

RESEARCH BRIEF #10-01

Crisis Standards of Care

Executive Summary:

This document represents the first in a series of research briefs designed to provide concise analyses of the most pressing disaster-related legal, regulatory, and policy issues facing MESH coalition members. Research Brief #10-01 is particularly relevant to healthcare providers and their counsel given the legal uncertainties associated with providing direct medical care during a disaster. Key findings indicate:

1. There is a growing movement calling for the development of “crisis standards of care” explicitly linked to provider immunity.
2. There is presently a lack of consensus in the academic, medical, and legal communities regarding “standard of care” terminology.
3. There is significant debate regarding the need for additional limitations on provider liability as a means to encourage response.
4. There is uncertainty as to what level of government should administer such protections if deemed necessary.

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Background

In 2004, the Agency for Healthcare Research and Quality (“AHRQ”) and the Assistant Secretary for Preparedness and Response (“ASPR”) convened a panel of experts to examine the need for altered standards of medical care during a mass casualty event.¹ The panel’s report largely addressed clinical issues (e.g., triage protocols, resource allocation guidelines, etc.); however, it also identified provider liability as an issue affecting care delivery.² Accordingly, the panel called for consideration of “mechanisms to allow for legal, regulatory, or accreditation adjustments” in a number of areas, including liability for care provided under stress with diminished resources; certification, licensing and scope of practice; institutional autonomy; facility standards; patient privacy and confidentiality; documentation of care; property seizures; and protocols for quarantine or mass immunization.³

Since the release of AHRQ’s report, few states have developed protocols for altered standards of medical care.⁴ Indiana has taken a leadership role in this area, as evidenced by the Indiana State Department of Health’s (“ISDH”) publication of *Altered Standards of Care Guidance with an Emphasis on Pandemic Influenza* in 2008.⁵ Created as a guide for hospital policymakers, this document recommends development of consistent procedures for allocation of scarce resources, particularly medical ventilators, in the event of an officially declared public health emergency.⁶ ISDH suggests that all rationing determinations be based on an ethical framework, coupled with clinical algorithms that attempt to “prioritize triage decisions regarding patients initially requiring ventilators over increasing the number of ventilators through withdrawal of ventilators from those patients who are currently mechanically ventilated.”⁷

In August 2009, ASPR requested that the Institute of Medicine (“IOM”) convene an ad hoc committee to provide national framework guidance for “state and local public health officials, healthcare facilities, and professionals in the development of systematic and comprehensive policies and protocols for standards of care in disasters where resources are scarce.”⁸ Phase 1 of this two-phase activity called for: (1) identification of key elements to be included in standards of care protocols; (2) identification of potential triggers for use by public health officials to develop standards of care protocols; and (3) creation of a template for use by public health officials when developing guidance for provider communities developing standards of care.⁹ Further, the Committee was directed to consider the roles, responsibilities, and views of various stakeholders, as well as general ethical principles, in development of its guidance.¹⁰

The Committee published its preliminary guidance in a Letter Report entitled *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations*.¹¹ Noting that ethical goals in medical care are absolute and that health care professionals are obligated to provide the best possible care regardless of the circumstances, the Committee recommended “crisis standards of care” as the optimal level of care that can be delivered during a disaster.¹² These standards were 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.¹³

Based on an assessment of various state, federal, and international protocols, published literature, and available guidance documents, the Committee offered the following recommendations to assist states in the early stages of developing crisis standards of care:

