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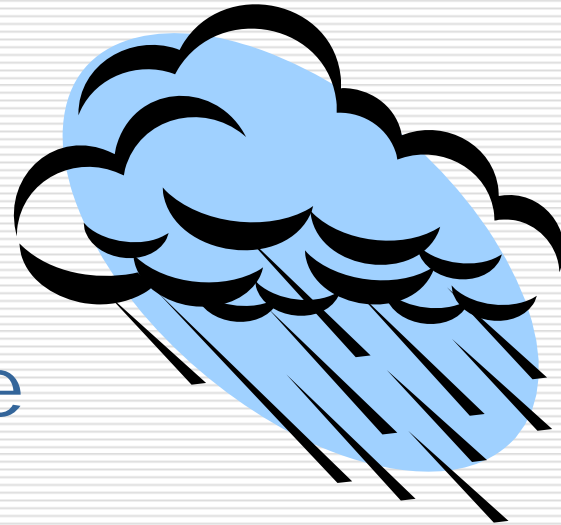
Legal Considerations in Real-time During Disasters and Public Health Emergencies

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Principal Objectives

- Legal Environment in Emergencies
- Legal Triage
- Legal Challenges in Allocating Scarce Resources

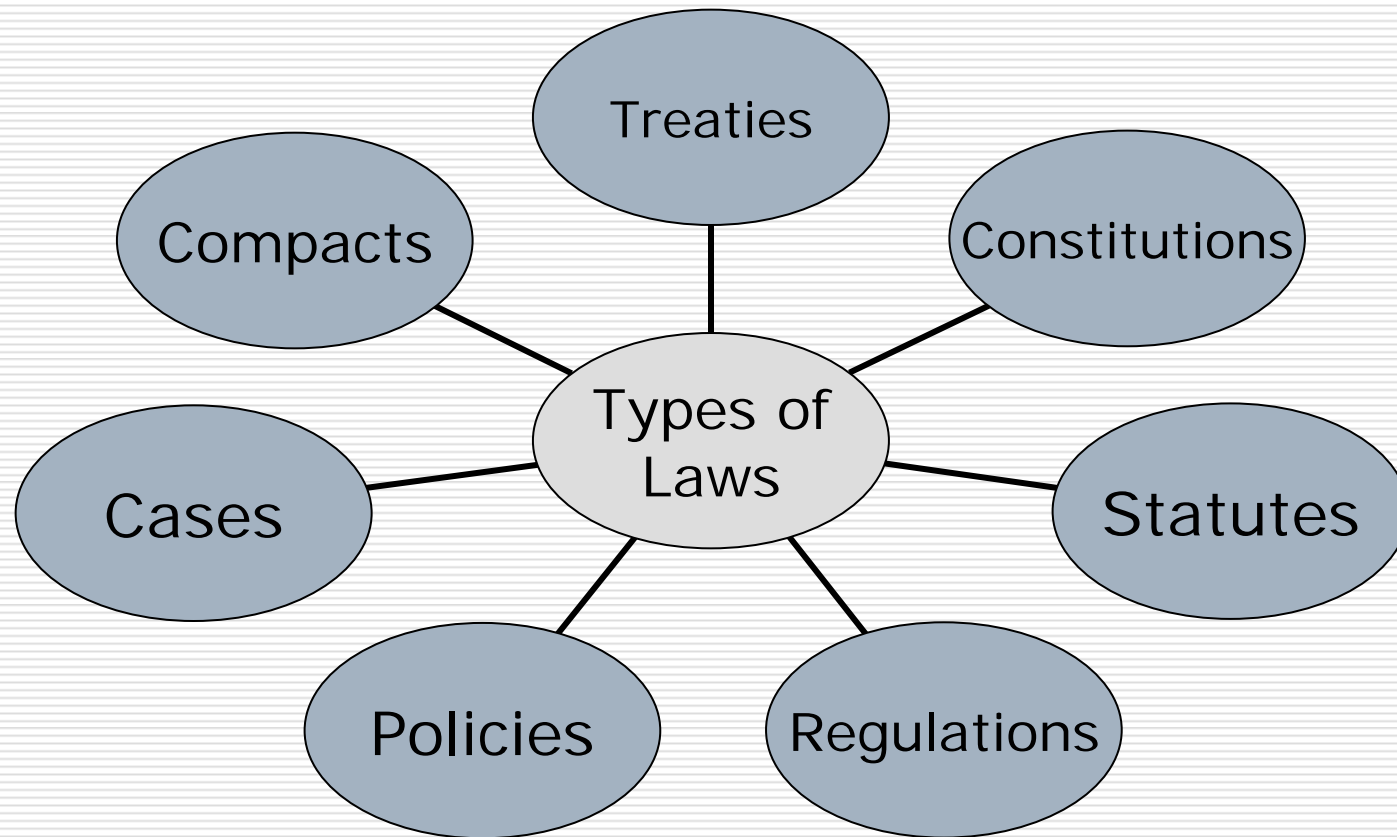


Assessing the Legal Environment in Emergencies

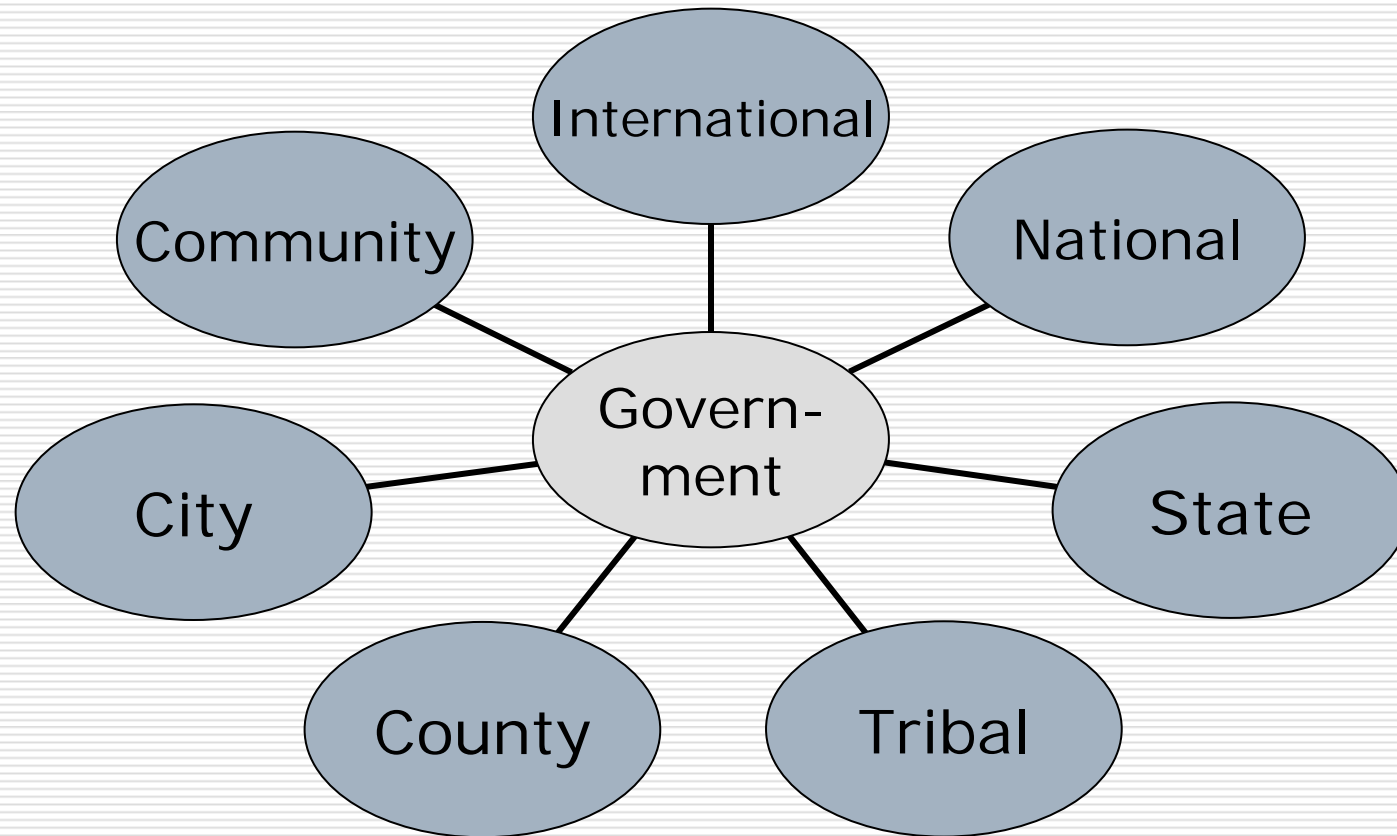
