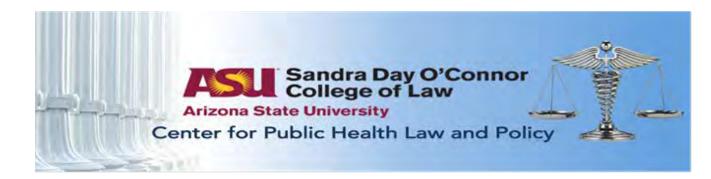
Arizona All-Hazards Legal & Ethical Preparedness Primer: COVID-19

AzCHER

James G. Hodge, Jr., JD, LLM

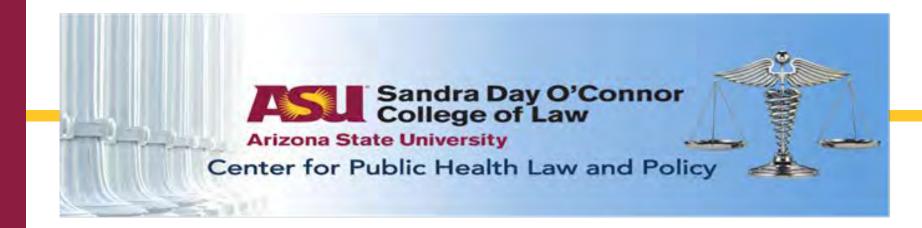
Professor & Director Center for Public Health Law & Policy



Special thanks to AzCHER for its support



ARIZONA COALITION FOR HEALTHCARE EMERGENCY RESPONSE



- Leading national center for public health law
- Home of the Western Region Office of the Network for Public Health Law (covering 11 states including Arizona)
- Provides legal technical assistance including:
 - Info & strategies about potential legal options
 - Help finding experts, resources & tools
 - Support for implementing & enforcing public health laws & policies

Disclaimer

Please note that the information in this primer does not constitute legal advice.

Always consult with legal counsel in your respective jurisdiction for specific legal advice.

Primary Objectives

- Report on COVID-19 outbreak globally and domestically
- Assess emergency legal preparedness on key topics
- Explore legal implications of emergency powers
- Examine crisis standards of care & related legal powers/duties in declared emergencies
- Identify potential legal risks & judicial responsibilities in emergencies
- Apply select principles of public health emergency ethics

COVID-19 Epi Snapshot

Transmission

- Transmissible person-to-person with potential infectivity rate exceeding annual influenza.
- Asymptomatic persons may clearly infect others.

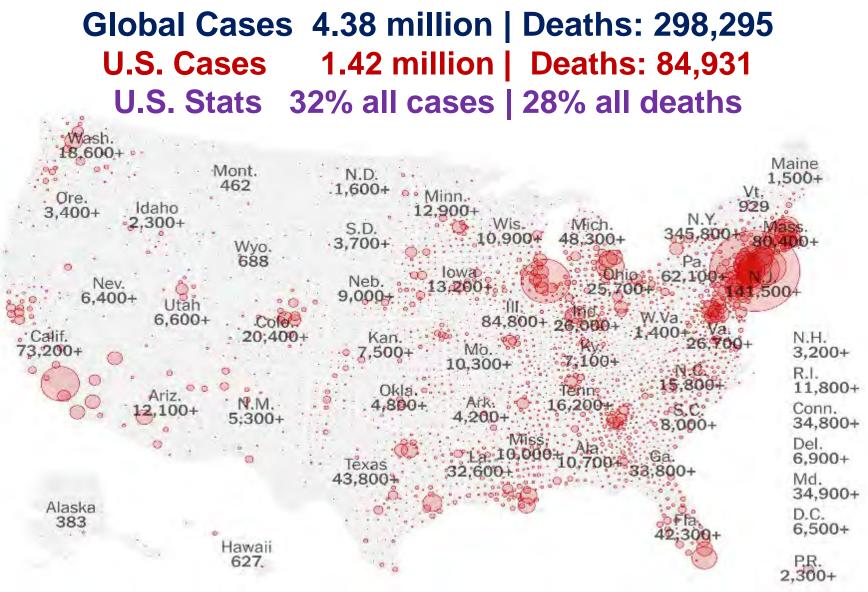
Symptoms

- Respiratory symptoms, fever, cough, breathing difficulties, chills, muscle pains, headache, sore throat & loss of smell/taste
- In severe cases infection can cause pneumonia, respiratory issues, kidney failure & death.

Vaccines & Treatment

• There are no effective treatments or vaccines although multiple options are under close review or assessment.

COVID-19 Confirmed Cases & Deaths



Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html

COVID-19 in Arizona

Total Confirmed Cases: 14,403

Total Deaths: 692



Role of Laws in Emergency Preparedness & Response

Define what constitutes an emergency Authorize the performance of emergency responses

Assign responsibility for potential/ actual harms that may arise

 Create the infrastructure for preventing & addressing emergencies Key Topics

Emergency declarations Public health surveillance 2 3 Standard of care 4 Scope of practice 5 Vaccination & treatment 6 Social distancing powers 7 Control of property 8 Liability 9 Emergency ethics Legal triage

Mass shooting in Tucson, AZ (2011)

Wildfire in Goodwin, AZ (2017)

