Standard of Care Plan. *See* Kathleen J. Ramos et al., "Heterogeneity in Survival in Adult Patients With Cystic Fibrosis With FEV1 < 30% of Predicted in the United States," *Chest* 151, no. 6 (2017): 1320–28, https://doi.org/10.1016/j.chest.2017.01.019.

- Colorado's pediatric exclusion criteria in its 2018 Crisis Standards of Care include SMA Type I and "progressive neuromuscular disorder e.g. muscular dystrophy and myopathy, with inability to sit unaided or ambulate when such abilities would be developmentally appropriate based on age" as examples of conditions with "> 80% mortality expected at 18 to 24 months." *See* Colorado Department of Public Health and the Environment, "CDPHE All Hazards Internal Emergency Response and Recovery Plan, ANNEX B: Colorado Crisis Standards of Care Plan," May 10, 2018, 82. https://cha.com/wp-content/uploads/2018/10/Crisis-Standards-of-Care-05102018-FINAL.pdf. Recent medical advances have made this inaccurate for SMA. The more general exclusion is likewise inaccurate – delay or inability to walk is not directly predictive of lifespan. This speaks more generally to the harms of diagnosis-based exclusion criteria - not only are they frequently not predictive of lifespan, but medical advances may render them obsolete even as institutional inertia continues to leave them in place within state and provider allocation plans. *See* Tamara Dangouloff and Laurent Servais. "Clinical Evidence Supporting Early

Treatment of Patients with Spinal Muscular Atrophy: Current Perspectives," *Therapeutics and Clinical Risk Management* 15: 1153-1161, https://doi.org/10.2147/TCRM.S172291.

- Washington State indicates "severe chronic lung disease" as a significant underlying disease that predicts poor short term survival that may impact a patient's access to ICU care in the event of scarce resources. With no clarity about the threshold of "severity" that would be necessary to accurately predict poor survival, people with disabilities may be inappropriately denied a ventilator merely based on the triage team's subjective judgment about their diagnosis. *See* Washington State Department of Health, "Scarce Resource Management & Crisis Standards of Care: Overview & Materials," by the Northwest Healthcare Response Network, March 2020, 34-35. https://nwhrn.org/wp-content/uploads/2020/03/Scarce_Resource_Management_and_Crisis_Standards_of_Care_Overview_and_Materials-2020-3-16.pdf.

[iv] The University of Pittsburgh Medical Center's model guidelines provide a positive example, avoiding all use of categorical exclusion criteria. They specify that "an allocation system should make clear that all individuals are 'worth saving' by keeping all patients who would receive critical care during routine circumstances eligible." Furthermore, they note that "the use of rigid categorical exclusions would be a major departure from traditional medical ethics and raise fundamental questions of fairness." *See* University of Pittsburgh School of Medicine, Department of Critical Care Medicine, "Allocation of Scarce Critical Care Resources During a Public Health Emergency," March 26, 2020, 7. https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy.pdf.

[v] For example:

- In a document since taken down from the state's website, Alabama had indicated that individuals with severe or profound intellectual disability "are unlikely candidates for ventilator support." *See* Alabama Disabilities Advocacy Program, "Complaint of Alabama Disabilities Advocacy Program and The Arc of the United States," letter to Roger Severino, March 24, 2020. https://www.centerforpublicrep.org/wp-content/uploads/2020/03/AL-OCR-Complaint_3.24.20.docx.pdf. Given that there is no evidence that intellectual disability plays any role in survival probability, this should be taken as an instance of an implicit quality of life judgment.

- Florida's draft criteria from 2011 incorporates an exclusion from hospital admissions individuals with "complex disorders with significant neurological component and prognosis for imminent expected lifelong assistance with most basic activities of daily living (*i.e.*, toileting, dressing, feeding, respiration)" (*see* Florida Department of Health. "Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines," by the Pandemic Influenza Technical Advisory Committee, April 5, 2011, 27. http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/_documents/acs-guide.pdf) may be best understood as an implicit quality of life judgment, as it is so broad as to have no relationship with survival probability.