Laws pervade emergency responses at every level of government:

- They determine what constitutes a public health or other emergency
- They help create the infrastructure through which emergencies are detected, prevented, and addressed
- They authorize the performance (or nonperformance) of various emergency responses by a host of actors
- They determine the extent of responsibility for potential or actual harms that arise during emergencies

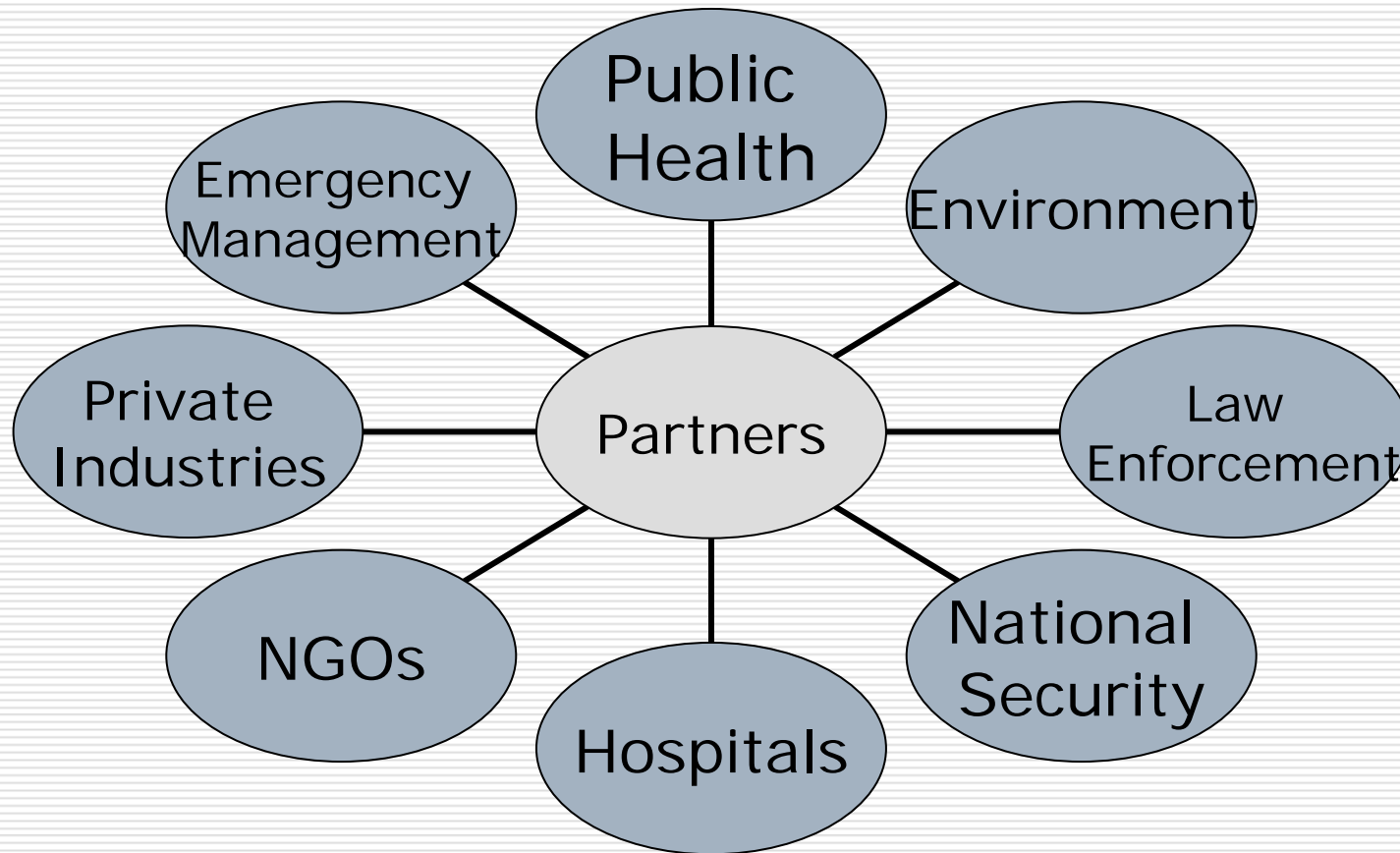
Assessing the Legal Environment in Emergencies



