
2021
VIRTUAL
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September 21-23

2021
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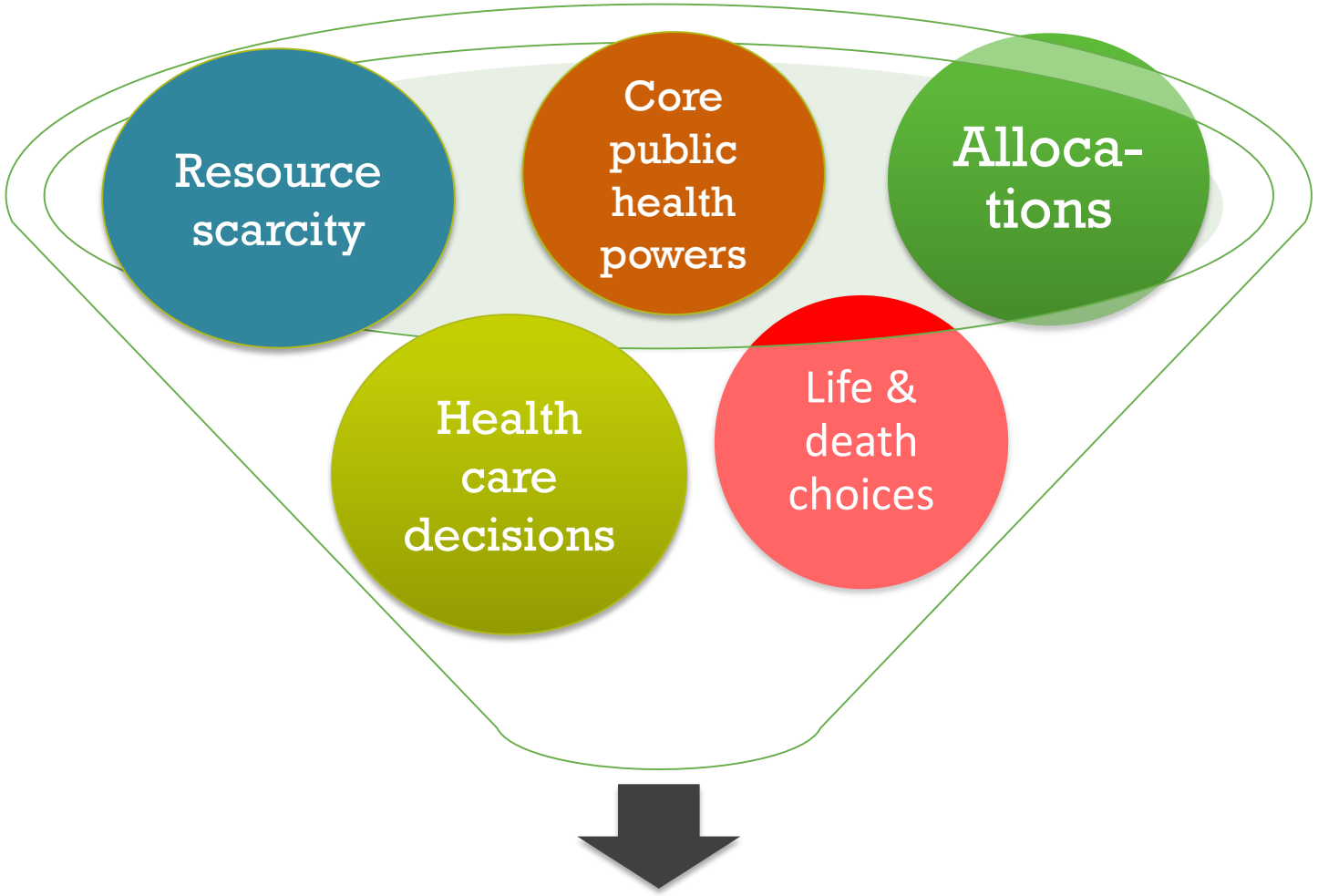
Revisiting Crisis Standards of Care: Law, Policy & Ethics Implementation

September 22, 2021

COVID-19 Pandemic



Crisis Standards of Care

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Dan Hanfling, M.D.
Vice President
In-Q-Tel

Jennifer L. Piatt, J.D.
Research Scholar, ASU Law
Deputy Director, Network – Western Region Office

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Revisiting CSC In the Midst of COVID: What Have We Experienced? What Comes Next?

Dan Hanfling, MD
Vice President, Technical Staff, In-Q-Tel
Clinical Professor of Emergency Medicine, GWU
Co-Chair, National Academy of Sciences, Forum on Medical/Public Health Preparedness

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Crisis Standards of Care During the COVID-19 Pandemic: Legal Issues and Solutions

September 22, 2021

Jennifer L. Piatt, J.D.
Research Scholar, ASU Law
Deputy Director, Network – Western Region Office

Please remember to fill out the conference survey location in the description of this session

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September 22, 2021

Accused Doctor Said to Have Faced Chaos at New Orleans Hospital

By CHRISTOPHER DREW and SHAILA DEWAN

NEW ORLEANS, July 19 — She arrived at Memorial Medical Center to treat several patients as Hurricane Katrina's winds were gathering and did not leave until days later, when the water and the temperature and the body count had risen beyond endurance.

By the time the ordeal ended, her friends and supporters say, Dr. Anna M. Pou was one of the few doctors left in a hospital that had become a nightmare.

Overheated patients were dying around her, and only a few could be taken away by helicopter, the only means of escape for the most fragile patients until the water receded. Medicines were running low, and with no electricity, patients living on machines were running out of battery power. In the chaos, Dr. Pou was left to care for many patients she did not know.

But did she cross a line during those harrowing days, using lethal injections to kill several patients who were in extreme distress? The attorney general of Louisiana says Dr. Pou did, and on Tuesday recommended that she be prosecuted for murder.

Her supporters, though, say there is another explanation: she was using drugs to try to calm and comfort patients who had nearly reached their limit.

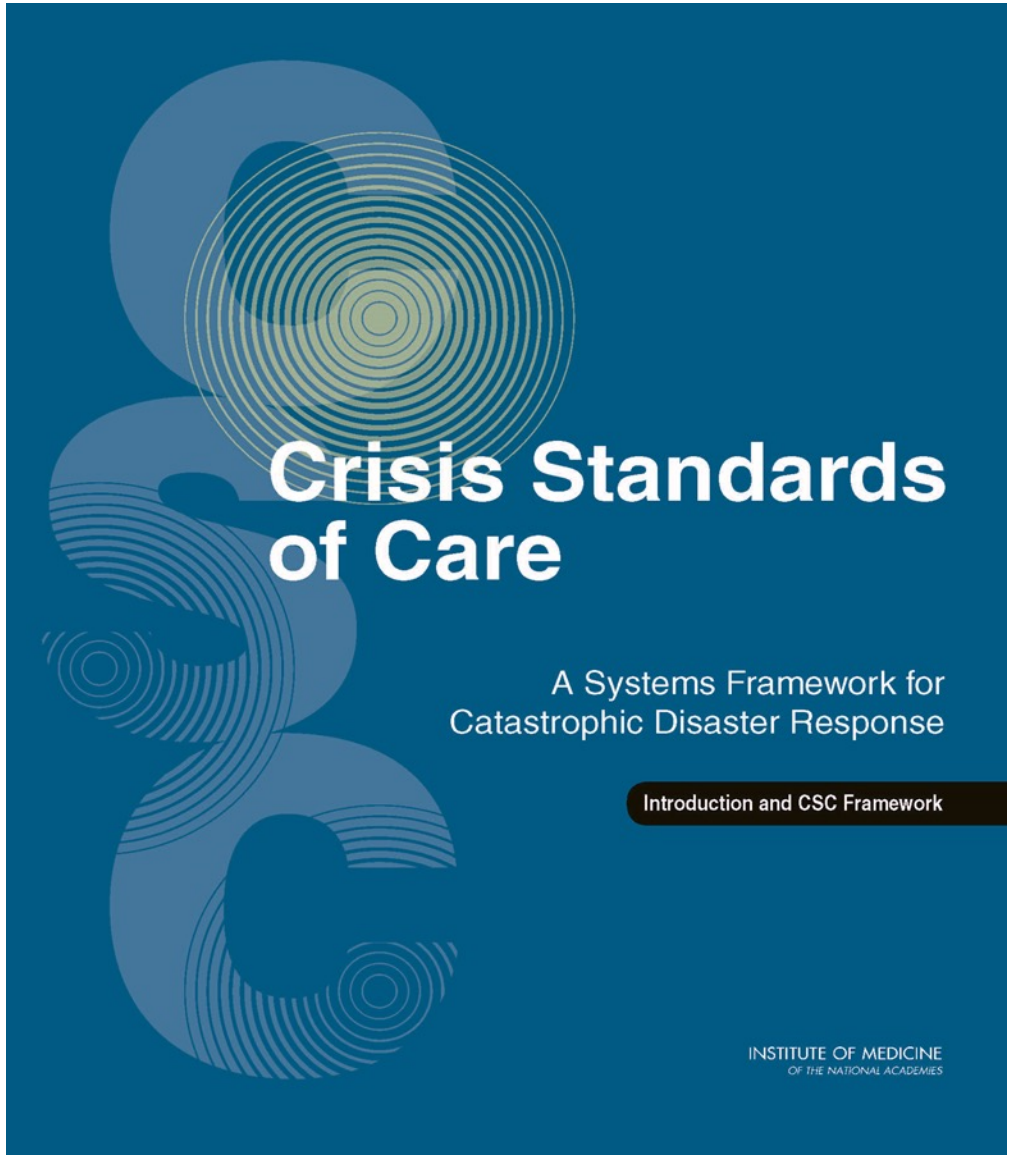
Eugene Myers, a professor at the University of Pittsburgh who helped train Dr. Pou, said that what she had told him shortly after the hurricane sounded heroic.

