Crisis Standards of Care Considerations: Legal/Regulatory

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Healthcare providers often face legal challenges during and after public health emergencies (PHEs) (e.g., COVID-19 pandemic, regional disease outbreaks) and other crisis conditions (e.g., natural disasters, medical supply shortages).

These emergencies also raise palpable fears among healthcare providers of legal liabilities, license infractions, personal injuries, loss of career or reputation, and associated delays in providing medical services. ASPR TRACIE identified the following legal and regulatory issues as particularly challenging for healthcare providers and facilities.

Limited Healthcare Provider Liability Protections

Federal and state laws often bestow broad legal protections to healthcare providers during declared emergencies or disasters via legislative, regulatory, and judicial routes.[1] While there are many prospective options to provide some level of liability protections, they may be limited in specific contexts including:

- Persons (e.g., volunteers, nurses, Disaster Medical Assistance Team [DMAT] personnel);
- Entities (e.g., DMAT teams, volunteer entities);
- Settings (e.g., hospitals, public health clinics); and
- Duration (e.g., only for the extent of the declared emergency).

In practice, facilities may operate in crisis conditions well before an emergency or disaster is formally declared or regulatory relief is provided. Crisis conditions may also persist after an emergency or disaster declaration is terminated. During the COVID-19 pandemic, emergency liability protections were terminated in some states prior to the most challenging waves of disease. Some crisis situations – such as drug shortages or seasonal increases in demand for pediatric beds – do not result in emergency or disaster declarations or regulatory relief. Some providers and facilities may have to make medical or public health decisions without knowing if they are fully protected from potential liability.

Furthermore, healthcare provider liability protections may only apply to the actual provision of medical care. Thus, provision of expert consultation to a facility caring for a patient awaiting transfer or to a state recommending resource allocation guidelines may not be protected. Lack of protections for healthcare provider advice during crises can inhibit equitable access to care across regions or development of standardized, consistent crisis standards of care (CSC) guidelines.

Additionally, protection from liability for patient care decisions does not provide relief for civil rights violations. In some cases, disability (including age) and discrimination against selected racial, social, or other

[1] The Network for Public Health Law. (2017). Legal Liability Protections for Emergency Medical/Public Health Responses.

disadvantaged groups can be subject to state and federal civil rights claims. Civil rights claims are generally not capped for damages in the same way that other claims may be under state law or order. The provider and facility must be careful to avoid patient-based discrimination through individual assessments of short-term prognosis that do not take factors into account that could be alleged to be discriminatory.

Inconsistencies among liability protections applicable to different providers presents additional challenges. Governmental employees (and those acting on behalf of a state/jurisdiction [e.g., Medical Reserve Corps volunteers]) may have greater insulation from liability than privately-employed medical providers or spontaneous volunteers, even though they work side-by-side during emergencies. Federal protections for healthcare providers include those deployed as temporary federal employees (e.g., DMAT members),[2] volunteer health providers, and persons acting pursuant to protections conferred via the Public Readiness and Emergency Preparedness (PREP) Act. When invoked, the PREP Act largely provides liability protections for entities and persons administering vaccines and other medical countermeasures.[3]

Though volunteers generally have less liability exposure than employees, they also generally have less workers' compensation and other protections in case of illness or injury. Volunteers should understand their protections and coverage prior to committing to deployment.

Constraints on Withdrawal of Care

Hospitals and healthcare providers may be challenged in the administration of policies related to the provision of futile or non-beneficial care in crises. While laws may support hospital withdrawal of care policies during emergencies, complex legal and administrative processes initiated by families opposing de-escalation of care can delay key decisions in real-time.

Some courts have prevented healthcare facilities from implementing medical triage practices based on established CSC principles. One court prevented a hospital from discontinuing futile care to a patient as determined by a hospital's routine processes during a COVID-19 surge even as many patients elsewhere awaited intensive care beds for transfer.[4] Conversely, another court's decision issued during a non-emergency entailing non-beneficial care case noted the need to balance patient access to resources with community needs.[5] These inconsistencies complicate interpretations of and adherence to CSC principles.

Lack of Licensure Portability

While the availability of interstate medical license recognition is improving post-COVID, physicians, nurses, pharmacists, behavioral health workers, and other licensed providers continue to face barriers to working across state lines in emergencies or disasters, and the ability to assist in the absence of state declarations is even more difficult. Insufficient medical licensure reciprocity, background check requirements, and differences in licensure requirements between states limit deployments of qualified personnel to areas of need. Facilities unable to rapidly verify credentialing and privileging of providers lends to further delays that inhibit staff onboarding and strain hospital staffing resources.

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[2] U.S. Department of Labor. (2024). USERRA – Uniformed Services Employment and Reemployment Rights Act.
[3] ASPR. (2024). Public Readiness and Emergency Preparedness (PREP) Act.
[4] Harlow, T. (2022). Mercy Hospital Must Keep COVID Patient on Ventilator, Judge Rules. The Minnesota Star Tribune.
[5] Hart vs. Hennepin County Medical Center, Hennepin County District Court 27-CV-23-9164.

Federal and State Regulatory Action

Routine conditions of participation required by the federal Centers for Medicare & Medicaid Services (CMS) and state agencies may be impossible to meet during CSC. Regulations designed to protect patients during typical operations may limit the ability of hospitals and their staff to maximally use space and meet patient needs during crisis. Hospital transparency regarding crisis conditions is essential to allocating resources across affected regions. CMS offers legal waivers during crises to help hospitals screen and treat patients as well as bill for services rendered under adaptive conditions.[6] Despite the need for transparency about the crisis conditions in order to grant available regulatory relief, maintain situational awareness, and allocate available assets fairly, hospitals may still be reluctant to report staff, space, and system shortages and adaptations over fears of regulatory inspections and legal sanctions, including liability.

Considerations for Action

ASPR TRACIE identified the following considerations for providers, facilities, and decision-makers to ease or resolve legal issues during crisis conditions:

1. Recognize that implementation of CSC may entail prospective liability risks which fall outside legal protections especially prior to or after formally-declared emergencies or disasters.
2. Ensure those providing crisis care understand what liability protections apply to them based on their employment or volunteer status, type of employer, location, setting, and federal or state laws.
3. Extend liability protections to healthcare providers offering expert consultations to other providers or who contribute to developing standardized care guidelines.
4. Establish consistent policies on futile, non-beneficial, and inappropriate care to allow streamlined decision-making based on patient characteristics and available resources.
5. Clarify statutory or executive actions to protect withdrawal of care determinations from protracted and unwarranted legal "red tape" during crises.
6. Pursue adoption of interstate licensure compacts to facilitate the provision of a full range of health care across a wide variety of providers.
7. Examine options for temporary practice non-disaster license recognition.
8. Expedite processes at the healthcare facility/system level to rapidly verify credentials and privilege healthcare providers.
9. Forego unwarranted regulatory inspections and actions against facilities voluntarily reporting implementation of contingency and crisis standards of care during emergencies.

Providing continuity of health care during crises is challenged by scarcity of resources and concerns over liabilities, penalties, or regulatory repercussions that can increase provider and patient stresses and affect outcomes. Balancing these considerations helps decision-makers create policies to ensure patient care is provided by clinicians supported and protected in their roles.

Access the other documents in this collection:

- CSC Considerations: De-Escalation of Care
- CSC Considerations: Non-Beneficial Care
- CSC Considerations: Pharmaceutical/Supply Shortages
- CSC Considerations: Recognizing and Mitigating Crisis Care
- CSC Considerations: Reducing Provider Distress

[6] CMS. (2024). 1135 Waivers.