









CRISIS STANDARDS OF CARE **Issue Brief**

Crisis Standards of Care: Legal Issues Underlying Key Decisions Regarding Scarce Resources

During the COVID-19 pandemic, hospitals across the nation confronted patient surges and resource shortages consistent with implementing crisis standards of care ("CSC"). The National Academies of Science, Engineering and Medicine (NASEM) <u>define CSC</u> as a "substantial change in usual health care operations and the level of care it is possible to deliver," often (but not always) triggered by a formally declared pervasive or catastrophic disaster. CSC contemplates the <u>need to shift the standard of care</u> from an individually-based "conventional" standard along a continuum through "contingency" and into population-health-focused "crisis" standards during emergency circumstances.

As illustrated in the image below, multiple legal issues underlie successful planning and implementation of CSC, as regularly observed during the COVID-19 pandemic.



However, no set of core legal issues are more profound than those implicated in making actual decisions about which patient[s] receive specific care in emergencies. At the crux of such decisions lie key legal concerns which can dictate allocation outcomes depending on their resolution. This brief memorandum lists core legal issues and concerns that may arise when a resource allocation or treatment decision is made under CSC.

Discrimination

Equal Protection Concerns

The <u>Institute of Medicine's 2012 System's Framework for Catastrophic Disaster Response</u> addressed equal protection concerns with respect to CSC and potential disproportionate effects on the basis of protected characteristics. Disparate impacts of CSC decisions across varied racial, ethnic, or other protected populations as documented during the COVID-19 pandemic raise the specter of equal protection violations related to state-based CSC plans, or public sector execution of such plans.

Disability

On March 28, 2020, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) <u>issued a Bulletin</u> explaining that applicable civil rights protections prevent discrimination in treatment of persons with disabilities. OCR expressly conveyed that persons with disabilities should not face treatment or care denials based on "stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities"

OCR has worked with multiple states throughout the COVID-19 pandemic to correct or eliminate language in CSC or triage plans which could be disability discriminatory (e.g., <u>Alabama</u>, <u>Arizona</u>, Connecticut, Kansas, Massachusetts, <u>Pennsylvania</u>, <u>Tennessee</u>, <u>Utah</u>, Washington), subsequently developing a list of <u>"best practices"</u> in this area.

Sex

While HHS OCR also enforces civil rights protections against discrimination on the <u>basis of sex</u>, to date no known claims of sex-based discrimination in the decision-making facets of CSC have led to specific legal claims or litigation.

Age

Age-related discrimination, like disability-related discrimination, has been repeatedly addressed by OCR in state CSC or triage plans throughout the pandemic (e.g., Alabama, Arizona, Tennessee, Utah). OCR published a technical assistance document addressing age- and disability-related concerns on January 14, 2021 after assisting North Carolina, the Indian Health Service, the North Texas Mass Critical Care Guidelines Task Force, and the Southwest Texas Regional Advisory Council to eliminate discrimination in their plans. OCR's suggested provisions were subsequently included in CSC plans as a result of this cooperation. OCR's generalized guidance relating to age-based discrimination and CSC prioritizes individualized patient assessments, "including clinical factors relevant and available to such determinations, which may include age

under limited circumstances." Still, this same guidance explains that OCR regulations prevent explicitly mentioning age as a denial/de-prioritization basis, "even if one factor among many."

Race, Color, or National Origin (including Limited English Proficiency (LEP))

On July 20, 2020, OCR issued a <u>Bulletin</u> to ensure that federally-funded entities would continue to comply with civil rights protections, including those designed to protect against race, color, and national origin discrimination. The bulletin provides illustrations of actions that covered entities should avoid, including hospital admission or intensive care unit rejections of persons on the basis of race.

Allocation schemes to mitigate COVID-19's disparate impact on non-white racial groups, particularly with respect to vaccine allocation, have <u>been suggested</u> both on the basis of the <u>Area Deprivation Index (ADI)</u> and the <u>Social Vulnerability Index</u> (indices which assess vulnerability or deprivation geographically); analyses indicate that the ADI may be preferable, but still may be subject to legal challenge.

A <u>study published on June 18, 2021</u> in JAMA Network Open directly questions the use of the Sequential Organ Failure Assessment (SOFA) score as a basis for rationing resources in CSC plans. Specifically, the authors concluded SOFA scores "are associated with overestimated mortality among Black patients compared with White patients, and this was associated with structural disadvantage for Black patients in CSC allocation systems."

On May 15, 2020, HHS OCR issued a <u>Bulletin</u> designed to ensure that covered entities continued fulfilling obligations to take "reasonable steps to providing meaningful access" to individuals with LEP.

Due Process Concerns

The <u>Institute of Medicine's 2012 System's Framework for Catastrophic Disaster Response</u> addressed due process concerns with respect to the decision among public sector hospitals or entities to withdraw/withhold treatment during an emergency.