He said Dr. Pou had told him that she and Lori Budo and Cheri Landry, two nurses who have also been arrested in the case either helped evacuate the last patients or tried to make them comfortable with pain medications.

Lee Celano for The New York Ti

Dr. Anna M. Pou at her mother's home yesterday in New Orleans. She and two nurses are accused of killing patients at Memorial Medical Center

From NYT, July 20, 2006



2009 – Establishing Guidance for Standards of Care in Disaster Situations – Letter Report

2012 – A Systems Framework for Catastrophic Disaster Response

2013 – Indicators and Triggers Toolkit

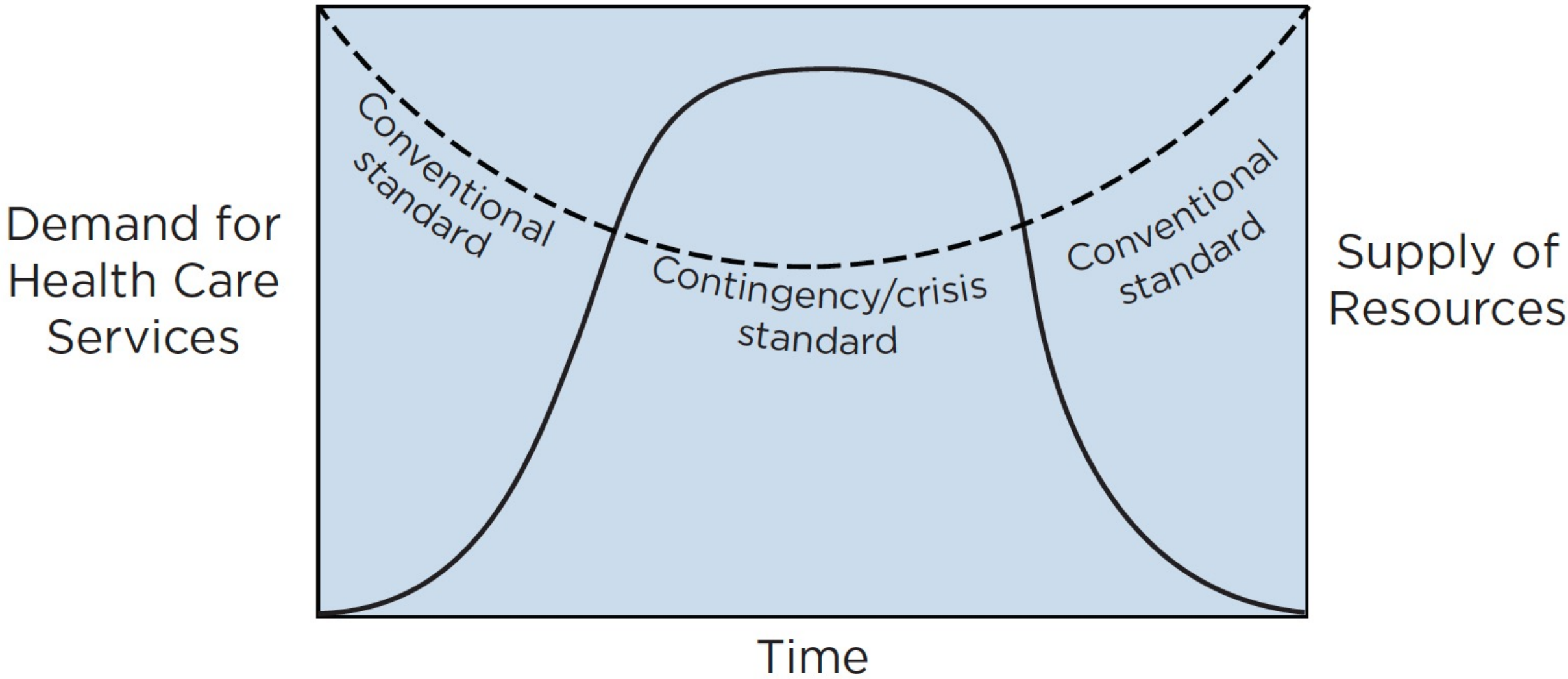


FIGURE 2-3
Demand for health care services and supply of resources as a function of time after disaster onset.