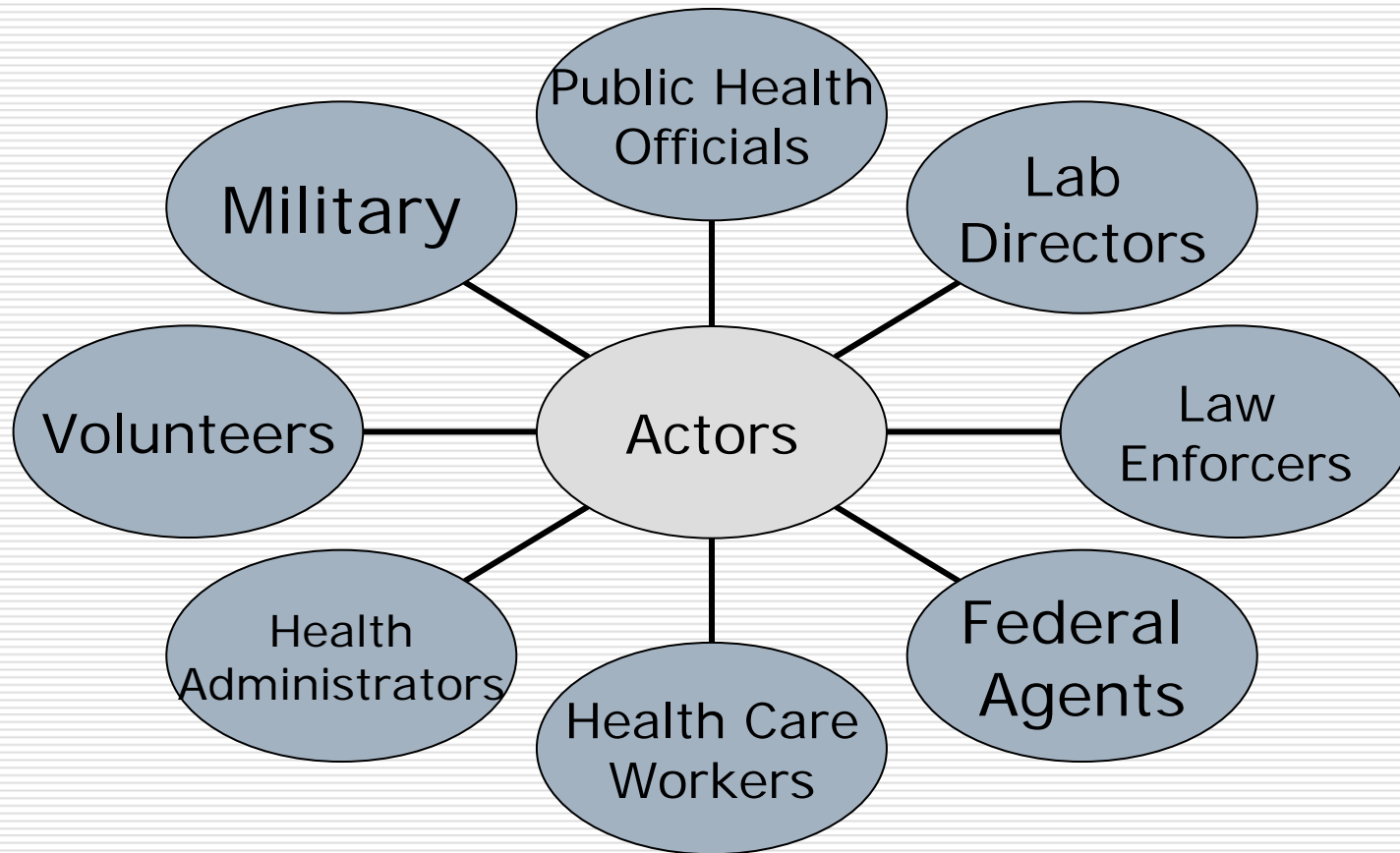
The Convergence of Governments During Emergencies



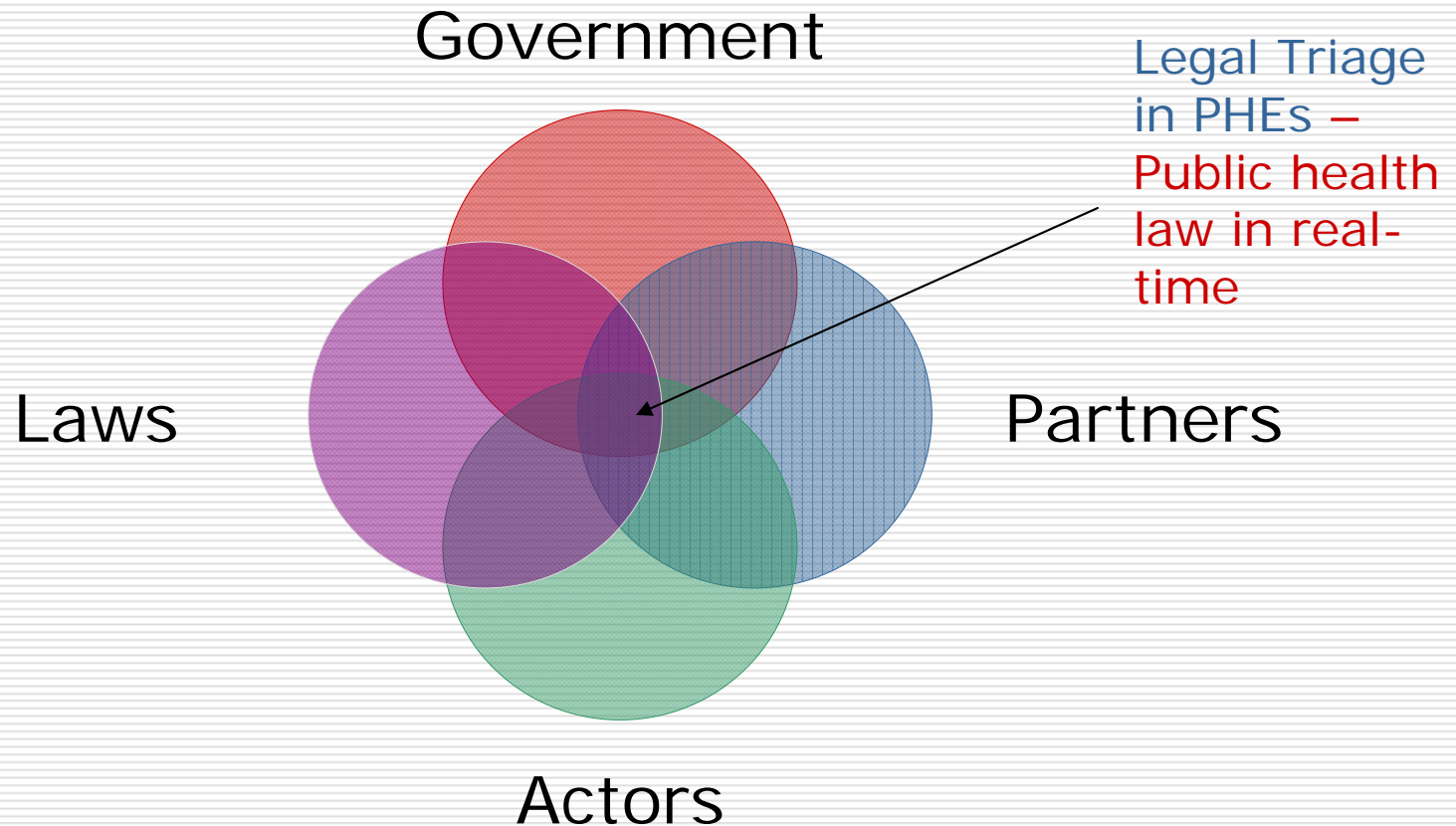
The Convergence of Partners During Emergencies



