

# The Crisis Standards of Care in the US: Applications & Implications

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This memo reviews what the crisis standards of care (alternatively “CSC”) is and how it is implemented in the United States. This memo also includes CSC recommendations and implications set forth by medical associations for medical professionals and counsels.

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### I. What is crisis standards of care?

The Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations (hereinafter “the committee”), convened by the Institute of Medicine at the request of the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, defines CSC as following:

*“Crisis standards of care” is defined as a substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. This change in the level of care delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period. The formal declaration that crisis standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations.*

Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010), available at: <https://www.ncbi.nlm.nih.gov/books/NBK32748/>

The committee thus sought to guide the local health care systems as they make difficult decisions such as how to distribute scarce medical resources during urgent times. To do so, the committee identified the key elements that need to be addressed in CSC and developed a matrix that can be

used by the state and local public health officials “... as a framework for developing specific guidance for healthcare provider communities to develop and implement crisis standards of care.”<sup>1</sup>

## II. The Vision for crisis standard of Care

With the purpose to achieve a just and consistent healthcare system during the time of disaster, the committee set forth the following standards:

- Fairness—standards that are, to the highest degree possible, recognized as fair by all those affected by them (including the members of affected communities, practitioners, and provider organizations); evidence based; and responsive to specific needs of individuals and the population focused on a duty of compassion and care, a duty to steward resources, and a goal of maintaining the trust of patients and the community
- Equitable processes—processes and procedures for ensuring that decisions and implementation of standards are made equitably
  - Transparency—in design and decision making
  - Consistency—in application across populations and among individuals regardless of their human condition (e.g., race, age, disability, ethnicity, ability to pay, socioeconomic status, preexisting health conditions, social worth, perceived obstacles to treatment, past use of resources)
  - Proportionality—public and individual requirements must be commensurate with the scale of the emergency and degree of scarce resources
  - Accountability—of individuals deciding and implementing standards, and of governments for ensuring appropriate protections and just allocation of available resources
- Community and provider engagement, education, and communication—active collaboration with the public and stakeholders for their input is essential through formalized processes
- The rule of law
  - Authority—to empower necessary and appropriate actions and interventions in response to emergencies
  - Environment—to facilitate implementation through laws that support standards and create appropriate incentives

Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010)

## III. Recommendations for Crisis Standards of Care Protocols

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<sup>1</sup> Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010), available at: <https://www.ncbi.nlm.nih.gov/books/NBK32748/>

The committee placed a special importance in creating protocols that can be applied with consistency.<sup>2</sup> To encourage achievement of such consistent guideline for a state that could be used within the state as well as while working with other neighboring states, the committee provided five key elements of crisis standards of care protocols, organized by the following chart.

Key Elements of Crisis Standards of Care Protocols	Components
Ethical Considerations	<ul style="list-style-type: none"> <li>○ Fairness</li> <li>○ Duty to care</li> <li>○ Duty to steward resources</li> <li>○ Transparency</li> <li>○ Consistency</li> <li>○ Proportionality</li> <li>○ Accountability</li> </ul>
Community and provider engagement, education, and communication	<ul style="list-style-type: none"> <li>○ Community stakeholder identification with delineation of roles and involvement with attention to vulnerable populations</li> <li>○ Community trust and assurance of fairness and transparency in processes developed</li> <li>○ Community cultural values and boundaries</li> <li>○ Continuum of community education and trust building</li> <li>○ Crisis risk communication strategies and situational awareness</li> <li>○ Continuum of resilience building and mental health triage</li> <li>○ Palliative care education for stakeholders</li> </ul>
Legal Authority and Environment	<ul style="list-style-type: none"> <li>○ Medical and legal standards of care</li> <li>○ Scope of practice for healthcare professionals</li> <li>○ Mutual aid agreements to facilitate resource allocation</li> <li>○ Federal, state, and local declarations of: <ul style="list-style-type: none"> <li>Emergency</li> <li>Disaster</li> <li>Public health emergency</li> </ul> </li> </ul>

<sup>2</sup> Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010), available at: <https://www.ncbi.nlm.nih.gov/books/NBK32748/>