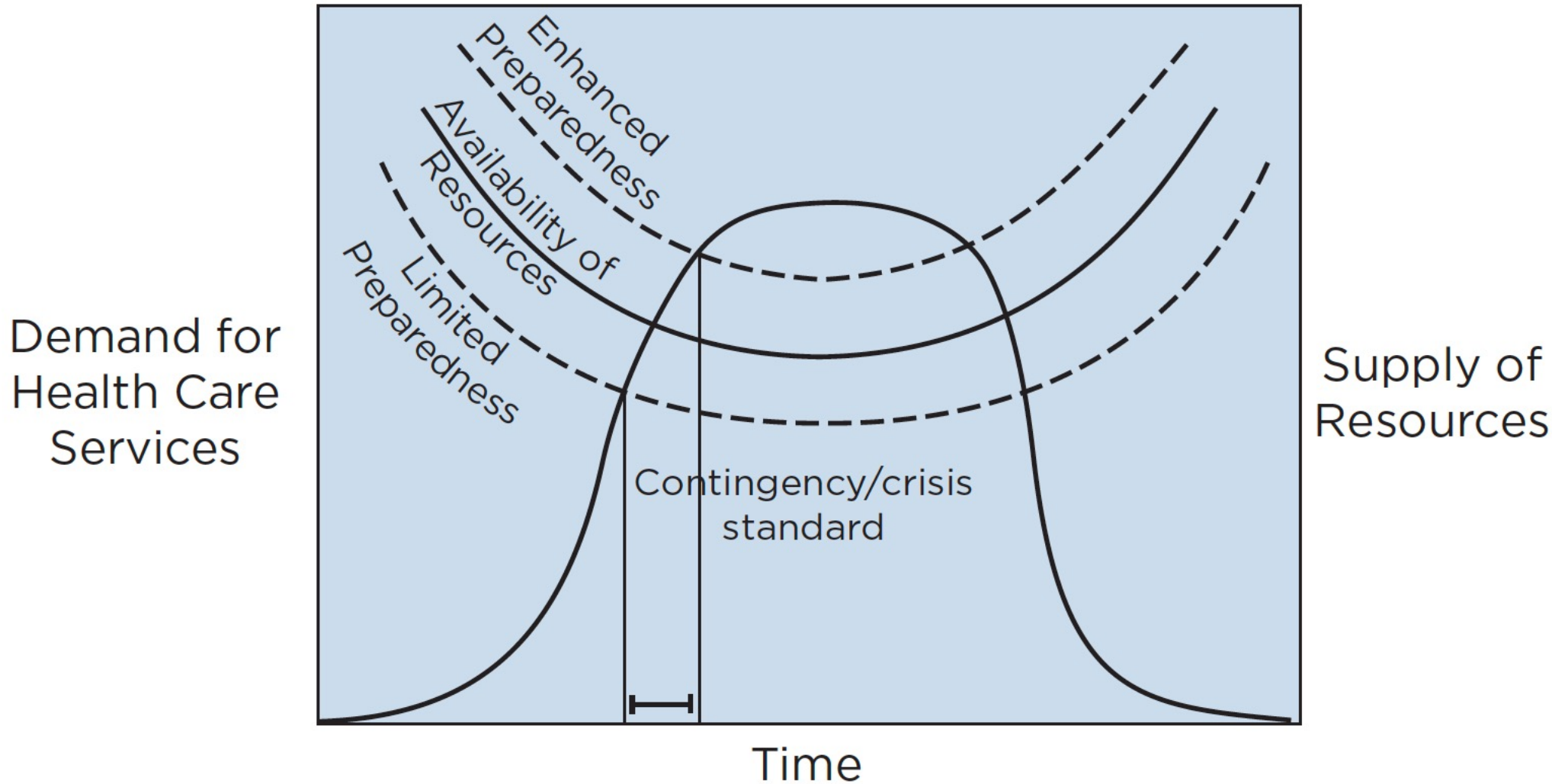
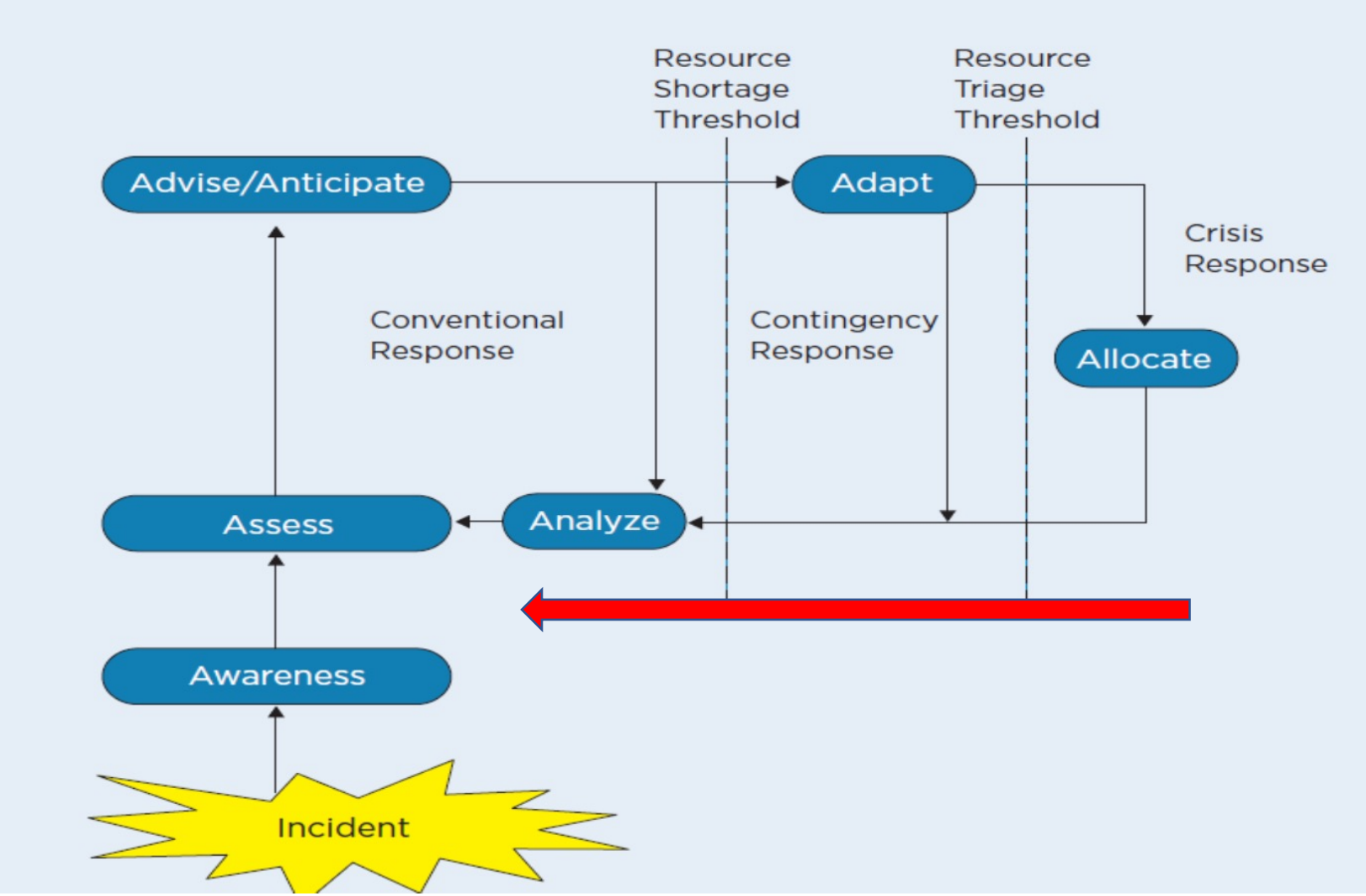
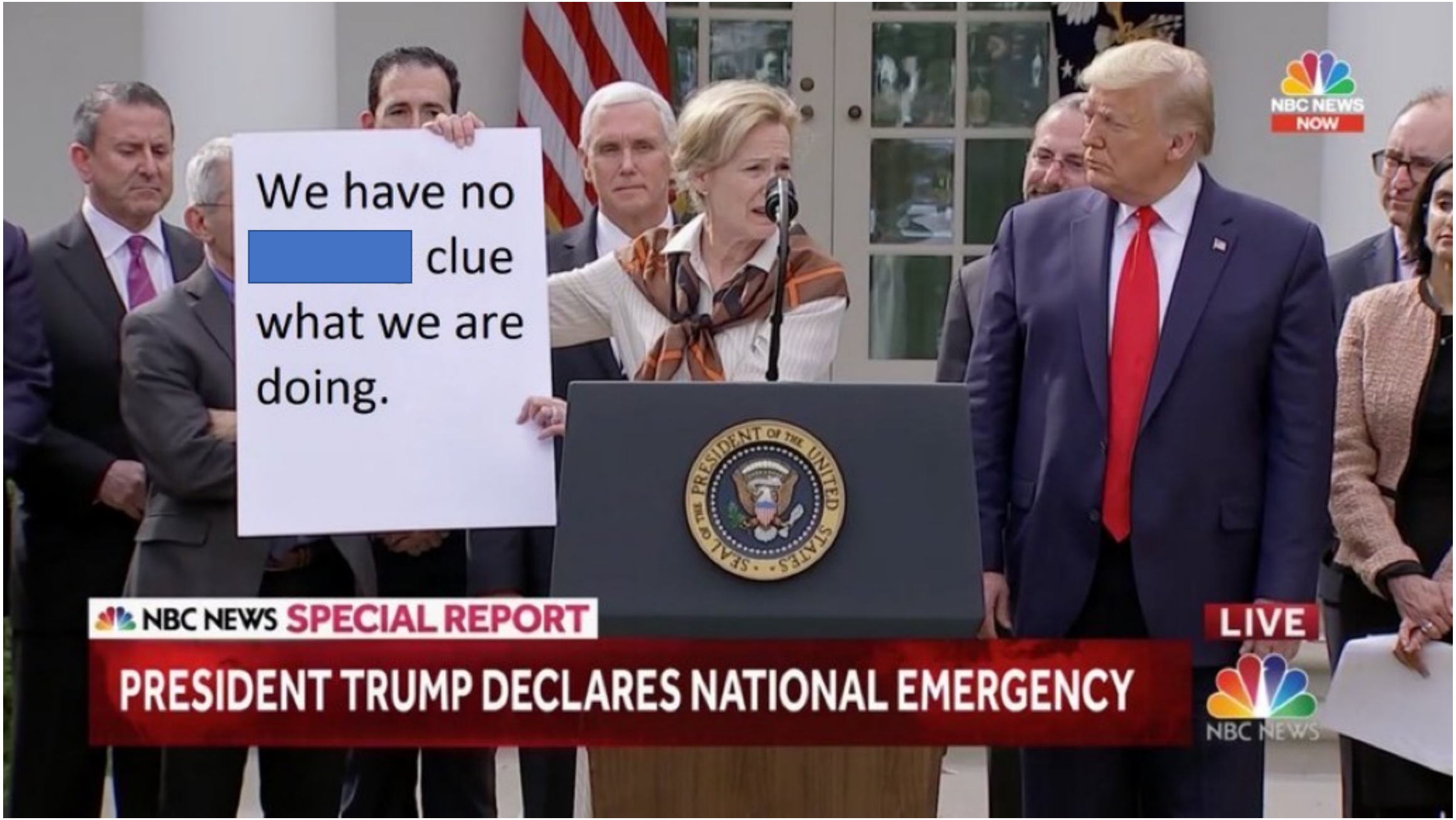


FIGURE 2-4
Demand for health care services and supply of resources as a function of time after disaster onset, taking into account care capacity as a function of time.