1. Relevant state agencies should collaborate with localities to develop crisis standards of care protocols that include a strong ethical grounding, integrated community and provider involvement, legal assurances, clear triggers and lines of responsibility, and evidence-based clinical processes.¹⁴
2. Healthcare providers should adhere to ethical norms when crisis standards of care are in effect.¹⁵
3. State, local, and tribal governments should collaborate with community and provider stakeholders, paying special attention to the needs of vulnerable and medical special needs populations.¹⁶
4. State or tribal governments should enable appropriate agencies to institute crisis standards of care, adjust licensed or credentialed providers' scopes of practice, and alter licensure and credentialing practices to encourage provider response.¹⁷
5. States should collaborate with the federal government and localities to develop communications processes that ensure both intrastate and interstate consistency in the implementation of crisis standards of care.¹⁸
6. Relevant state agencies should collaborate with localities to ensure consistent implementation of crisis standards of care.¹⁹

The Committee concluded its Letter Report by noting the need for additional discussion, evaluation, and study, particularly in areas where barriers might “make implementation and operationalization of crisis standards of care difficult to achieve.”²⁰ As such, Phase 2 of the activity will include a deliberative effort to increase stakeholder engagement, as well as an update and expansion of Phase 1 guidance based on provider community and public feedback.²¹ The Committee is required to publish its Final Report in November 2010, in accordance with ASPR’s project requirements.²²

Discussion

Liability resulting from alleged civil, criminal, and Constitutional violations is a basic concern for all healthcare providers—one that may be heightened during a disaster.²³ The IOM Letter Report asserts that “[a]bsent national comprehensive liability protections, state and local governments should explicitly tie existing liability protections (e.g., through immunity or indemnification) for healthcare practitioners and entities to crisis standards of care.”²⁴ However, significant concerns exist regarding terminology, the need for expanded provider protections, and administration of said protections if deemed necessary.

Terminology

There is presently a lack of consensus in the academic, medical, and legal communities regarding “standard of care” terminology. In its Letter Report, the IOM Committee seeks to distinguish between the medical standard of care (defined as the “type and level of medical care required by professional norms, professional

requirements, and institutional objectives”) and the legal standard of care (defined as “the care and skill that a healthcare practitioner must exercise in particular circumstances based on what a reasonable and prudent practitioner would do in similar circumstances”).²⁵ Given the flexible nature of the latter, the Committee asserts that legal standards of care are “subject to differing interpretations nationally,” and do not lead to predictable outcomes in legal disputes.²⁶ Therefore, states should formally recognize situations when crisis standards of care are necessary, and tie such standards to immunity provisions for healthcare practitioners in order to alleviate “actual or perceived risks of liability.”²⁷

Opponents of the IOM Committee’s position criticize the attempt to distinguish between medical and legal standards of care, citing several key arguments. First, organizations seeking to develop guidelines for emergencies are addressing a need for modified standard procedures, not altered standards of care.²⁸ As the standard of care is inherently flexible, it need not be “altered” during a disaster. In other words, there is no altered standard of care, only altered circumstances.²⁹ Second, customary medical practice does not conform to a precisely defined concept; rather it is variable and based on environmental and demographic factors, cultural expectations, and reimbursement patterns.³⁰ Finally, the Committee’s failure to reference applicable litigation undermines its premise that courts differ in their interpretation of the legal standard of care.³¹

Need for Provider Protections

Frontline provider participation will be critical to maintaining a functioning healthcare system during a disaster. Therefore, the IOM Letter Report states that “[l]aws and the legal environment must . . . create incentives for healthcare practitioners to care for affected populations,” such as liability protections tied to crisis standards of care that “provide immunity or indemnify practitioners for acts that constitute *gross negligence, willful or wanton misconduct, or crimes.*”³²

Opponents of comprehensive immunity provisions cite a lack of data to support the IOM’s assertion that providers will not respond without legal safeguards, and specifically note the ambiguity of recent surveys and historical reviews,³³ as well as various perceptual and physical barriers.³⁴ In addition, opponents reference numerous mechanisms that already limit provider liability during a disaster. First, certain state protections may be available to providers who act in good faith and without willful misconduct, gross negligence, or recklessness, when responding to an emergency (e.g., “Good Samaritan” statutes, Volunteer Protection Acts, and Tort Claims Acts).³⁵ Second, the Public Readiness and Emergency Preparedness Act, and Section 1135 of the Social Security Act, both allow for limitations on provider liability following the formal declaration of a disaster by the federal government.³⁶ Third, formal disaster declarations by state governments often trigger statutory immunity provisions for negligent conduct on the part of emergency and public health workers.³⁷ Generally, legislatures link these provisions to compliance with government instructions, contracts, or other legal requirements; public health statutes; or emergency statutes.³⁸