	<ul style="list-style-type: none"> <li>○ Special emergency protections (e.g., PREP Act, Section 1135 waivers of sanctions under EMTALA and HIPAA Privacy Rule)</li> <li>○ Licensing and credentialing</li> <li>○ Medical malpractice</li> <li>○ Liability risks (civil, criminal, Constitutional)</li> <li>○ Statutory, regulatory, and common-law liability protections</li> </ul>
	<ul style="list-style-type: none"> <li>○ Indicators for assessment and potential management</li> <li>Situational awareness (local/regional, state, national)</li> <li>Event specific: <ul style="list-style-type: none"> <li>- Illness and injury—incidence and severity</li> <li>- Disruption of social and community functioning</li> <li>- Resource availability</li> </ul> </li> </ul> <p>Triggers for action</p> <ul style="list-style-type: none"> <li>○ Critical infrastructure disruption</li> <li>○ Failure of “contingency” surge capacity (resource-sparing strategies overwhelmed) <ul style="list-style-type: none"> <li>Human resource/staffing availability</li> <li>Material resource availability</li> <li>Patient care space availability</li> </ul> </li> </ul>
Clinical process and operations	<p>Local/regional and state government processes to include:</p> <ul style="list-style-type: none"> <li>○ State-level “disaster medical advisory committee” and local “clinical care committees” and “triage teams”</li> <li>○ Resource-sparing strategies</li> <li>○ Incident management (NIMS/HICS) principles</li> <li>○ Intrastate and interstate regional consistencies in the application of crisis standards of care</li> <li>○ Coordination of resource management</li> <li>○ Specific attention to vulnerable populations and those with medical special needs</li> <li>○ Communications strategies</li> </ul>

	<ul style="list-style-type: none"> <li>○ Coordination extends through all elements of the health system, including public health, emergency medical services, long-term care, primary care, and home care</li> </ul>
	<p>Clinical operations based on crisis surge response plan:</p> <ul style="list-style-type: none"> <li>○ Decision support tool to triage life-sustaining interventions</li> <li>○ Palliative care principles</li> <li>○ Mental health needs and promotion of resilience</li> </ul>

TABLE B-1 Five Key Elements of Crisis Standards of Care Protocols and Associated Components, Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010), available at: <https://www.ncbi.nlm.nih.gov/books/NBK32748/table/nap12787.app2.t1/?report=objectonly>

Based on these elements, the committee recommends that states develop CSC by following these steps:

1. Outline Ethical Considerations: Convene a “Guideline Development Working Group” of appropriate stakeholders to establish ethical principles that will serve as the basis for the crisis standards of care.
2. Review Legal Authority for Implementation of Crisis Standards of Care: Review existing legal authority for the implementation of crisis standards of care and address legal issues related to the successful implementation of these standards, such as liability protections or temporary changes in licensure or certification status or scope of practice.
3. Develop Guidance for Provision of Medical Care Under State Crisis Standards of Care: Establish an “Advisory Committee” that will find a comprehensive set of materials to inform its deliberations in the “Indicators and Triggers” and “Clinical Process and Operations” sections of the report.
4. Conduct a Public Stakeholder Engagement Process: Although representatives of various healthcare and other interested professional groups and the public have been involved in drafting the ethical principles and crisis standards of care, a robust engagement process is also necessary to provide an opportunity for review and comment by the provider and public community at large. Particular attention should be paid to conduct outreach to and gather input from vulnerable populations, including those with medical special needs.
5. Establish a Medical Disaster Advisory Committee: During a disaster, this committee will provide ongoing advice to the state authority regarding changes to the situation and potential corresponding changes in the implementation of crisis standards of care.

Institute of Medicine (US) Forum on Medical and Public Health Preparedness for Catastrophic Events. Crisis Standards of Care: Summary of a Workshop Series, B: Summary of Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report (2010), available at: <https://www.ncbi.nlm.nih.gov/books/NBK32748/> (More details about each step, as well as recommendation can also be found here.)