Incident demand/resource imbalance
Risk of morbidity/mortality



From, IOM 2012


We have no [redacted] clue what we are doing.
NBC NEWS NOW
NBC NEWS SPECIAL REPORT
LIVE
PRESIDENT TRUMP DECLARES NATIONAL EMERGENCY
NBC NEWS

https://nam.edu/112920-crisis-standards-of-care-resources/

Duty to Plan: Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2

Rapid Expert Consultation on Crisis Standards of Care During the COVID-19 Pandemic

Rapid Expert Consultation on Staffing Considerations for Crisis Standards of Care for the COVID-19 Pandemic

Crisis Standards of Care and COVID-19: What Did We Learn? How Do We Ensure Equity? What Should We Do?

Nine National Organizations Call for Action to Improve Crisis Standards of Care Implementation During Future COVID-19 Surges and Beyond

The National Academy of Medicine and eight other national organizations call for system-wide actions to share clinical and operational lessons learned in order to make improvements based on this past year's experiences and ready our health care system and communities for the potential for further surges in demand for care.

https://nam.edu/national-organizations-call-for-action-to-implement-crisis-standards-of-care-during-covid-19-surge/

https://nam.edu/national-organizations-share-strategies-to-improve-crisis-standards-of-care-implementation-during-future-covid-19-surges-and-beyond/

U.S. Army Veteran Dies of Treatable Illness After Being Unable to Get ICU Bed Due to Pandemic Shortages

"After all he went through in Afghanistan a little gall stone took him out," U.S. Army veteran Daniel Wilkinson's mother said after her son died on Aug. 21

By **Katie Campione** | August 27, 2021 10:11 PM

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Tweet

More

CREDIT: GOFUNDME

U.S. Army veteran Daniel Wilkinson needed an ICU bed to save his life.

The Dallas Morning News

North Texas doctor's group retreats on policy saying vaccination status to be part of care decisions

This would have been a big change in health care, and it was all outlined in a memo obtained by the Watchdog.

Dallas-Fort Worth medical doctors are quietly planning for a worst-case scenario if they run out of intensive care beds. The Watchdog reveals the plan to include vaccination status as part of triage. (Hani Mohammed)

Coronavirus hospitalizatio close to peaki Dallas County experts say

Justice Depar 'protect' abor seekers in Te

North Texas s districts feel (surge, report of new cases

After Roe, rol religion in ba abortion in T became more prominent

Labor Day we

August 19, 2021

Tampa Bay Times

I need a kidney transplant, and here's what I think hospitals should do with the unvaccinated | Column

I fear that our movement toward mandated vaccines is missing a logical element.

Listen 04:37

COVID-19 hospitalizations are on the rise across the nation. Here, a team intubated a COVID-19 patient in North Memorial Health Hospital in the greater Minneapolis-St. Paul, Minn., area.

August 24, 2021

75 Doctors from Florida Hospitals Hold Event Urging People to Get Vaccinated: 'We Are Exhausted'

"They're getting this from a preventable illness," said Dr. Ethan Chapin of the unvaccinated COVID-19 patients flooding South Florida hospitals

By **Julie Mazziotta** | August 24, 2021 12:28 PM

Doctors in South Florida walk out in protest of unvaccinated patients | CREDIT: LANNIS WATERS/PALM BEACH POST/USA TODAY

The Washington Post

Democracy Dies in Darkness

Opinion: Doctors should be allowed to give priority to vaccinated patients when resources are scarce

A nurse looks out the door of a covid-19 patient room in the CoxHealth Emergency Department in Springfield, Mo., on July 16. (Nathan Papes/The Springfield News-Leader via AP)

Opinion by Ruth Marcus
Deputy editorial page editor

3.7k

September 3, 2021 at 3:32 p.m. EDT

CSC: At an Inflection Point?

- Letter Report Recommendations hold
- Ethical Framework in the midst of a national crisis bears some re-consideration
  - accountability; reciprocity
  - ADI/SVI appropriate for planning, not for response
- Investment in capabilities more important than ever (diagnostics, therapeutics, data analytics → situational awareness)
- Community engagement more important than ever (engage the vaccine hesitators)

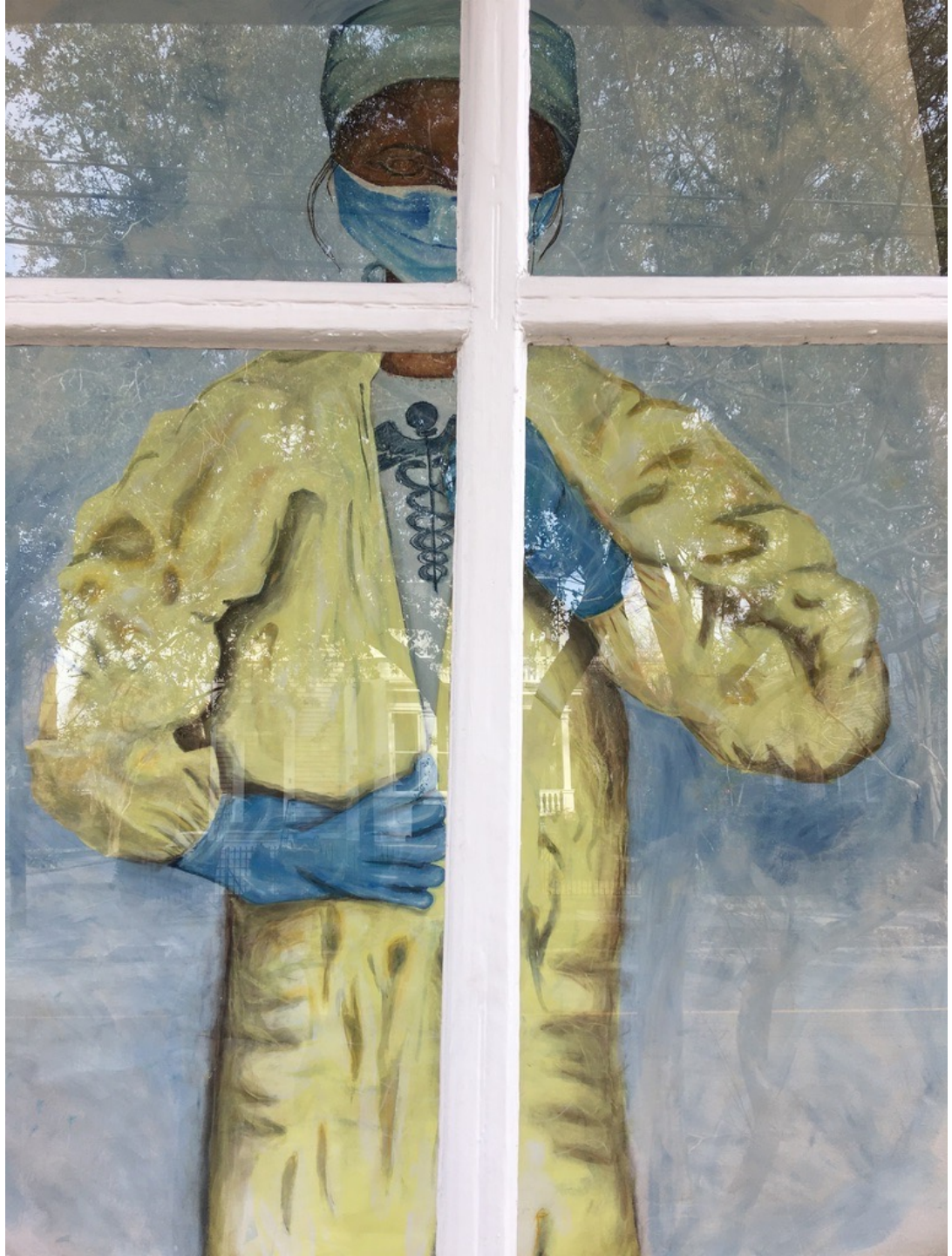
Evolving Crisis Standards of Care and Ongoing Lessons from COVID-19: A Workshop Series: Webinar No. 1