The Convergence of Specific Actors During Emergencies



Legal Triage During Emergencies



Legal Triage During Emergencies

Legal triage refers to the efforts of legal actors and others to construct a favorable legal environment during emergencies through a prioritization of issues and solutions that facilitate legitimate public health responses

Legal Triage During Emergencies

Legal actors must be prepared to:

- **assess and monitor changing legal norms** during emergencies;
- **identify legal issues** that may facilitate or impede public health responses as they arise;
- **develop innovative, responsive legal solutions** to reported barriers to public health responses;
- **explain legal conclusions** through tailored communications to planners and affected persons; and
- consistently **revisit the utility, efficacy, and ethicality** of legal guidance.

State of Emergency

Once an emergency has been declared, the legal landscape changes.

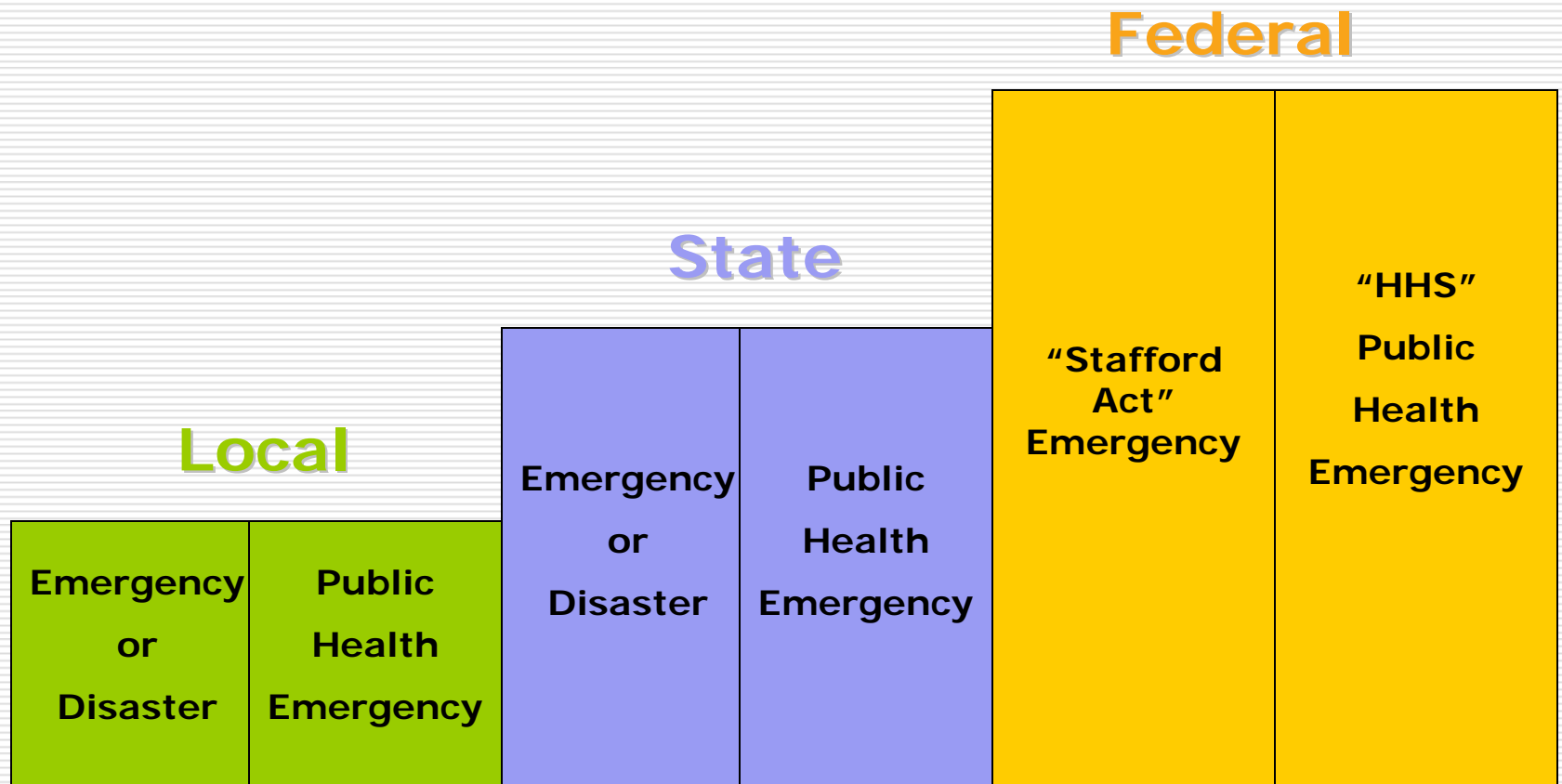


Emergency Declarations

How the legal landscape changes depends on the type of emergency declared



Multiple Levels of Emergency Declarations



Pandemic and All-Hazards Act (PAHPA)