New York state's ventilator guidelines expressly state: "[t]he Guidelines recognize that an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process." Most states' CSC plans include similar due process standards of varying degrees of specificity. Failure to adequately provide procedural due process standards in state or local CSC plans, or implement such practices in public sector entities, may result in constitutional challenges.

Whether or not patients may be transferred, from overwhelmed hospitals to those with more resources, and what means hospitals may use to decline transfers, are subject to EMTALA requirements and potentially applicable CMS waivers; though waivers will not allow action that discriminates on the basis of ability to pay.

Bodily Privacy Concerns

Implementation of emergency procedures without consent (by the patient or surrogate) may violate state health care laws and policies, as well as bodily privacy protections under federal or state constitutions.

The New York State Department of Health's 2015 <u>ventilator allocation guidelines</u> note that procedures performed in the absence of consent could trigger 4th Amendment privacy-related protections.

Though not implicated specifically during the COVID-19 pandemic, additional consent issues over decisions governing children or other "wards" of the state may arise in relation to allocation of limited resources, including to what extent mandatory testing can be considered minimally-invasive.

Liability

Decision-Related Liability

Liability for allocation-based decisions <u>may be assuaged</u> by emergency declarations and CSC invocations protecting against ordinary negligence claims.

Invocation of a declaration by HHS' Secretary pursuant to the federal PREP Act provides limited liability coverage for acts, *or omissions*, by individuals or entities in the administration of medical countermeasures (MCMs). This may include liability protections for failures to allocate MCMs to one patient over another.

Advance planning and provision of recommended actions in CSC plans, along with state and hospital recognition of the existence of the crisis and recommended use of such plans, may better serve to support provider actions as reasonable.

Liability claims may still arise, however, in cases where "a resource-such as a ventilator [is stripped] away from a person using it to another person with a more favorable prognosis." State CSC plans, such as in Arizona, expressly prohibit this practice. Additional federal and state statutory protections may apply.

Additional scenarios addressing liability which might arise include liability of expert panels contributing to CSC/triage plans that thereafter prove to be inaccurate; liability of practicing beyond scope in the absence of viable alternatives; and institutional liability for employee-related harms based on restrictions of personal protective equipment (PPE) or other resources.

Regulatory Concerns

Billing-related issues may arise in the midst of crisis. In one example, described in a <u>national survey</u> completed by HHS' Office of the Inspector General (OIG), hospital administrators reported "difficulty getting reimbursed for treating patients in non-traditional spaces because there were no qualifying billing codes when treating patients in these locations."

OCR Resolution of Civil Rights Complaints in State CSC Plans

The table below lists state- and entity-specific technical assistance or complaint resolutions issued by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) addressing civil rights protections and CSC/triage plans during the COVID-19 pandemic. Information is categorized by state, date, type of document, and the specific technical assistance/complaint resolution reached. Resolutions are quoted directly from OCR press announcements. The resolutions largely address age-based and disability-based discrimination.

State/Date	Document Type	Resolution
Arizona	OCR Provides Technical	Technical Assistance led to an updated CSC plan including:

State/Date	Document Type	Resolution
May 25, 2021	Assistance to the State of Arizona to Ensure Crisis Standards of Care Protect Against Age and Disability Discrimination	 "Prohibition on the use of a patient's long-term life expectancy as a factor in the allocation and re-allocation of scarce medical resources" "Prohibition on the use of categorical exclusion criteria, instead requiring an individualized assessment based on the best available objective medical evidence" "Prohibition on the use of resource-intensity and duration of need as criteria for the allocation or re-allocation of scarce medical resources" "Inclusion of reasonable modifications to the use of clinical instruments for assessing likelihood of short-term survival when necessary for accurate use with patients with underlying disabilities" "Inclusion of new protections against providers 'steering' patients into agreeing to the withdrawal or withhold life-sustaining treatment, clarifying that patients may not be subject to pressure to make particular advanced care planning decisions or require patients to consent to a particular advanced care planning decision in order to continue to receive services from a facility" "Inclusion of language ensuring that long-term ventilator users will be protected from having a ventilator they bring with them into a hospital setting taken from them to be given to someone else"
North Carolina, North Texas Mass Critical Care Guidelines Task Force, Southwest Texas Regional Advisory Council, Indian Health Service January 14, 2021	OCR Provides Technical Assistance to Ensure Crisis Standards of Care Protect Against Age and Disability Discrimination	 Technical Assistance led to an updated CSC plan including: "Prohibition on the use of a patient's long-term life expectancy as a factor in the allocation and re-allocation of scarce medical resources" "Prohibition on the use of categorical exclusion criteria, instead requiring an individualized assessment based on the best available objective medical evidence" "Prohibition on the use of resource-intensity and duration of need as criteria for the allocation or re-allocation of scarce medical resources" "Inclusion of language stating that reasonable modifications to the use of clinical instruments for assessing likelihood of short-term survival should be made when necessary for accurate use with patients with underlying disabilities" "Inclusion of new protections against providers 'steering' patients into agreeing to the withdrawal or withholding of life-sustaining treatment, clarifying that patients may not be subject to pressure to make particular advanced care planning decisions, must be given information on the full scope of available alternatives, and that providers may not impose blanket 'Do Not Resuscitate' policies for reasons of resource constraint, or require patients to consent to a particular advanced care planning decision in order to continue to receive services from a facility" "Inclusion of language stating that hospitals should not re-allocate personal ventilators brought by a patient to an acute care facility to continue pre-existing personal use with respect to a disability"
Utah August 20, 2020	OCR Resolves Complaint with Utah after It Revised Crisis	Technical Assistance led to an updated CSC plan to: "Remove prior language permitting the use of a patient's long-term life expectancy as a factor in the allocation and re-allocation of scarce medical resources, and instruct providers to remove such factors from existing provider CSC plans"