SHARE

September 27, 2021, 12pm ET
October 11, 2021, 12pm ET
October 25, 2021, 12pm ET
November 8, 2021, 12pm ET
November 22, 2021, 12pm ET

Thank you

Dan Hanfling, MD
dhanfling@iqt.org

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Crisis Standards of Care During the COVID-19 Pandemic: Legal Issues and Solutions

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Evolutions in CSC

National Organizations Share Strategies to Improve Crisis Standards of Care Implementation During Future COVID-19 Surges and Beyond

May 13, 2021 | News

The Best Time to Address Crisis Standards of Care Issues Is Now

Although the late winter wave of COVID-19 in the United States seems to have crested, the emergence of variant strains and ongoing questions about immunity and vulnerability leave open the real possibility of additional waves later this year. Meanwhile, there is a growing humanitarian crisis befalling South Asia – in particular, the tragedy unfolding in India, where the health care system has essentially collapsed and many victims of COVID-19 are unable to receive any level of care whatsoever. These current events should make clear how important it is to prepare for future waves of the virus, as the fight against COVID-19 is not over. We must promote vaccination at every turn, support efforts to share clinical and operational lessons learned in order to make improvements based on this past year's experiences, and ready our health care system and communities for the potential for further surges in demand for care.

The prospect of once again facing decisions about whether to transition to crisis standards of care (CSC) calls for action now, while a relative lull in cases allows stakeholders to plan thoughtfully for such decisions. This is especially important in light of painful lessons the pandemic has taught about the need for clarity and consistency across institutions and jurisdictions about invoking CSC and the disproportionate impact COVID-19 has had on historically minoritized and marginalized populations. Going forward, addressing equity must be recognized as a vital consideration for refining and deploying CSC. The challenge of CSC that are not sensitive to issues of equity can be compounded when they are put into practice through processes that similarly fail to embed considerations of equity.

Source: https://nam.edu/national-organizations-share-strategies-to-improve-crisis-standards-of-care-implementation-during-future-covid-19-surges-and-beyond/

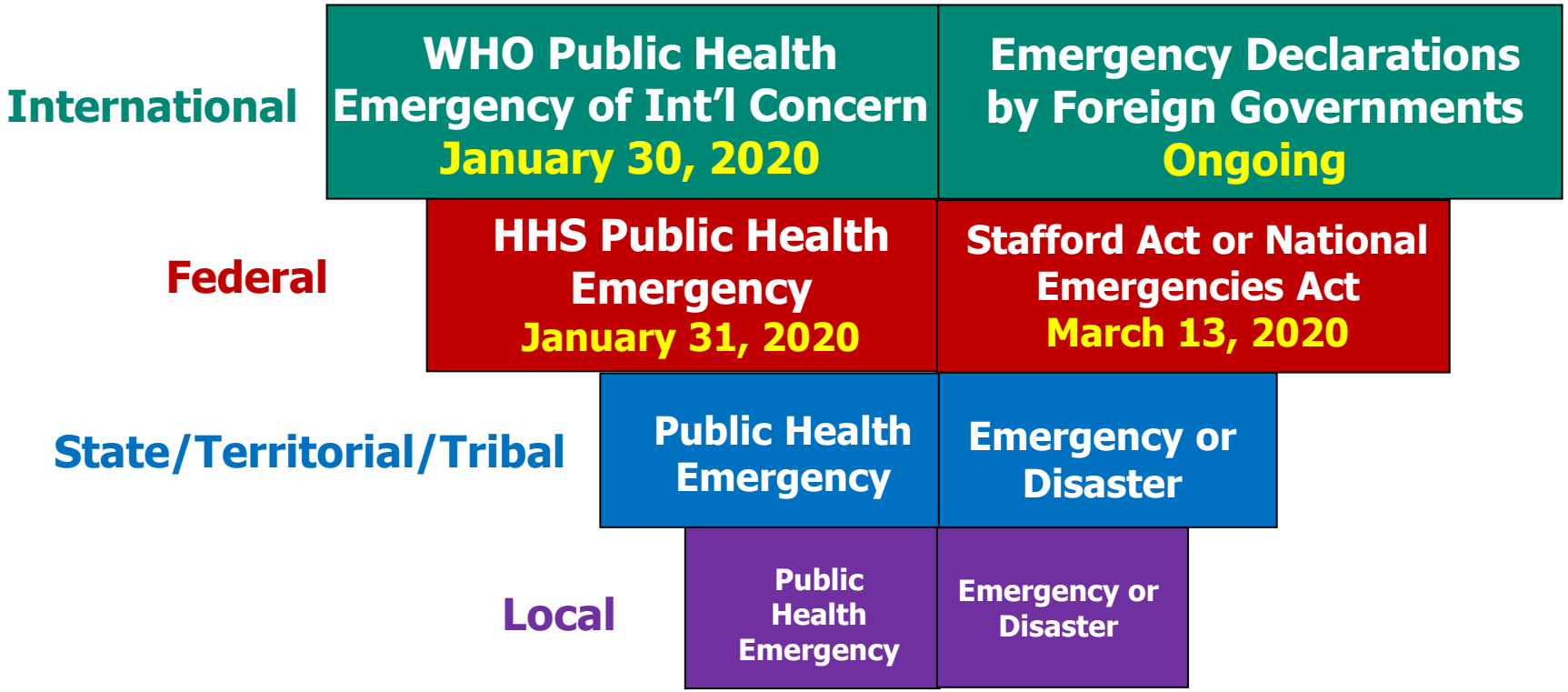
CSC Legal Issues – Premier Topics

1. Understanding the role & effect of emergency declarations
2. Invoking CSC in public & private sectors
3. Resolving jurisdictional challenges within & across states
4. Understanding Federal waivers
5. Alleviating licensure & scope of practice concerns
6. Assessing legal duties to care
7. Avoiding discrimination in resource & treatment allocation
8. Protecting against unwarranted risks of liability
9. Allocation of scarce resources: making real-time decisions

1. Emergency Declarations

UNPRECEDENTED RESPONSES

Public health authorities & powers vary depending on the type of emergency declared at every level of government



Emergency Legal Tools & Powers

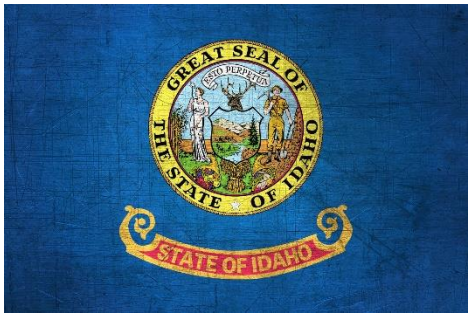
2. Invoking CSC

CSC Legal Triggers

Federal Guidance	• National Academies • HHS, ASPR, CDC, and other federal agencies
Emergency Declarations	• State/territory/tribal public health emergencies • Local public health emergencies
Executive Orders	• Gubernatorial order via emergency declaration • State or local health commissioner
Existing CSC Plans	• Express language of extant plans • Specific addenda or clarifications
Regional Agreements	• Specific guidance from healthcare coalitions • Resource sharing contracts among hospitals
Health Care Entity Experiences	• Express allowances via state CSC plans • Committee reports based on field experiences