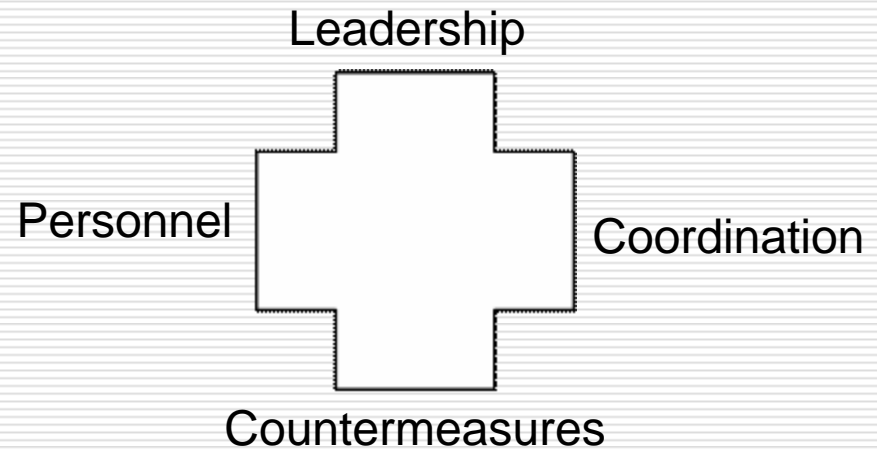
- ❑ On December 19, 2006, President Bush signed the Pandemic and All-Hazards Act (PAHPA)
- ❑ Substantially reorganizes and prioritizes public health emergency responses at the federal level
- ❑ Amends the existing federal Public Health Service Act (PHSA) to add four new titles

PAHPA: Title I

- Title I: National Preparedness and Response, Leadership, Organization, and Planning
 - Establishes that the Secretary of the Department of Health and Human Services (DHHS) shall lead federal public health and medical responses to public health emergencies under the National Response Plan
 - In collaboration with the Secretaries of Homeland Security, Veterans Affairs, Defense, and others through interagency agreements on coordination of efforts during emergencies

PAHPA: Title I

- Assistant Secretary for Preparedness and Response (ASPR) [[RADM Craig Vanderwagen, MD](#)] is appointed to assume a myriad of leadership, personnel, and coordination functions concerning the medical and public health aspects during emergencies



PAHPA: Title II

□ Title II: Public Health Security Preparedness

- DHHS is authorized to track the initial distribution of federally purchased influenza vaccine and to promote communication among public health agencies regarding distribution in the event of an outbreak.



PAHPA: Title III

□ Title III: All-Hazards Medical Surge Capacity

- The existing National Disaster Medical System is to be transferred from the Department of Homeland Security (DHS) to DHHS.
- DHHS must work with tribal, state, and local officials to supplement current programs to provide volunteer health personnel during public health emergencies.
- Existing state volunteer registration systems will be linked into a single national system to verify the credentials, training, and licenses of volunteers during public health emergencies.

PAHPA: Title IV

- Title IV: Pandemic and Biodefense Vaccine and Drug Development
 - A Biomedical Advanced Research and Development Authority (BARDA) and a National Biodefense Science Board will be established to integrate infectious disease requirements and biodefense with new medical innovations, research developments, and countermeasure procurements



Emergencies – State Approaches

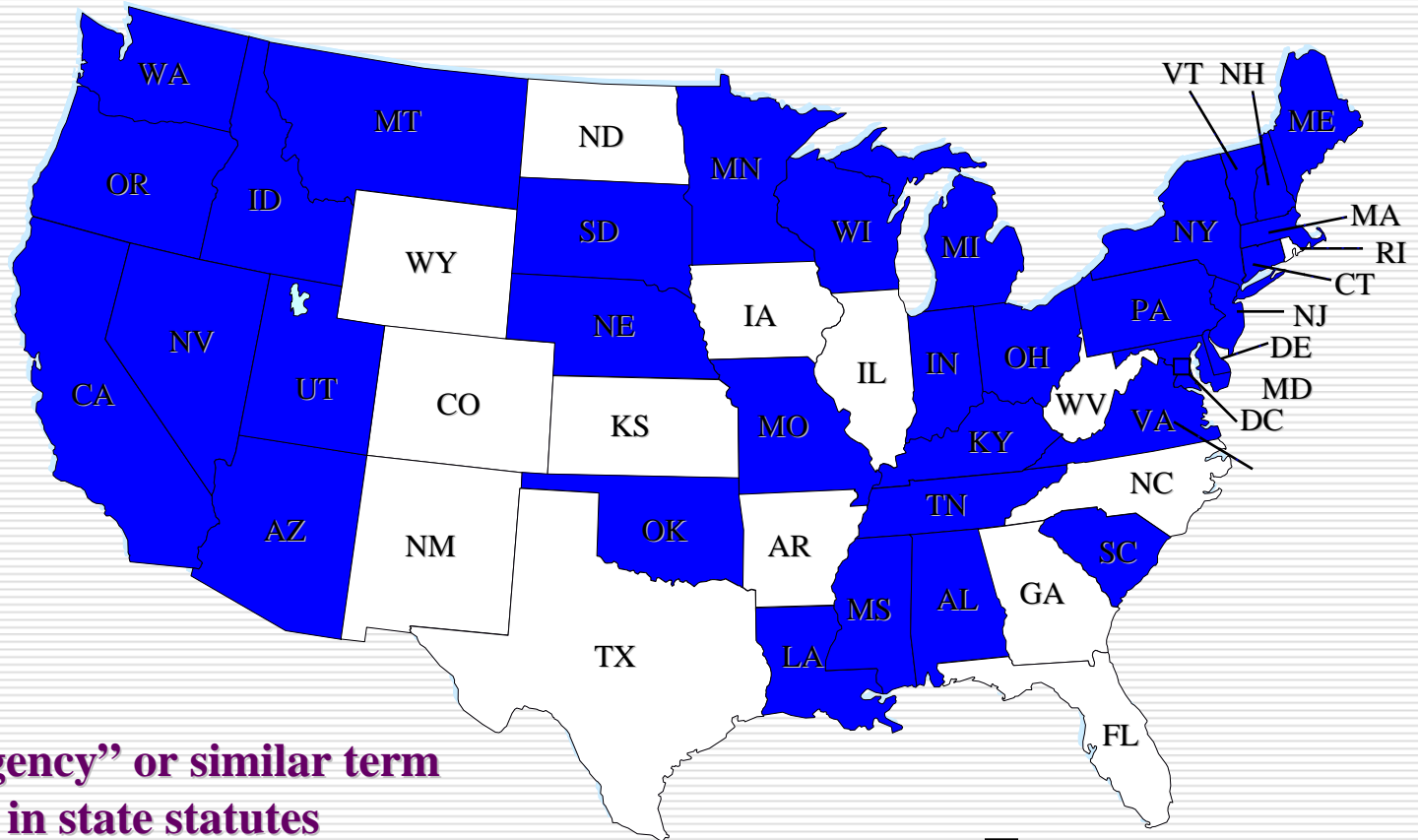
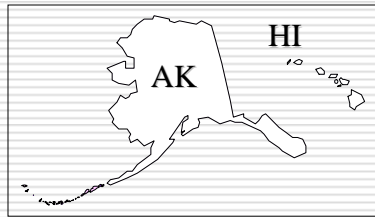
Before 9/11:

- Existing state legal infrastructures focused on general emergency or disaster responses
- “All hazards” approach

After 9/11:

- Reforms of emergency laws by most state governments to address “public health emergencies”
- Based in part on the *Center’s Model State Emergency Health Powers Act (MSEHPA)*

States That Define “Emergency”



“Emergency” or similar term defined in state statutes

PR - (Puerto Rico)
VI - (U.S. Virgin Islands)

“Emergency” Defined - Florida

“**Emergency**” is defined as “any occurrence, or threat thereof, whether natural, technological, or manmade, in war or in peace, which results or may result in **substantial injury or harm to the population** or substantial damage to or loss of property.”

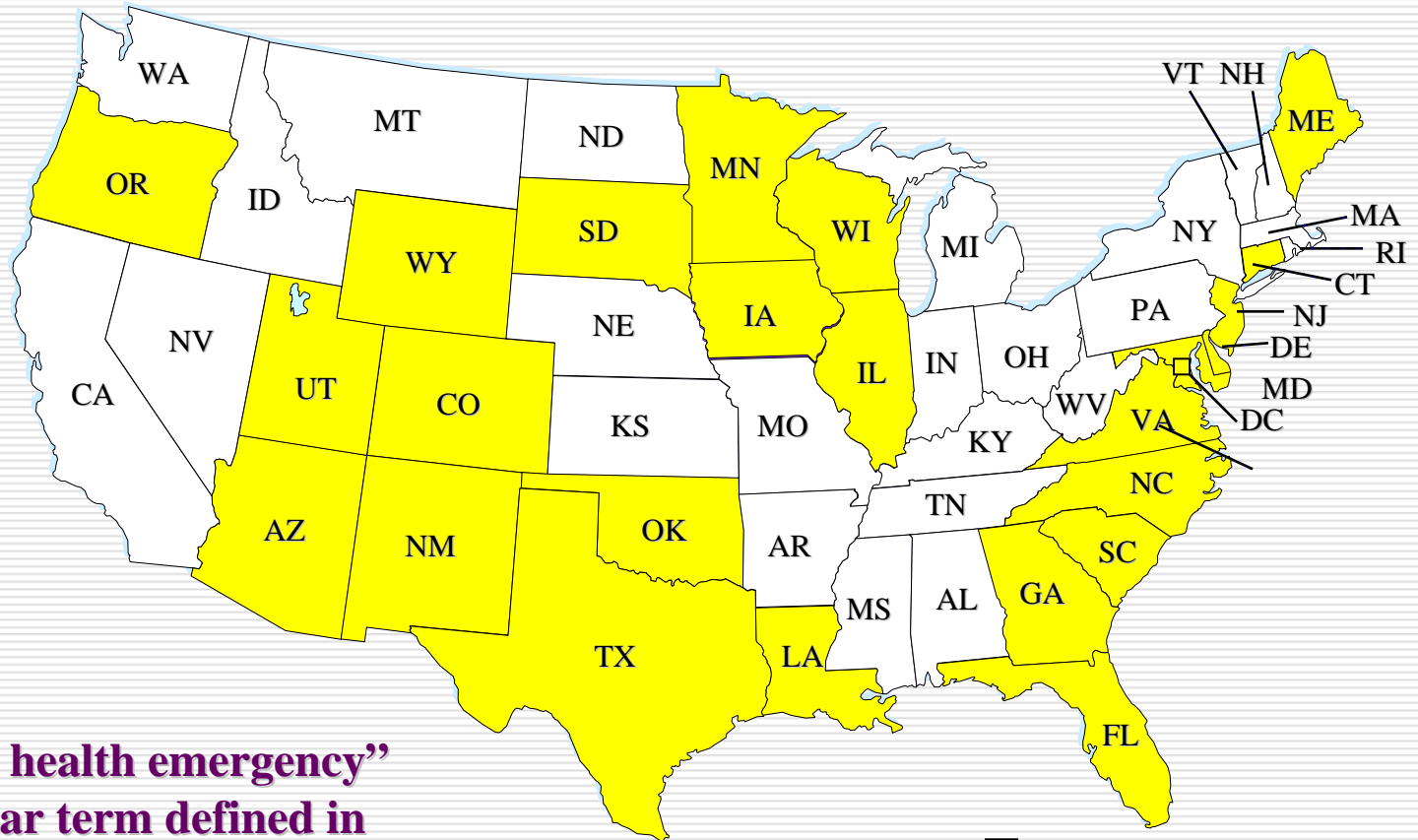
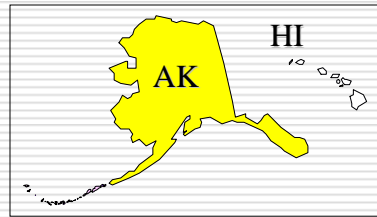
F.S.A. § 252.34(3) (2005).