#### IV. Application: Selective State Examples

Based on the guideline by the committee, states have devised their CSC guidelines. Examples of such state guidelines, where the crisis standards of care have been activated, can be found below:

##### **Alabama**

Alabama's Crisis Standards of Care Guidelines can be found at: <https://www.adph.org/CEPSecure/assets/alabamacscguidelines2020.pdf>

##### **Alaska**

The Yukon-Kuskokwim Health Corporation (hereinafter "YKHC") in Alaska has declared activation of CSC on September 29, 2021.<sup>3</sup> Its' guideline on CSC can be found at: [https://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/HumanCoV/SOA\\_DHSS\\_CrisisStandardsOfCare.pdf](https://dhss.alaska.gov/dph/Epi/id/SiteAssets/Pages/HumanCoV/SOA_DHSS_CrisisStandardsOfCare.pdf)

##### **Arizona**

Effective as of September 29, 2021, § 36-791 (Crisis standards of care plan; crisis guidelines or standards; requirements; modification of existing plan, guidelines or standards; definition) states:

- A. If the department of health services adopts or establishes a crisis standards of care plan or crisis guidelines or standards to address resource allocation when the demand for certain health care services exceeds the supply of necessary resources, the plan, guidelines or standards must include the following provisions:
  1. The allocation of health care resource decisions shall be made on the basis of valuing all life.
  2. A patient or the patient's health care decision maker has the right to make the patient's health care choices.
  3. Decisions on the allocation of health care resources may not discriminate on the basis of disability, age, race, religion, sex, veteran status or income status.
  4. Health care providers may consider only short-term survival when making decisions regarding the allocation of health care resources.
  5. Treatment resources may not be allocated based on any of the following:
    - (a) Quality of life judgments.
    - (b) Consideration of long-term mortality and long-term life expectancy.
    - (c) Resource intensity and duration of need due to disability or age.
  6. Each patient has the right to an individualized assessment on the basis of the best available objective medical evidence and not on assumptions about the patient's perceived health, preexisting conditions or medical diagnosis.

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<sup>3</sup> YKHC, Situation Reports: YKHC Activates Use of COVID-19 Clinical Guidelines (Sep. 29, 2021), available at: <https://www.ykhc.org/ykhc-activates-covid19-clinical-guidelines/>

7. Persons with disabilities and the aged have the right to reasonable modifications to ensure that all patients have equal access to medical care, including reasonable modification in patient assessment, communication and support needs due to disability or age.

8. A patient or the patient's family or health care decision maker has the right to appeal any triage decision.

B. A health care provider or health care institution staff member may not require a patient or the patient's health care decision maker to do either of the following:

1. Sign a do-not-resuscitate order.
2. Make a particular health care treatment decision.

C. The department of health services shall modify any existing crisis standards of care plan or crisis guidelines or standards within sixty days after September 29, 2021 to comply with the requirements of this section.

D. Representatives of the state protection and advocacy agency and advocates for the aged shall be members of the state disaster medical advisory committee, which is responsible for developing the crisis standards of care and other incident-specific priorities and guidance for delivering health care and using scarce medical resources during a public health emergency.

E. For the purposes of this section, "short-term survival" means a near-term survival from the episode of care that directly resulted from the illness or injury that required hospitalization.

Ariz. Rev. Stat. Ann. § 36-791

## **Hawaii**

David Y. Ige, Governor of the State of Hawai'i, by Executive Order NO. 21-06, including measures, such as, cancelling or postponing elective surgeries and procedures (1.d.) and providing immunity from civil liability for health care facilities and health care professionals, in good faith compliance with all federal and state orders, from any death or injury to persons or property caused by act or omission (3. & 4.). The order can be found at: [https://governor.hawaii.gov/wp-content/uploads/2021/09/2109007-ATG\\_Executive-Order-No.-21-06-distribution-signed.pdf](https://governor.hawaii.gov/wp-content/uploads/2021/09/2109007-ATG_Executive-Order-No.-21-06-distribution-signed.pdf)

## **Idaho**

In Idaho, CSC has been activated statewide by the Department of Health and Welfare on September 16, 2021, with each hospital in the state left with its own discretion to activate CSC according to their policies and standards.<sup>4</sup> Idaho's CSC guideline can be found at: [https://coronavirus.idaho.gov/wp-content/uploads/2020/10/Crisis-Standards-of-Care-Plan\\_Final\\_Posted\\_Signed.pdf](https://coronavirus.idaho.gov/wp-content/uploads/2020/10/Crisis-Standards-of-Care-Plan_Final_Posted_Signed.pdf)

## **Montana**

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<sup>4</sup> Crisis Standards of Care, Idaho Department of Health & Welfare (Sep. 16, 2021), available at: <https://healthandwelfare.idaho.gov/crisis-standards-care>