3. Jurisdictional Challenges

State



Federal

Tribal

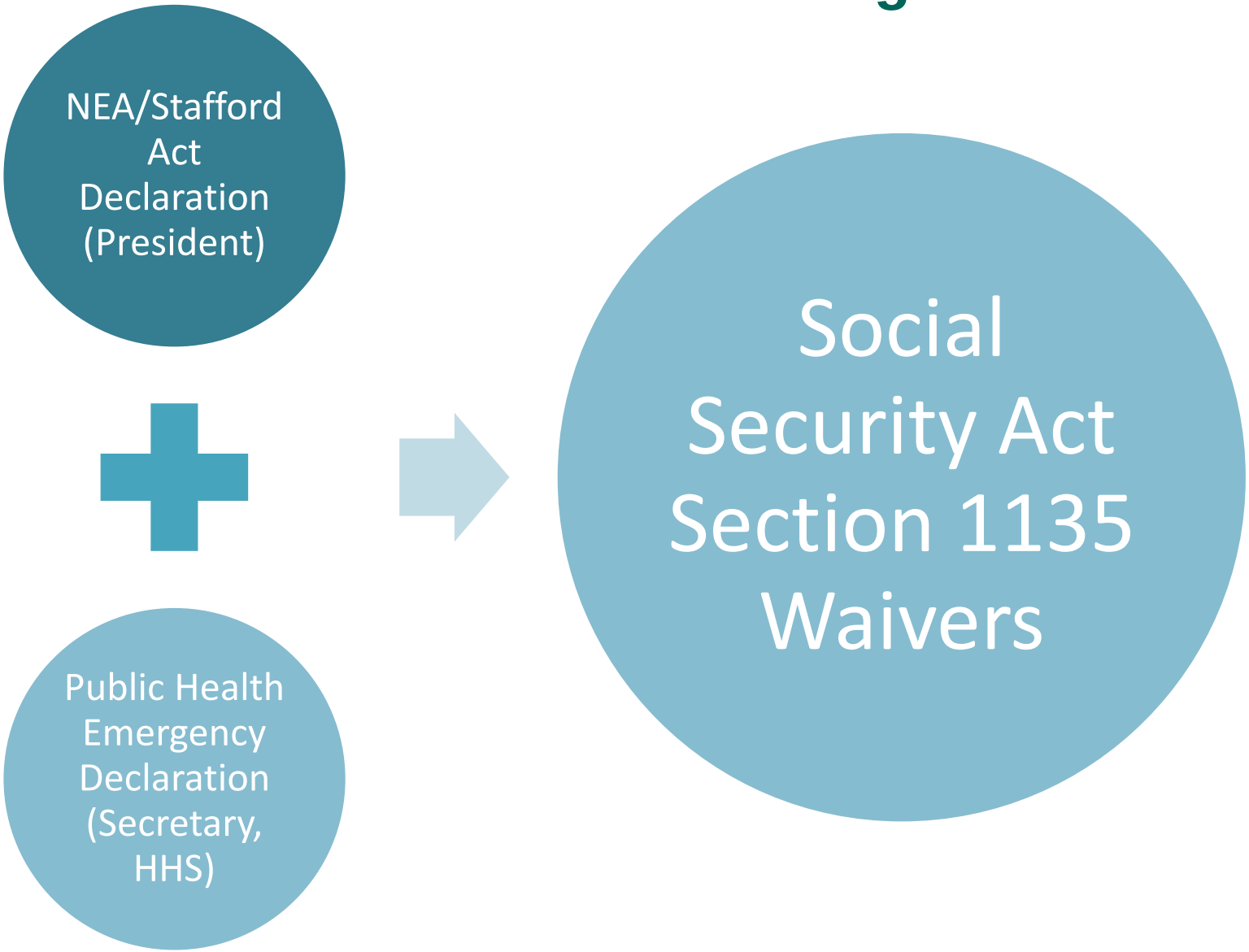
Local

No single emergency declaration provides all necessary coverage, resources, or authorities.

How might intra-jurisdictional conflicts relating to scope of practice limitations be solved?

- Statutory/Regulatory Waivers
- Scope of Practice Expansion
- Executive Orders

4. Understanding Federal Waivers



Federal Waiver Powers

Waiver or Modification of Requirements Under Section 1135 of the Social Security Act

March 13, 2020

1. Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I, Alex M. Azar II, Secretary of Health and Human Services, hereby waive or modify the following requirements of titles XVIII, XIX, and XXI of the Act and regulations thereunder, and the following requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, and XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the consequences of the 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19) pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse:

   a. Certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services, and pre-approval requirements.

   b. Requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area).

   c. Sanctions under section 1867 of the Act (the Emergency Medical Treatment and Labor Act, or EMTALA) for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic.

   d. Sanctions under section 1877(g) (relating to limitations on physician referral) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.

   e. Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.

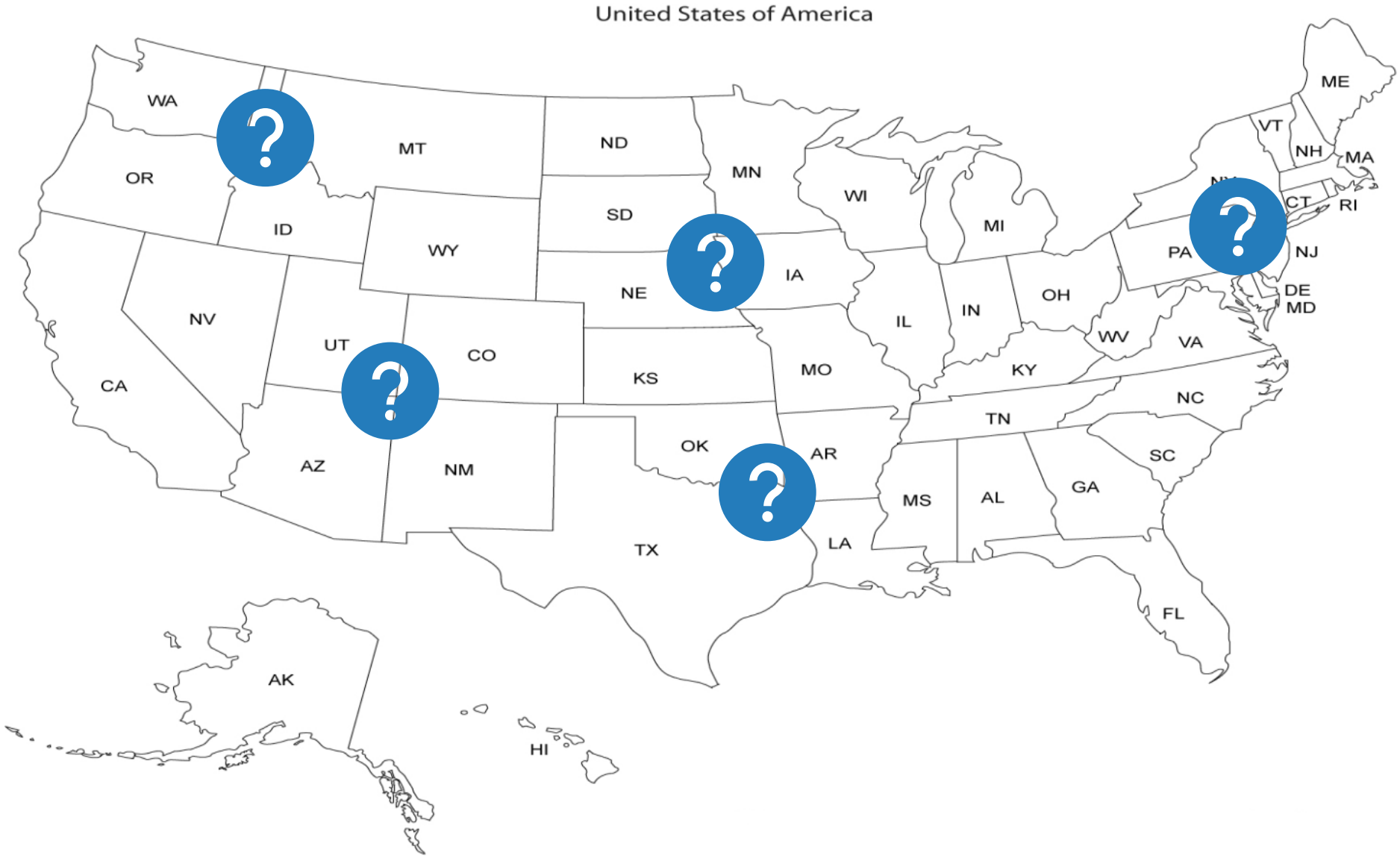
2. Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.