"Disaster" Defined - West Virginia



"**Disaster**" is defined as "the occurrence or imminent threat of widespread or severe damage, injury, or loss of life or property resulting from any natural or man-made cause, including fire, flood, earthquake, wind, snow, storm, chemical or oil spill or other water or soil contamination, **epidemic**, air contamination, blight, drought, infestation or other public calamity requiring emergency action."

W. Va. Code. § 15-5-2(h) (1990).

States That Define “Public Health Emergency”



 **“Public health emergency”
or similar term defined in
state statutes**

 PR - (Puerto Rico)
 VI - (U.S. Virgin Islands)

“Public Health Emergency” Defined - MSEHPA

- **“Public health emergency:”**

An occurrence or imminent threat of an illness or health condition that (1) is believed to be caused by any of the following:

- *Bioterrorism*
- *Natural disaster*
- *Appearance of a novel or previously controlled or eradicated infectious agent or biological toxin*
- *Chemical attack or accidental release*
- *Nuclear attack or accident; **and***

“Public Health Emergency” Defined - MSEHPA

(2) poses a high probability of any of the following harms occurring in a large number of the affected population:

- Death
- Serious or long-term disability
- Widespread exposure to infectious or toxic agent posing significant risk of substantial future harm

The Model State Emergency Health Powers Act (MSEHPA)

Individuals are bestowed special protections and entitlements



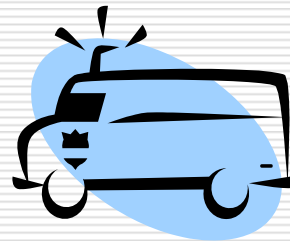
Government is vested with specific, expedited powers to facilitate emergency responses



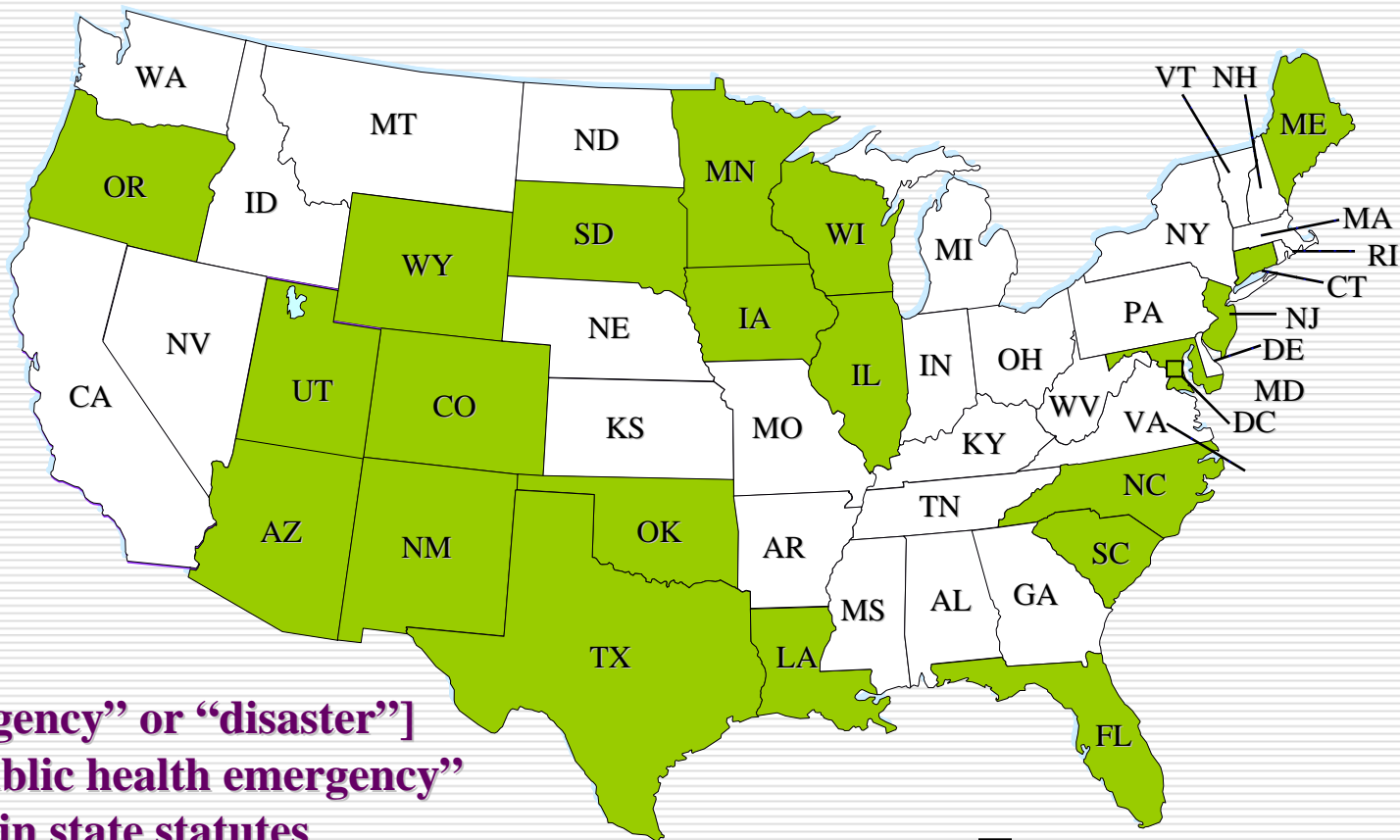
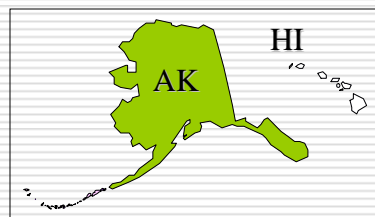
State medical licensure requirements may be waived



Responders may be protected from civil liability



States That Define “Public Health Emergency” **and** “Emergency” or “Disaster”