With sudden and uncontrollable increase in COVID-19 cases, Several hospitals, including Billings Clinic, the state’s largest hospital, St. Patrick Hospital in Missoula and St. Joseph Medical Center in Polson, have declared activation of CSC.<sup>5</sup>

Montana’s CSC guidance can be found at:

<https://dphhs.mt.gov/publichealth/cdepi/diseases/coronavirusmt/MontanaCrisisCareGuidanceFromMatter.pdf>

## V. Application: Physician’s Care

The AMA Code provided by American Medical Association (hereinafter “AMA set forth the following foundational guidance for developing ethically sound CSC guidelines:

Opinion 11.1.3, “Allocating Limited Health Care Resources,” along with Opinion 5.3, “Withholding or Withdrawing Life-sustaining Treatment,” provide guidance on making initial triage decisions about limited critical care resources for individual patients and for periodically reassessing those decisions.

- Triage decisions must be based on criteria related to medical need, not on non-medical criteria such as patients’ social worth.
- When criteria of medical need distinguish among patients, allocate limited resources first based on likelihood of benefit or to avoid premature death, and then to promote the greatest duration of benefit after recovery.
- When criteria of medical need do not substantially distinguish among patients, allocate limited resources by an objective and transparent mechanism, such as random choice or lottery to minimize potential bias, as opposed to “first come, first served,” which may unfairly privilege patients who have the means to seek care promptly.
- Periodically reassess ongoing life-sustaining treatments for all patients. When continued treatment is substantially unlikely to achieve the intended goal of care it may be withdrawn.
- Explain the policies and procedures by which triage decisions that allocate life-sustaining treatments are made and provide a process for appealing decisions when such treatments will be withheld or withdrawn.
- Palliative care must be provided when life-sustaining treatments are withheld or withdrawn.

Principle IX supports “access to medical care for all people” and Opinion 11.1.1, “Defining Basic Health Care,” states that “health care is a fundamental human good because it affects our opportunity to pursue life goals.”

- Triage protocols must be applied fairly and consistently for all patients.

Opinion 10.7, “Ethics Committees in Health Care Institutions,” and Opinion 10.7.1, “Ethics Consultation,” provide guidance for establishing “triage teams” or “triage officers” to take responsibility for implementing CSC guidelines for allocating resources, which may help to relieve treating clinicians of the moral burden such decisions impose and minimize conflicts among all relevant parties.

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<sup>5</sup> Justin Franz, Montana hospitals in ‘dire’ straits as COVID rages, Montana Free Press (Sep. 17, 2021), available at: <https://montanafreepress.org/2021/09/17/montana-hospitals-enter-crisis-care/>



- Triage teams should include members with expertise, experience, and perspective that are relevant in a public health emergency. Triage officers should similarly have appropriate expertise or training.
- Institutions should provide appropriate support to enable the triage team or officer to meet the needs of the institution and its patient population.

Opinion 8.3, “Physicians’ Responsibilities in Disaster Response and Preparedness,” recognizes physicians’ obligation to provide care even in the “face of greater than usual risk to [their] own safety, health or life,” and

Opinion 9.3.1 “Physician Health and Wellness,” states that when physician health is compromised, “so may the safety and effectiveness of the medical care provided.”

- Physicians and all workers who risk their health when responding to and caring for others have a strong ethical claim on resources that will preserve or restore their ability to work in the future. Triage protocols may ethically take this into account in directing decisions to allocate limited resources.

Opinion 5.4, “Orders Not to Attempt Resuscitation,” provides that, unless a patient explicitly declines it, cardiopulmonary resuscitation (CPR) should be provided. However, guidance in Opinion 8.3, “Physician Responsibilities in Disaster Response and Preparedness,” indicates that physicians also have a responsibility “to evaluate the risks of providing care to individual patients versus the need to be available to provide care in the future.”

- In public health emergencies, when CPR is unlikely to provide the intended clinical benefit and participating in resuscitation significantly increases already higher than usual risk for health care professionals, it may be ethically justifiable to withhold CPR without the patient’s consent.