Source: https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx

Section 1135 waivers issued during a PHE can result in waiver of:

- Conditions of participation
- Licensure requirements
- Pre-approval requirements
- Sanctions under EMTALA, HIPAA
- Deadlines or Timelines
- Payment Limitations

5. Licensure/SOP Expansion



Licensure Reciprocity

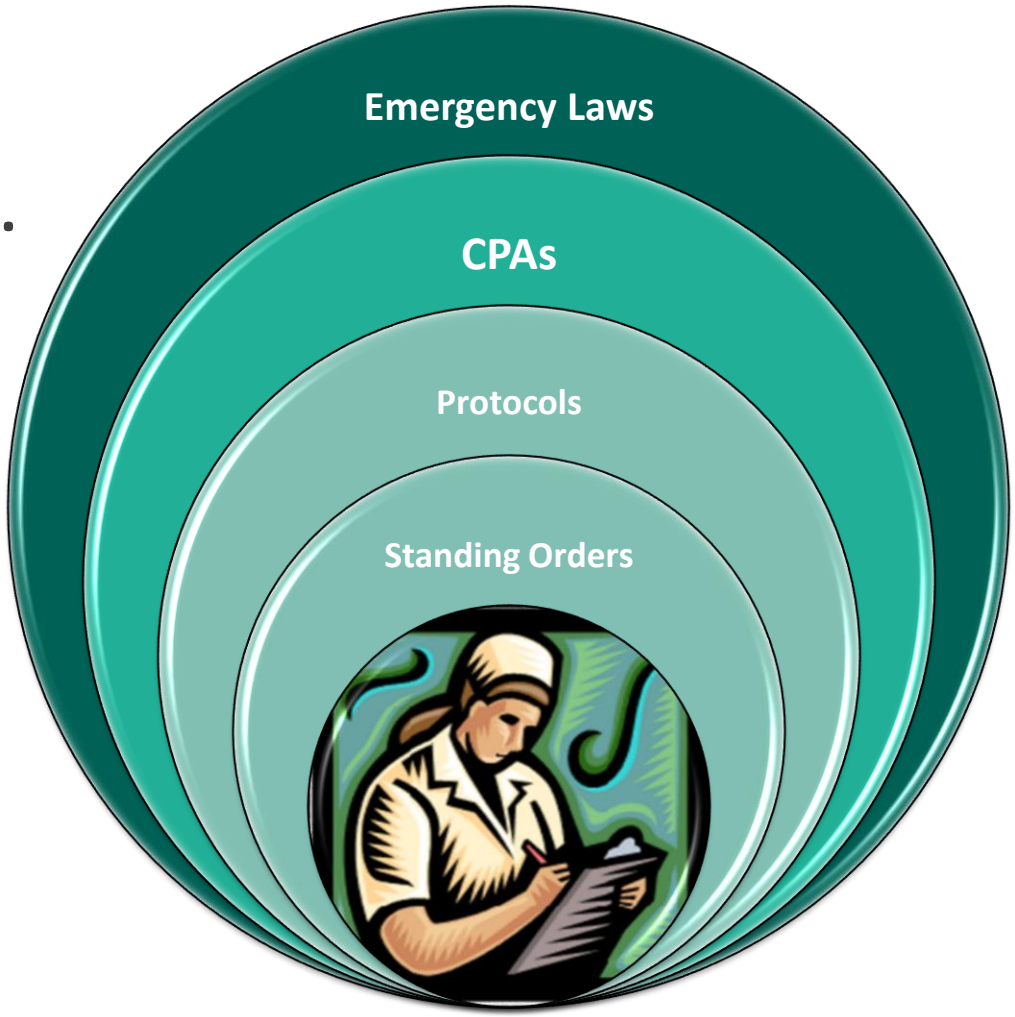
No available reciprocity provisions

Reciprocity triggered by emergency declaration or waiver

Non-emergency reciprocity; multi-state licenses

Scope of Practice

Emergency laws may provide for scope of practice expansions which CSC plans may incorporate or reference.



Example: Potential nursing SOP expansions

6. Legal Duties Under CSC

CSC anticipates the difficulties of ***meeting routine standards of care during sustained emergencies.***

Navigating CSC Duties

Common duties expressly required in CSC plans:

- Duty NOT to abandon.
- Duty to care despite risks;
- reciprocal duty to support
- and protect HCWs.
- Duty to provide comfort care.

Additional duties:

- Duty not to experiment.
- Duty to screen or accept patients.

7. Avoiding Discrimination

"Persons with disabilities, with limited English skills, and older persons should not be put at the end of the line for health care during emergencies."

- Roger Severino, former Director of HHS OCR

HHS Office for Civil Rights in Action

March 28, 2020

BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)

In light of the Public Health Emergency concerning the coronavirus disease 2019 (COVID-19), the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) is providing this bulletin to ensure that entities covered by civil rights authorities keep in mind their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs.[1]

In this time of emergency, the laudable goal of providing care quickly and efficiently must be guided by the fundamental principles of fairness, equality, and compassion that animate our civil rights laws. This is particularly true with respect to the treatment of persons with disabilities during medical emergencies as they possess the same dignity and worth as everyone else.

The Office for Civil Rights enforces Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act which prohibit discrimination on the basis of disability in HHS funded health programs or activities. These laws, like other civil rights statutes OCR enforces, remain in effect. As such, persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative "worth" based on the presence or absence of disabilities or age. Decisions by covered entities concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence.

Source: https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf

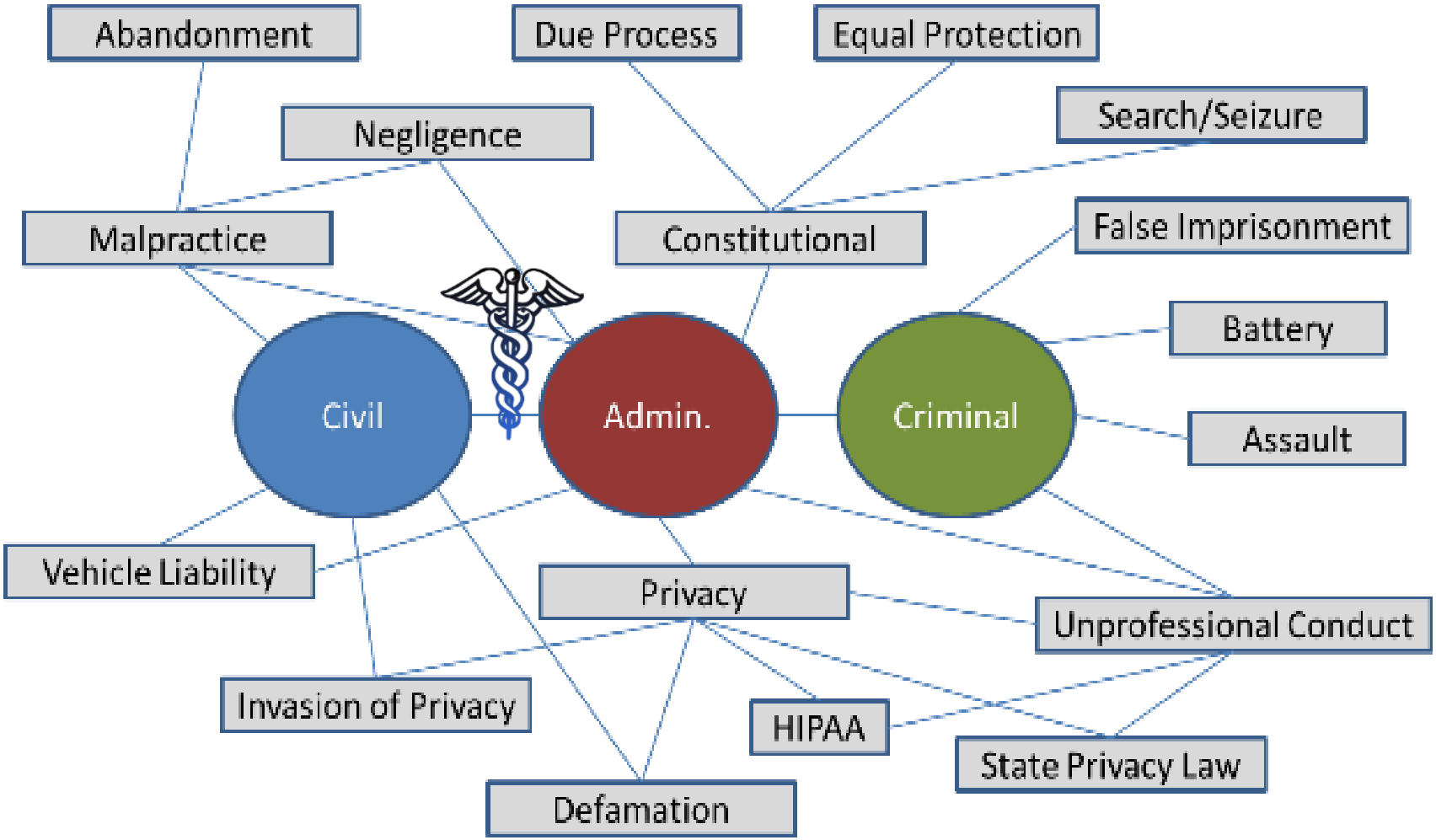
Non-Discrimination in CSC

- Categorical exclusions based on age or disability;
- Long-term survivability as a categorization basis