Indiana follows the above model, as provider liability protections are tied to the State’s Emergency Management and Disaster Laws. Specifically, the governor is authorized to declare a disaster emergency if it is determined that one has occurred or is imminent.³⁹ This declaration remains in effect no longer than thirty days, unless renewed or terminated by executive order, or terminated by the general assembly by concurrent resolution.⁴⁰ Though not linked to an “altered standard of care,” clinicians who provide services within the scope of their license, at a location where health care services are provided during a declared disaster emergency, are immune from civil liability absent gross negligence or willful misconduct.⁴¹ This protection is available retroactively to the occurrence of the event, and is also applicable to facilities or other locations providing healthcare services.⁴²

State v. Federal Approach

To the extent that liability protections affect provider response, the importance of, and ability to achieve, consistency among the states is debated. As noted, the IOM's Letter Report was "intended to assist federal, tribal, state, and local officials . . ."⁴³ In addition, the Committee generally assumed that disaster events would be handled primarily at the state level.⁴⁴ Opponents of this state-based approach argue that no disaster could possibly be managed by a single state, as circumstances requiring providers from other states invariably require federal intervention.⁴⁵ Therefore, if it were determined that a comprehensive liability scheme is necessary to ensure sufficient provider response during a disaster, a federal solution may be required to ensure uniformity of such protections.⁴⁶

Conclusion

Public policies that empower healthcare providers to act in the public interest during a disaster are critical to an effective emergency response; however, it is arguable whether such policies should directly infringe on patients' opportunity for redress should they suffer harms as a result of provider negligence. Given the lack of consensus regarding "standard of care" terminology, debate as to the need for expanded limitations on provider liability as a means to encourage response, and uncertainty as to what level of government (i.e., state or federal) should administer such protections if deemed necessary, further research is required. As such, MESH will continue to follow this debate closely and will update coalition members of any important developments.

Please contact Bobby Courtney, MESH Legal/Public Health Intern, at bobcourt@iupui.edu, with any questions.

¹ See generally AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, NO. 05-0043, ALTERED STANDARDS OF CARE IN MASS CASUALTY EVENTS (2005), available at <http://www.ahrq.gov/research/altstand/altstand.pdf>.

² *Id.* at 2-3.

³ *Id.* at 24-25.

⁴ See e.g., UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, GAO-08-668, EMERGENCY PREPAREDNESS: STATES ARE PLANNING FOR MEDICAL SURGE, BUT COULD BENEFIT FROM SHARED GUIDANCE FOR ALLOCATING SCARCE MEDICAL RESOURCES 5-6, 21-2 (2008), available at <http://www.gao.gov/new.items/d08668.pdf> (The GAO's twenty-state survey found that seven states had adopted, or were in the process of drafting, altered standards of care for specific medical issues.).

⁵ See INDIANA STATE DEPARTMENT OF HEALTH, ALTERED STANDARDS OF CARE COMMUNITY ADVISORY GROUP, ALTERED STANDARDS OF CARE GUIDANCE WITH AN EMPHASIS ON PANDEMIC INFLUENZA (Draft Document for Review and Comment, August 2008), available at http://www.in.gov/isdh/files/ASC_FINAL%28twb%29%2808_18_2008%29.pdf [hereinafter ISDH].