AMA, Ethics, Crisis standards of care: Guidance from the AMA Code of Medical Ethics (Apr. 2020), available at: <https://www.ama-assn.org/delivering-care/ethics/crisis-standards-care-guidance-ama-code-medical-ethics>

## VI. Legal Implications: AAMC’s FAQs for Counsel

Association of American Medical Colleges (hereinafter “AAMC”) has provided a frequently-asked-questions guidelines for counsel:

### **What are crisis standards of care?**

Crisis standards of care guide decision-making designed to achieve the best outcome for a group of patients rather than focusing on an individual patient. According to a July 28, 2020 National Academies of Science Engineering & Medicine working group report, “[w]hen crisis conditions exist, the goal is to ‘gracefully degrade’ services to the minimum degree needed to meet the demands, maintaining the maximum patient and provider safety.”

### **How do crisis standards of care differ from other standards of care?**

Standards of care fall along a continuum of three levels. Conventional, or everyday, care is the norm. Contingency care involves adjustments to everyday care but the level of care

on an individual patient basis remains functionally equivalent. Crisis standards of care are applied when circumstances make it necessary to adjust the delivery of care.

### **What goals drive crisis standards of care?**

According to a March 28, 2020 NASEM working group report, crisis standards of care have the joint goals of “extending the availability of key resources and minimizing the impact of shortages on clinical care.”

### **What ethical principles are crisis standards of care grounded in?**

According to NASEM, crisis standards of care must uphold the following core principles:

1. Fairness (e.g., ensure consideration of vulnerable groups);
2. Duty to care (aided by distinguishing triage decision-makers from direct care providers)
3. Duty to steward resources (balances duty to community with duty to individual patient);
4. Transparency in decision making (candor and clarity about available choices as well as acknowledgement of the painful consequences of resource limitation);
5. Consistency (treating like groups alike through institution/system/region policies, with careful deliberation and documentation when local practices do not follow common guidance);
6. Proportionality (burdens should be commensurate with need and appropriately limited in time and scale); and
7. Accountability (maximizing situational awareness and incorporating evidence into decision-making).

### **What can be done to avoid needing to shift to crisis standards of care?**

It is inevitable that crisis standards of care mean an increase in morbidity and mortality, so planning and proactive resource adjustment (reuse, substitution, conservation, and administrative controls) should be employed to forestall the need for crisis standards of care as long as possible. One example is establishing Medical Operations Coordination Cells (MOCCs) to “load balance” patient surge among hospitals and regions. In another example from the Spring of 2020, health care professionals from other regions deployed to the Northeast to bolster capacity.

### **What should crisis standards of care include?**

When it’s no longer possible to “surge” to maintain normal care, a crisis standards of care plan for a hospital or health system should describe the incremental changes to the way health care – particularly critical care – will be delivered. A crisis standards of care plan should --

- provide expectations for how staff will be “stretched” to cover the demand for services as fairly as possible;
- define the role of any centralized team (incident command team, allocation team);
- direct how each facility will interact with other parts of the health system in its region;
- identify just-in-time clinical and resource support for bedside providers, including evidence-based care guidelines.

### **Is a Governor’s declaration necessary to deploy crisis standards of care?**

A Governor’s declaration can spur needed action among health departments and health care facilities, as well as aid in providing additional legal protections. However, the ability to provide care will change as demand outstrips available resources, even in the absence of a Governor’s declaration. A November 2020 “Lessons from New York City Hospitals’ COVID-19 Experience” report published by Johns Hopkins Center for Health Security recommends that crisis standards of care plans “must factor in that a formal declaration from the state may not be made in time and should include how to proceed without it.”

### **What is situational awareness and why is it so important for effectively implementing crisis standards of care?**

Situational awareness is having a current and accurate understanding about the supply of key resources in relation to actual patient demand. It is important for decision-makers, whether at the bedside or as part of a group, to know the current status of resources in determining the care for each patient. Health systems and institutions should prioritize the sharing and updating of this critical information among hospitals, across systems, and across a region or state, as well as at all levels of an institution.

### **What process for allocating insufficient resources or deciding whether an intervention like CPR is appropriate should be included in crisis standards of care?**

For each institution, ethical principles should be agreed upon and a decision-making process should be defined in advance, before allocation or intervention decisions are needed. The process and criteria should be clearly stated and widely shared, and an incident management team should be fully aware and in a position to make any needed adjustments. Guidance on critical care planning posted by HHS’s Assistant Secretary for Preparedness and Response advises that “[a]llocation decisions should ideally involve clinicians that are NOT the bedside provider.” The New York City Lessons Learned report New York City Lessons Learned report recommends that “[r]apid decision processes must be developed that involve the treating physician but also other physicians.”