State/Date	Document Type	Resolution
	Standards of Care to Protect Against Age and Disability Discrimination	 "Remove categorical exclusion criteria on the basis of age, disability, and functional impairment, instead requiring an individualized assessment based on the best available objective medical evidence" "Rescind resource-intensity and duration of need as criteria for the allocation or re-allocation of scarce medical resources, and instruct providers to remove such factors from existing provider CSC plans" "Add language stating that reasonable modifications to the use of the state's primary instrument for assessing likelihood of short-term survival should be made when necessary for accurate use with patients with underlying disabilities" "Incorporate new protections against providers 'steering' patients into agreeing to the withdrawal or withholding of life-sustaining treatment, clarifying that patients may not be subject to pressure to make particular advanced care planning decisions, must be given information on the full scope of available alternatives, and that providers may not impose blanket 'Do Not Resuscitate' policies for reasons of resource constraint, or require patients to consent to a particular advanced care planning decision in order to continue to receive services from a facility" "Incorporate language stating that hospitals should not re-allocate personal ventilators brought by a patient to an acute care facility to
Tennessee June 26, 2020	OCR Resolves Complaint with Tennessee After it Revises its Triage Plans to Protect Against Disability Discrimination	 continue pre-existing personal use with respect to a disability" Technical Assistance led to an updated CSC plan which: "Clarified that resource-intensity and duration of need on the basis of age or disability should not be used as criteria for the allocation or reallocation of scarce medical resources" "Removed language permitting the use of a patient's long-term life expectancy as a factor in the allocation and re-allocation of scarce medical resources, instead indicating that providers should consider only risk of imminent mortality" "Added language stating that reasonable modifications to the use of the state's primary instrument for assessing the likelihood of short-term survival should be made when necessary for accurate use with patients with underlying disability" "Removed categorical exclusion criteria that prohibited people with disabilities from receiving care on the basis of their diagnosis, and required individualized assessments of patients based on the best available objective medical evidence" "Incorporated language stating that hospitals should not re-allocate personal ventilators brought by a patient to an acute care facility to continue pre-existing personal use with respect to a disability"
Pennsylvania April 16, 2020	OCR Resolves Civil Rights Complaint Against Pennsylvania After it Revises	 Technical Assistance led to an updated CSC plan: "Removing criteria that automatically deprioritized persons on the basis of particular disabilities" "Requiring individualized assessments based on the best available, relevant, and objective medical evidence to support triaging decisions"

State/Date	Document Type	Resolution
	its Pandemic	"Ensuring no one is denied care based on stereotypes, assessments of
	Health Care	quality of life, or judgements about a person's 'worth' based on the
	Triaging Policies	presence or absence of disabilities"
	to Protect	
	<u>Against</u>	
	<u>Disability</u>	
	Discrimination	
		Alabama's 2010 ventilator triage criteria allegedly allowed denying
	OCR Reaches	ventilators to persons with disabilities and also "appeared to reference age
	Early Case	as a potential category for exclusion."
	Resolution with	
Alabama	Alabama After it	After working with OCR, Alabama "agreed to remove all links to the 2010
	Removes	Criteria from its websites and to comply with applicable civil rights law. It
April 8, 2020	Discriminatory	has further agreed to clarify publicly that the 2010 Criteria are not in effect;
	<u>Ventilator</u>	that it will not, in future CSC guidelines, include similar provisions singling
	<u>Triaging</u>	out certain disabilities for unfavorable treatment or use categorical age
	<u>Guidelines</u>	cutoffs; and that it will also not interpret the current Guidelines in such a
		manner."

SUPPORTERS



Robert Wood Johnson Foundation

Support for the Network provided by the Robert Wood Johnson Foundation. The views expressed in this document do not necessarily reflect the views of the Foundation.

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June 2021