⁶ *Id.* at 3, 11 (Though largely focused on allocation of medical ventilators, the ISDH guide briefly notes that "altered standards also refer to the use of supplies and equipment," which "may be rationed and used in ways consistent with achieving the ultimate goal of saving the most lives." Specifically, facilities are encouraged to implement existing re-use procedures and to "make treatment decisions based on clinical judgment if laboratory resources or radiology resources are exhausted.")

⁷ ISDH, *supra* note 2, at 6-7.

⁸ INSTITUTE OF MEDICINE, GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT 10 (Washington, D.C: National Academies Press, 2009), available at http://www.nap.edu/openbook.php?record_id=12749&page=R1 [hereinafter IOM GUIDANCE].

⁹ *Id.* at 1.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at 18.

¹³ *Id.*

¹⁴ *Id.* at 20.

¹⁵ *Id.* at 36.

¹⁶ *Id.* at 40.

¹⁷ *Id.* at 47.

¹⁸ *Id.* at 75.

¹⁹ *Id.* at 89-90.

²⁰ *Id.* at 91.

²¹ *Id.* at 71.

²² *Project: Standards of Care for Use in Disaster Situations*, THE NATIONAL ACADEMIES, <http://www8.nationalacademies.org/cp/projectview.aspx?key=49130> (last visited July 28, 2010).

²³ IOM GUIDANCE, *supra* note 5, at 48. See generally CAROL K. KANE, AMERICAN MEDICAL ASSOCIATION, MEDICAL LIABILITY CLAIM FREQUENCY: A 2007-2008 SNAPSHOT OF PHYSICIANS (2010) (noting that over the course of a career, 61% of physicians age 55 and older had been sued, with an average of 1.6 claims per physician).

²⁴ IOM GUIDANCE, *supra* note 5, at 49.

²⁵ *Id.* at 45.

²⁶ *Id.*

²⁷ *Id.*

²⁸ George Annas, *Standard of Care—In Sickness and in Health and in Emergencies*, 362 N. ENGL. J. MED. 2126, 2128-9 (2010) (Professor Annas notes that while physicians determine practice standards as a profession, there are two exceptions to this general rule, neither of which undermine it.). See generally INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Washington, D.C: National Academies Press, 1990), available at http://www.nap.edu/openbook.php?record_id=1626&page=R1 (The IOM classifies medical standards of care as: 1) standards of quality (minimum acceptable level of performance), clinical practice guidelines (systematically developed statements to assist practitioner decision-making in specific settings), medical review criteria (statements to assess appropriateness of practitioner decision-making), and performance measures (quantitative measures to monitor compliance with quality standards, clinical practice guidelines, and medical review criteria).).

²⁹ Annas, *supra* note 25, at 2128-9.

³⁰ George Annas & F. Miller, *The Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., the U.K., and Japan*, 20 AM. J. L. & MED. 357, 381-3 (1994).

³¹ Annas, *supra* note 25, at 2129.

³² IOM GUIDANCE, *supra* note 5, 49 (emphasis added).

³³ See INSTITUTE FOR BIOETHICS, HEALTH POLICY AND LAW UNIVERSITY OF LOUISVILLE SCHOOL OF MEDICINE, QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS: A REPORT TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION (2003), available at <http://www.iaclea.org/members/pdfs/SARS%20REPORT.Rothstein.pdf> (noting that countries where medical malpractice liability is not a significant physician concern also experienced unwillingness of some providers to respond during the SARS outbreak of 2003); G. Caleb Alexander & Matthew K. Wynia, *Ready and Willing? Physicians' Sense of Preparedness for Bioterrorism*, 22 HEALTH AFF. 189 (2003) (noting that 80 percent of surveyed physicians affirmed a willingness to treat affected patients during an "unknown but potentially deadly" outbreak); George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 N. ENGL. J. MED. 1337 (2002) (noting that healthcare providers showed no reluctance to cooperate in the response to the September 11 attacks or the anthrax attacks that followed); Charles DiMaggio, *The Willingness of U.S. Emergency medical Technicians to Respond to Terrorist Incidents*, 3 BIOSECURITY & BIOTERRORISM 331 (2005) (concluding that basic and paramedic emergency medical service providers were considerably less willing than able to respond to smallpox outbreaks, chemical attacks, or radioactive dirty bombs); M. J. Erwin, et al., *Health Care Workers' Ability and Willingness to Report to Duty During Catastrophic Disasters*, 82 J. URB. HEALTH 378 (2005) (concluding that health care workers were most willing to report during a mass casualty incident or environmental disaster, as compared to a SARS outbreak, radiological event, smallpox epidemic, or chemical event); Kenneth V. Iserson, et al., *Fight or Flight: The Ethics of Emergency Physician Disaster*