### **Do crisis standards of care involve the engagement of families?**

Communicating with families in real-time is important so that there is a common understanding of what can be expected in terms of treatment options. Palliative care departments should be involved in end-of-life discussions, especially when resource triage issues are involved. End-of-life wishes should be documented.

### **How might crisis standards of care raise concerns about vulnerable and minority populations?**

The COVID-19 pandemic has disproportionately affected vulnerable and minority populations. To avoid disparities, most crisis standards of care guidelines explicitly prohibit prioritization of access to resources based on demographic factors. Plans should be especially careful in addressing factors that could be seen as constituting an unfair categorical exclusion. In one recent instance, on August 20, 2020, the HHS Office of Civil Rights announced it had resolved a complaint about the State of Utah’s crisis

standards of care. Utah agreed to stop using a patient’s long-term life expectancy as an allocation factor and agreed to remove age, disability, and functional impairment as bases for exclusion, in favor of requiring an individualized assessment based on the based available objective medical evidence.

**How are health care institutions managing legal liability in the context of crisis standards of care?**

Health care institutions are mitigating legal risk by developing and sharing widely a crisis standards of care plan that demonstrates a commitment to consistency in decision-making.

**What new liability protections may apply to decisions made under crisis standards of care?**

Some Governors and State legislatures have taken steps to extend liability protections in cases where resource constraints and patient demand attributable to the COVID-19 pandemic affect the delivery of care.

In April 2020, the Governor of Virginia issued Executive Order 60 declaring that “emergency and subsequent conditions caused by a lack of resources, attributable to the disaster [may] render the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency”, and explicitly referred to “implementation or execution of triage protocols necessitated by healthcare provider declaration of crisis standards of care.”

New York provides immunity for any health care facility or professional from civil or criminal liability for providing COVID-19 care in good faith, Article 30-D of New York's Public Health Law provides that “acts, omissions or decisions ... resulting from resource or staffing shortages” are within the scope of immunity.

Federal law provides additional liability protections to health care professionals who are serving as volunteers during the COVID-19 crisis (CARES Act, Pub. L. No. 116-136 (March 27, 2020)) or who are prescribe or dispense drugs and other covered products (referred to as “countermeasures”) to treat, diagnose, or prevent the onset of COVID-19 (PREP Act, 42 U.S.C. § 247d-6d).

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AAMC, Health Care: COVID-19 Crisis Standards of Care: Frequently Asked Questions for Counsel (Dec. 18, 2020), available at: <https://www.aamc.org/coronavirus/faq-crisis-standards-care>

**V. Legal Implications II: A case of *Smith by and through Smith v. Ivey***

The United States Court of Appeals, Eleventh Circuit, dismissed an appeal by M. R. Smith, by and through her sister J.R. Smith, for the district court’s dismissal of her complaint.<sup>6</sup>

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<sup>6</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

In 2017, Alabama’s Governor Kay Ivey published an updated Emergency Operations Plan, pursuant to Ala. Code § 31-9-6.<sup>7</sup> The Plan, among others, requested state agencies to produce a functional annex.<sup>8</sup> The problem was with the Annex provided by the Alabama Department of Public Health’s Annex, a part of Emergency Support function 8, which included protocol for mechanical ventilator triage in case of statewide emergencies.<sup>9</sup> Along with other instructions, a part of the protocol specified that “[p]ersons with severe or profound mental retardation... are unlikely candidates for ventilator support.”<sup>10</sup>

In 2019, as Alabama’s new Crisis Standards of Care Working Group was advised that the criteria was not appropriate, the Annex has been subsequently removed from the new Crisis Standard of Care, although it has remained available online for a while.<sup>11</sup> In March 2020, as the COVID-19 pandemic worsened, the Office for Civil Rights and the United States Department of Health and Human Services investigated the matter pursuant to a complaint filed by disability advocacy organizations<sup>12</sup>, but closed its investigation once Alabama agreed to remove the Annex from the Internet and make public declaration that such criteria will not be implemented in the future.<sup>13</sup>