- Diagnostic tools which are facially valid but can be applied in a discriminatory manner in specific circumstances

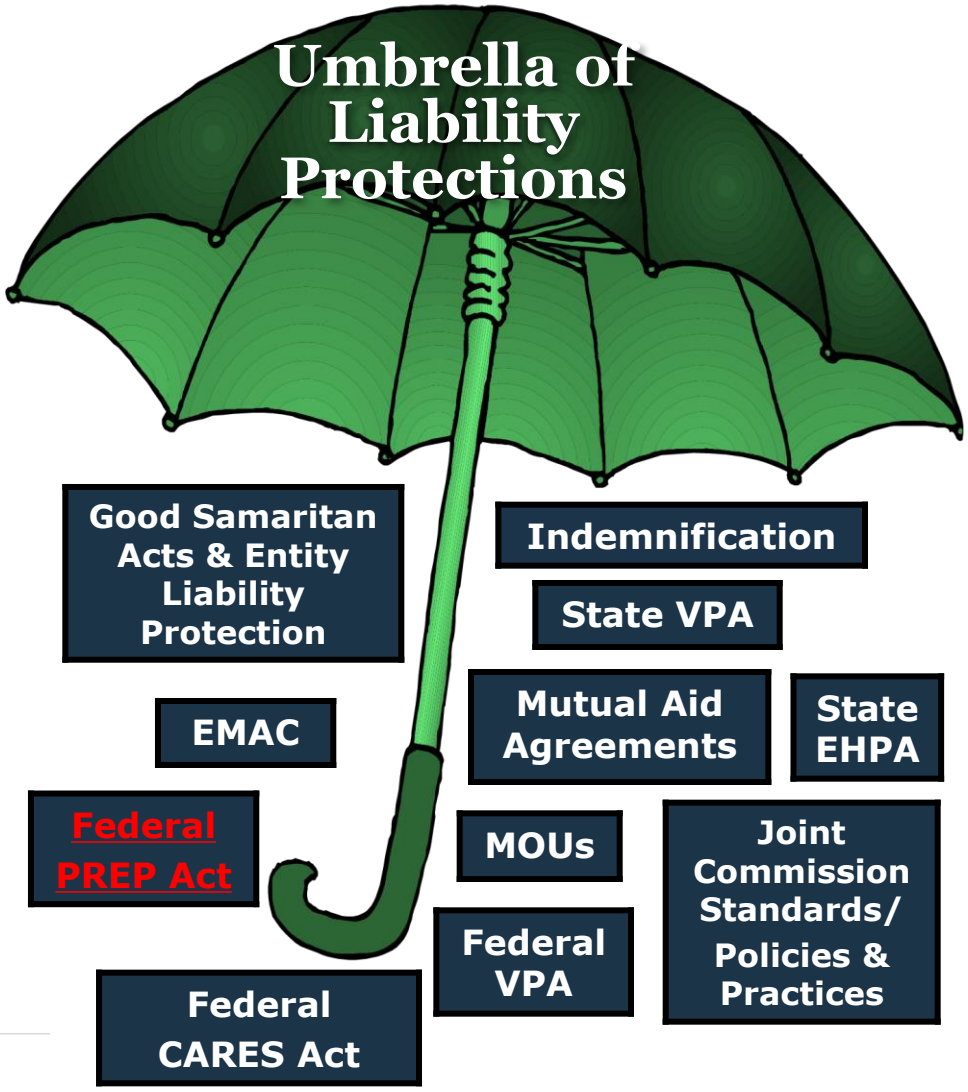
- Individualized assessment of each patient;
- Based on the best medical evidence available;
- Concerning likelihood of death prior to or immediately after hospital discharge

8. Protections from Liability



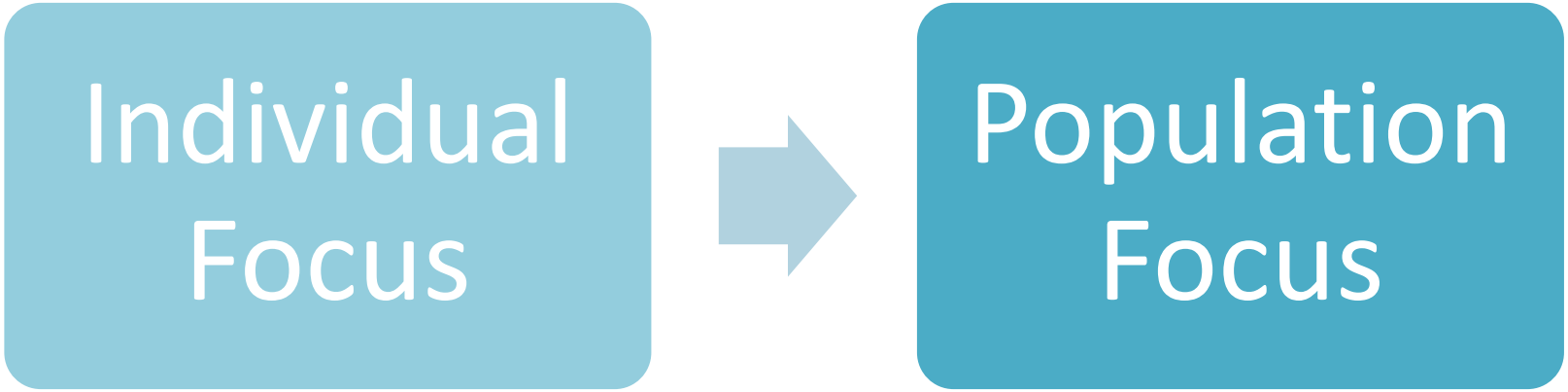
Emergency Liability Protections

Multiple liability protections may apply to HCWs, volunteers & entities for acts of negligence – but not intentional misconduct.



9. Resource/Allocation Decisions

Upon invocation of CSC:



How do we approach difficult resource allocation decisions forced by limited resources in circumstances of crisis?

Prohibited/Possible Bases

Prohibited Allocation Bases

- Race/color
- Ethnicity
- Sex
- Gender
- Age
- Veteran Status
- Marital Status
- Religion/Exercise of Conscience
- Limited English Proficiency
- Long-term Mortality or Life Expectancy
- Assumptions of Perceived Health Status
- Disability – Physical or Mental
- Quality of Life
- Individual's Relative Worth
- Inequitable Clinical Assessment Scores
- Resource Intensity Due to Disability/Age
- Duration of Need Due to Disability/Age
- Advanced Planning/Steering Decisions
- Categorical Exclusions
- Blanket Applications
- Stereotypes

Possible Allocation Bases

- Specific Resource Limitations or Suitability
- Current Medical/Public Health Information
- Individualized Patient Assessments
- Objective Medical Evidence
- Equitable Clinical Assessment Scores
- Short-term Survival
- Age (as a limited prognostic factor)
- Patient/Surrogate Consent and Choices
- Health Care Worker Status
- Reasonable Modifications to Assure Equal Access for Disabled or Aged Patients
- Appeals
- ***Vaccination Status?***

CSC Legal Issues – Key Take-aways

1	Emergency declarations authorize numerous powers essential to effectuating CSC
2	Legal invocation of CSC may arise via different routes and entail multiple options for public and private sectors
3	Resolving jurisdictional challenges across states may require utilizing emergency authorities to resolve conflicts
4	Understanding applicable federal waivers can help ensure continued compliance while alleviating certain requirements
5	Alleviating licensure & scope of practice concerns through SOP expansions or reciprocity can ameliorate shortages
6	Shifting standards of care do not belie general legal duties or additional CSC duties owed to patients
7	Avoiding discrimination in CSC requires patient-specific assessments rather than prohibited categorizations
8	Manifold liability protections help assure HCWs, volunteers, and entities can implement CSC
9	Real-time resource allocation or triage decisions must avoid legal pitfalls and utilize permissible decision bases

Please remember to fill out the conference survey location in the description of this session

- Jennifer.Piatt@asu.edu | @Jen_Piatt
- For more information & ongoing updates, please see the Network for Public Health Law COVID-19 Resources