Response, 51 ANN. EMERG. MED. 345 (suggesting that although individual physicians may be unpredictable in the face of danger, they generally tend to stay and treat patients despite personal risks).

³⁴ Daniel J. Barnett, et al., *Applying Risk Perception Theory to Public Health Workforce Preparedness Training*, J. PUB. HEALTH MGMT. PRACTICE, Nov. (Supp.), at 34-35 (Perceptual barriers may include family member safety, working environment safety, and unclear expectations of role-specific emergency response requirements as perceptual barriers. Physical barriers may include inadequate transportation access to emergency response worksites or lack of backup caregivers for dependents.).

³⁵ Jennifer Ray, Office of the General Counsel, Department of Health and Human Services, Federal Public Health Emergency Law: Implications for State and Local Preparedness and Response (Apr. 28, 2009) (transcript available at http://www2a.cdc.gov/phlp/webinar_04_29_2009.asp). See also NONPROFIT RISK MANAGEMENT CENTER, STATE LIABILITY LAWS FOR CHARITABLE ORGANIZATIONS AND VOLUNTEERS (2009), available at <http://nonprofitrisk.org/downloads/state-liability.pdf> (provides a comprehensive summary of state statutory and common law liability protections for volunteers).

³⁶ See Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified at 42 U.S.C. 247d-6d) (PREP provides tort liability protection to all involved in the development, distribution, and deployment of covered countermeasures used to protect the public in the event of a pandemic or epidemic, absent willful misconduct.); 42 U.S.C. § 1320b-5 (2010) (Section 1135 permits the Secretary of Health and Human Services to waive certain regulatory requirements for healthcare facilities in response to emergencies. Requirements include, but are not limited to state-specific provider licensing requirements, EMTALA requirements, certain prohibitions on physician referrals, and the Health Insurance Portability and Accountability Act.).

³⁷ Sharona Hoffman, *Responders' Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L.J. 1913, 1923-24, 1946-50 (2008). See also Emergency Management Assistance Compact, Pub. L. No. 104-321, 110 Stat. 3877 (Oct. 19, 1996), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=104_cong_public_laws&docid=f:publ321.104.pdf, BRUCE R. LINDSAY, CONG. RESEARCH SERV., RL 34585, THE EMERGENCY MANAGEMENT ASSISTANCE COMPACT (EMAC): AN OVERVIEW (2008). (EMAC is a Congressionally approved mutual aid agreement whereby states requesting assistance with a formally declared emergency agrees to indemnify a responding state for any liability incurred by its employees, absent willful misconduct, gross negligence, or recklessness. Presently, all fifty states, the District of Columbia, the Virgin Islands, Puerto Rico and Guam, are parties to the agreement.).

³⁸ Hoffman, *supra* note 34, at 1946-50.

³⁹ IND. CODE ANN. § 10-14-3-12 (LexisNexis 2010).

⁴⁰ *Id.*

⁴¹ *Id.* at § 34-30-13.5-1, -3.

⁴² *Id.* at § 34-30-13.5-3.

⁴³ IOM GUIDANCE, *supra* note 5, 8.

⁴⁴ *Id.* at 23.

⁴⁵ Annas, *supra* note 25, at 2128.

⁴⁶ *Id.*