M.R. Smith, a profoundly mentally disabled individual, by and through her sister J.R. Smith, has filed complaint that the criteria violated her constitutional rights, requesting that the court issue a declaratory judgment that the Annex is null and void and in violation of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973, as well as that the Annex has violated her constitutional rights under 42 U.S.C. §1983.<sup>14</sup> The district court dismissed the complaint, finding no injury as the Emergency Operation Plan was no longer in effect.<sup>15</sup> Smith argued otherwise, arguing that the state, as it did not officially revoke the Annex with the ventilator triage protocol. The Court of Appeals, affirming the decision of the district court, found that the Annex is not a rule that needs to be under the Alabama Administrative Procedure Act that must be officially repealed nor is Annex promulgated as a rule under the Alabama Emergency Management Act under Ala. Code §§ 31-9-6(2).<sup>16</sup> Simply put, the court found that the state’s express renunciation of the Annex was sufficient.<sup>17</sup>

The case presents two points for considerations. First, the case demonstrate when states make guidelines for crisis of standards of care, whether certain parts of the guideline can be considered a part of a law or not, may a significant point of legal dispute. Second, some standards, as in the revoked ventilator triage protocol in Alabama, may become an object of legal dispute if they, in assigning priority, may violate constitutional rights of some groups of people.

In fact, Along with those on Alabama’s discriminatory practice<sup>18</sup>, in 2020, disability advocacy organizations have filed a complaint to U.S. Department of Health and Human Services, Office for Civil Rights, alleging discriminatory practice in its crisis standard of care in

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<sup>7</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>8</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>9</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>10</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>11</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>12</sup> [http://thearc.org/wp-content/uploads/2020/03/AL-OCR-Complaint\\_3.24.20.docx.pdf](http://thearc.org/wp-content/uploads/2020/03/AL-OCR-Complaint_3.24.20.docx.pdf)

<sup>13</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>14</sup> At \*1252, *Smith by & through Smith v. Ivey*, 501 F. Supp. 3d 1248, 1252 (M.D. Ala. 2020), *aff’d*, No. 20-14765, 2021 WL 3074120 (11th Cir. July 21, 2021)

<sup>15</sup> At \*1, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>16</sup> At \*2, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>17</sup> At \*2, *Smith by & through Smith v. Ivey*, No. 20-14765, 2021 WL 3074120, at \*1 (11th Cir. July 21, 2021).

<sup>18</sup> [http://thearc.org/wp-content/uploads/2020/03/AL-OCR-Complaint\\_3.24.20.docx.pdf](http://thearc.org/wp-content/uploads/2020/03/AL-OCR-Complaint_3.24.20.docx.pdf)

the state of Washington<sup>19</sup>, Tennessee<sup>20</sup>, Utah<sup>21</sup>, Oklahoma<sup>22</sup>, North Carolina<sup>23</sup>, Oregon<sup>24</sup>, Arizona,<sup>25</sup> and Texas.<sup>26</sup> The number of complaints in regard to unfair treatment in crisis standard care may indicate that while *Smith by & through Smith v. Ivey* have been dismissed on the grounds for standing, many more cases like it may be expected.

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<sup>19</sup> [http://thearc.org/wp-content/uploads/2020/03/OCR-Complaint\\_3-23-20.pdf](http://thearc.org/wp-content/uploads/2020/03/OCR-Complaint_3-23-20.pdf)

<sup>20</sup> <http://thearc.org/wp-content/uploads/2020/03/2020-03-27-TN-OCR-Complaint-re-Healthcare-Rationing-Guidelines.pdf>

<sup>21</sup> <http://thearc.org/wp-content/uploads/2020/04/Utah-HHS-OCR-Complaint.pdf>

<sup>22</sup> <http://thearc.org/wp-content/uploads/2020/04/4.21-Oklahoma-OCR-Complaint-Final.pdf>

<sup>23</sup> <http://thearc.org/wp-content/uploads/2020/05/HHS-OCR-Complaint-North-Carolina.pdf>

<sup>24</sup> <http://thearc.org/wp-content/uploads/2020/05/HHS-OCR-Complaint-Oregon.pdf>

<sup>25</sup> <http://thearc.org/wp-content/uploads/2020/07/HHS-OCR-Complaint-re-Crisis-Standards-of-Care-Arizona.pdf>

<sup>26</sup> <http://thearc.org/wp-content/uploads/2020/07/HHS-OCR-Complaint-Re-Crisis-Standards-of-Care-North-Texas.pdf>