- Similarly, Washington State's use of "baseline functional status" (including energy, physical ability, cognition and general health) is so broad as to suggest that an implicit quality of life judgment is being made. *See* Washington State Department of Health, "Scarce Resource Management & Crisis Standards of Care: Overview & Materials," by the Northwest Healthcare Response Network, March 2020, 34-35. https://nwhrn.org/wp-content/uploads/2020/03/ Scarce_Resource_Management_and_Crisis_Standards_of_Care_Overview_and_Materials-2020-3-16.pdf.

[vi] Oregon's Crisis Care Guidance document provides a positive example representing a potential promising practice. This document specifies that "[I]n a public health crisis, decisions about who should receive critical care and other medical services should be based on clinical experience using objective clinical information, just as they are in non-crisis situations. Care decisions should not be based on non-clinical factors such as race, ethnicity, clinician-perceived quality of life [emphasis added], profession, social position, or ability to pay." Oregon Medical Association, "Oregon Crisis Care Guidance," by the Crisis Care Guidance Workgroup, June 2018, 7. https://www.theoma.org/CrisisCare.

[vii] For example:

- The University of Washington Medical Center's Material Resource Allocation Principles and Guidelines for the COVID-19 Outbreak indicates that what should be prioritized is "healthy, long-term survival, recognizing that this represents weighting the survival of young otherwise healthy patients more heavily than that of older, chronically debilitated patients." *See* University of Washington Medical Center, "Material Resource Allocation Principles and Guidelines: COVID-19 Outbreak," 2020, 1. https://covid-19.uwmedicine.org/Screening%20and%20Testing%20Algorithms/Other%20Inpatient%20Clinical%20Guidance/Clinical%20Care%20in%20ICU/Material%20Resource%20Allocation.COVID19.docx.

- Colorado lists "little likelihood of long-term survival" as one of the rationales used to compile the state's list of exclusion criteria from critical care resources. *See* Colorado Department of Public Health and the Environment, "CDPHE All Hazards Internal Emergency Response and Recovery Plan, ANNEX B: Colorado Crisis Standards of Care Plan," May 10, 2018, 78. https://cha.com/wp-content/uploads/2018/10/Crisis-Standards-of-Care-05102018-FINAL.pdf. A recent update to Colorado's crisis standard of care plan sets an explicit goal to "save the most life-years", utilizing a modified Charlson Comorbidity Index Score that prioritizes individuals in part based on their likelihood of survival over the next decade. *See* Colorado Department of Public Health and the Environment. "Subject Matter Experts Advisor Panel for the Governors Expert Emergency Epidemic Response Committee on Crisis Standards of Care Guidelines for Hospitals for the COVID-19 Pandemic," April 5, 2020, 6. https://www.colorado.gov/pacific/cdphe/colorado-crisis-standards-care

- Oregon permits the consideration of long-term prognosis "when multiple people have the same potential for benefit". While we would prefer this factor be removed from consideration, their plan does specify that this is meant to serve as a tiebreaker rather than being factor into an overall score used for triage. They note that estimated long-term survival probability "should be secondary to the initial assessment of the benefit of resource use and its ability to increase the presenting patient's baseline probability of surviving her/his acute illness or injury." Only conditions with an estimated maximum survival of 6-12 months are considered absolute exclusion criteria in this plan. *See* Oregon Medical Association, "Oregon Crisis Care Guidance," by the Crisis Care Guidance Workgroup, June 2018, 44-45. https://www.theoma.org/CrisisCare.

- While many plans restrict prioritization based on remaining life-years to a span of 1-2 years after the acute illness, the University of Pittsburgh Medical Center's model guidelines add an intermediate prioritization level that penalizes even people with a longer expected survival. *See* University of Pittsburgh School of Medicine, Department of Critical Care Medicine, "Allocation of Scarce Critical Care Resources During a Public Health Emergency," March 26, 2020, 6. https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy.pdf. The list of examples of "major comorbid conditions with substantial impact on long-term survival" includes "malignancy with an expected < 10 year survival" and "moderately severe chronic lung disease."