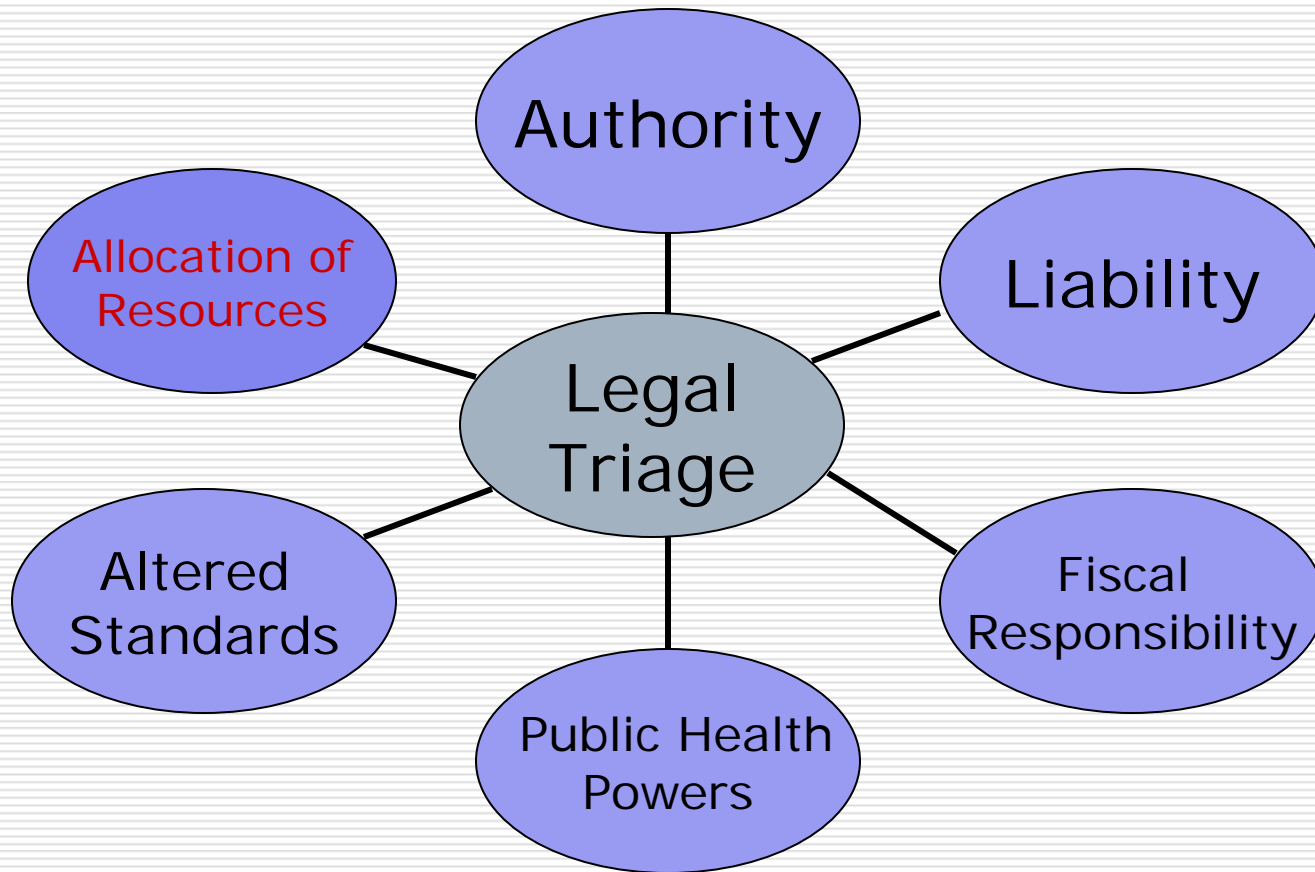
■ [“Emergency” or “disaster”]
and “public health emergency”
defined in state statutes

□ PR - (Puerto Rico)
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Dilemmas of Dual Declarations

- Triggering of distinct powers and responsibilities
- Assignments of powers to different governmental agencies (e.g., public health agency vs. emergency management agency) can lead to overlapping priorities
- Widely divergent responses and decisions on key issues

The Proliferation of Emergency Issues During Legal Triage



Legal Challenges in Allocating Scarce Resources

Emergency laws at every level of government can support community decisions in allocating scarce resources by:

- Authorizing expedited uses of public health powers by public and private sectors;
- Requiring unified efforts of public and private sectors to protect the public's health;
- Temporarily suspending statutes or regulations that may interfere with emergency medical responses (e.g. EMTALA, HIPAA Privacy Rule);

Legal Challenges in Allocating Scarce Resources

- Allowing interjurisdictional sharing of resources across local or state boundaries (e.g., EMAC);
- Helping governmental entities to quickly acquire essential supplies or services to meet surge capacity; and
- Clarifying specific options and priorities for resource allocations when supplies are scarce (e.g. flu vaccine distribution requirements).

Legal Challenges in Allocating Scarce Resources

Emergency laws and responses can also impinge ethical judgments by:

- Discounting strong ethical input in the face of exigent circumstances or in favor of political objectives;
- Stripping control of resources from private to public sectors, or within public sectors; and
- Overriding ethical judgments on grounds of conflicts with constitutional norms or other legal principles, however defined during emergencies

Ethical Challenge

How can ethically-sound practices or decisions be infused into legal responses in real-time emergencies?

Responding to this Challenge

PRINCIPLES OF LAW AND ETHICS TO GUIDE ALLOCATION DECISIONS INVOLVING SCARCE RESOURCES IN PUBLIC HEALTH EMERGENCIES

Based on input and discussion provided by participants at the:

Summit on Legal and Ethical Issues on the Frontlines of Public Health Emergency Response

Johns Hopkins Center for Public Health Preparedness
Johns Hopkins Berman Institute of Bioethics
Center for Law and the Public's Health

Principles of Legal/Ethical Process

- Maintain **transparency** (e.g., openness and public accessibility) in decision-making processes.
- Conduct public health **education and outreach** to encourage and facilitate community participation.
- Adhere to and communicate applicable **standards of care**.

Principles of Legal/Ethical Process

- Identify public health priorities based on modern, scientifically-sound **evidence**.
- Implement and coordinate initiatives that are **well-targeted** to accomplishing essential emergency public health services and functions.
- **Assess public health outcomes** following a specific allocation decision.
- Ensure **accountability** concerning the specific duties and liabilities of persons making allocation decisions.

Principles of Legal/Ethical Process

- Consider equally the public health needs of various individuals or groups regardless of their **human condition** (e.g., race, ethnicity, nationality, religious beliefs, sexual orientation, residency status, or ability to pay).

Conclusions

- *Questions, comments, suggestions*
- For more information, please contact me or visit the *Center's* website at: www.publichealthlaw.net
- *Thank you*