- Pennsylvania takes into account a patient's "prognosis for long-term survival," assessing a patient's comorbid conditions with the goal to "save the most life-years." *See* Pennsylvania Department of Health. ""Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines," March 22, 2020, 30. https://int.nyt.com/data/documenthelper/6850-pennsylvania-triage-guidelines/02cb4c58460e57ea9f05/optimized/full.pdf.

[viii] New York State's ventilator guidelines offers a positive example representing a potential promising practice, indicating that their "definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). By adopting this approach, every patient is held to a consistent standard. Triage decision-makers should not be influenced by subjective determinations of long-term survival, which may include biased personal values or quality of life opinions." *See* New York State Department of Health, "Ventilator Allocation Guidelines," by the New York Taskforce on Life and the Law, November 2015, 34. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf.

[ix] Several states, including Colorado and Tennessee, use a set of guidelines developed by the Minnesota Healthcare Preparedness Program that suggest making re-allocation decisions based either on "significant differences in prognosis or resource utilization." *See* Colorado Department of Public Health and the Environment, "CDPHE All

Hazards Internal Emergency Response and Recovery Plan, ANNEX B: Colorado Crisis Standards of Care Plan," May 10, 2018, 48. https://cha.com/wp-content/uploads/2018/10/Crisis-Standards-of-Care-05102018-FINAL.pdf; Tennessee Altered Standards of Care Workgroup, "Guidance for the Ethical Allocation of Scarce Resources during a Community-Wide Public Health Emergency as Declared by the Governor of Tennessee," July 2016, 37; https://www.tn.gov/content/dam/tn/health/documents/2016_Guidance_for_the_Ethical_Allocation_of_Scarce_Resources.pdf; Minnesota Department of Health, Emergency Preparedness and Response, "Patient Care Strategies for Scarce Resource Situations," by the Minnesota Health Care Preparedness Program, April 2019, 16. https://www.health.state.mn.us/communities/ep/surge/crisis/standards.pdf. This includes duration of need, with re-allocation suggested when the patient's condition suggests a long duration of need, "e.g., ARDS, particularly in setting of preexisting lung disease (estimate > 7 days on ventilator)."

[x] New York's ventilator guidelines mostly reject the use of duration of need as an allocation criteria. Though earlier draft criteria considered utilizing resource-utilization, New York's final criteria indicate that "resource utilization with respect to estimated duration of ventilator need as a stand-alone triage factor was rejected because it does not affect a patient's likelihood of survival." *See* New York State Department of Health, "Ventilator Allocation Guidelines," by the New York Taskforce on Life and the Law, November 2015, 85-86. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf.

[xi] For example, the New York State Task Force on Life and the Law indicates that when chronic ventilator users arrive at the hospital "they are treated like any other patient who requires a ventilator and need to meet certain criteria to be eligible for ventilator therapy," arguing that "if chronic care patients were permitted to keep their ventilators rather than be triaged, the policy could be viewed as favoring this group over the general public." *See* New York State Department of Health, "Ventilator Allocation Guidelines," by the New York Taskforce on Life and the Law, November 2015, 42. https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf. According to a 2009 report from the New York Times, state health care officials took this to mean that should a chronic ventilator user need to enter the hospital, "the guidelines call for the machine that keeps him alive to be given to someone else." *See* Sheri Fink, "Worst Case: Choosing Who Survives in a Flu Epidemic," *The New York Times*, October 24, 2009, sec. Week in Review, https://www.nytimes.com/2009/10/25/weekinreview/25fink.html. Kansas makes use of similar criteria borrowed from the New York Task Force guidelines. The underlying meaning of these guidelines has been contested, but regardless of intent, additional clarity is needed to ensure that people with disabilities are not deprived of their ventilators if they enter an acute care setting. *See* Ari Ne'eman, "Do New York State's Ventilator Allocation Guidelines Place Chronic Ventilator Users at Risk? Clarification Needed," The Hastings Center, April 3, 2020, https://www.thehastingscenter.org/do-new-york-states-ventilator-allocation-guidelines-place-chronic-ventilator-users-at-risk-clarification-needed/.