1. Emergency declarations

Zika virus

Opioid overdose

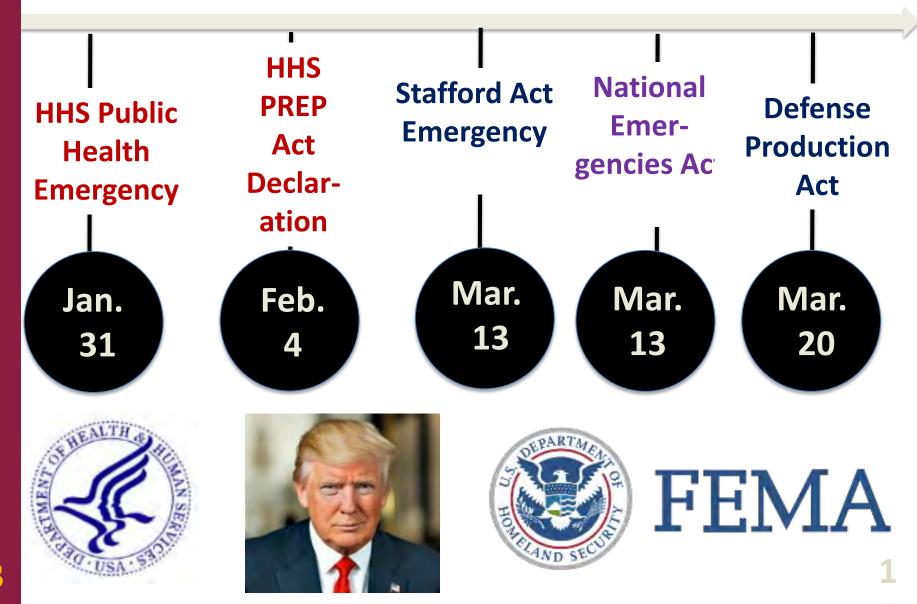


Unprecedented Emergency Declarations

Public health authorities, powers, liabilities & immunities vary depending on the type of emergency declared at each level of government

International	WHO Public Health Emergency of Int'l Concern January 30, 2020				Emergency Declarations by Foreign Governments Ongoing			
Fed	eral			or National ies Act	HHS Public Health Emergency			
		State	Emergency or Disaster		Public Health Emergency			
		Local		Emergency or Disaster	Public Health Emergency			

Federal Emergencies/ Invocations



HHS Public Health Emergency (PHE)

<u>1/31/20</u>: HHS Sec. Alex Azar declares national <u>public health</u> <u>emergency</u>



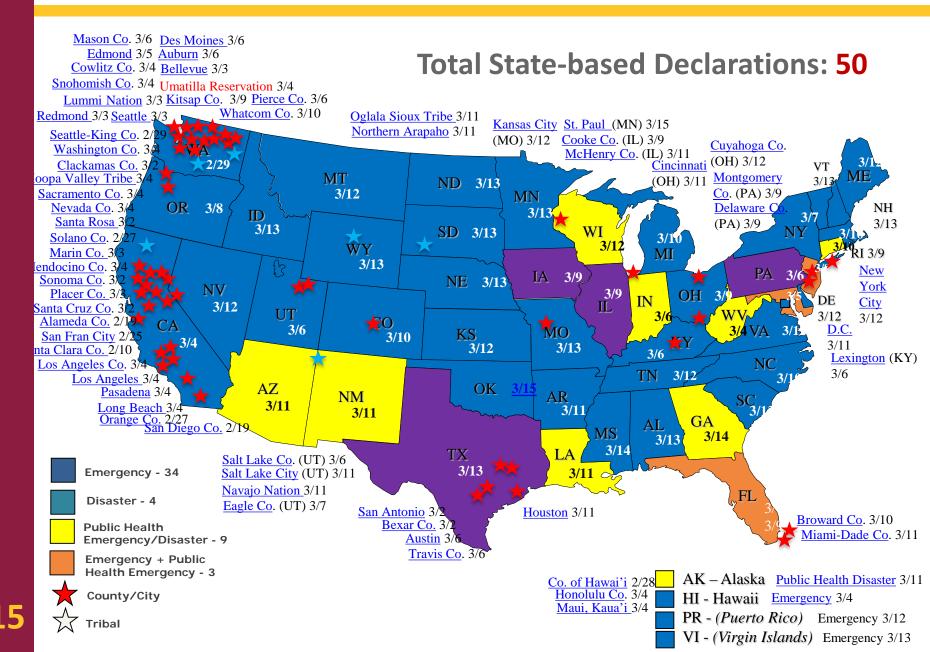
4/21/20: HHS Sec. Alex Azar renews PHE declaration for an additional 90 days

Public Health Service Act:

§ 319: declare a PHE for significant outbreaks of infectious diseases, bioterrorist attacks or other conditions.

§ 311: assist state/local authorities to prevent & suppress communicable diseases

State and Local Declared Emergencies



Emergency A.R.S. § 26-303

State of War Emergency A.R.S. § 26-303

Tucson Metropolitan Medical Response Systems Exercise

Different types of AZ emergency declarations

Opioid overdose

Public Health Emergency A.R.S. § 36-787

Harrah's Ak-Chin

HEALTH ALERT

Safeway

AZ measles outbreak

Apostolic Assembly

AZ Dep't Emergency Affairs

Local Emergency A.R.S. § 26-311

MEASLES OUTBREAK RISES TO 11 CONFIRMED CASES

BRACE FOR POTENTIALLY THOUSANDS OF EXPOSURES

Cheddar's

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Arizona State Emergency

March 11, 2020: Governor Doug Ducey issues a Declaration of Emergency



"There is no greater priority than the health and safety of Arizonans, and today's efforts are a proactive approach to ensure the state has all the tools necessary to address the global spread of COVID-19"

Public Health Emergency A.R.S. § 36-787

Occurrence or **imminent threat** of an illness or health condition that poses a **substantial risk** of a significant number of human fatalities or incidents of permanent or long-term disability



- Bioterrorism
- Biological toxin
- Epidemic/pandemic disease
- Highly fatal infectious agent
- Escalating fatal overdose rates



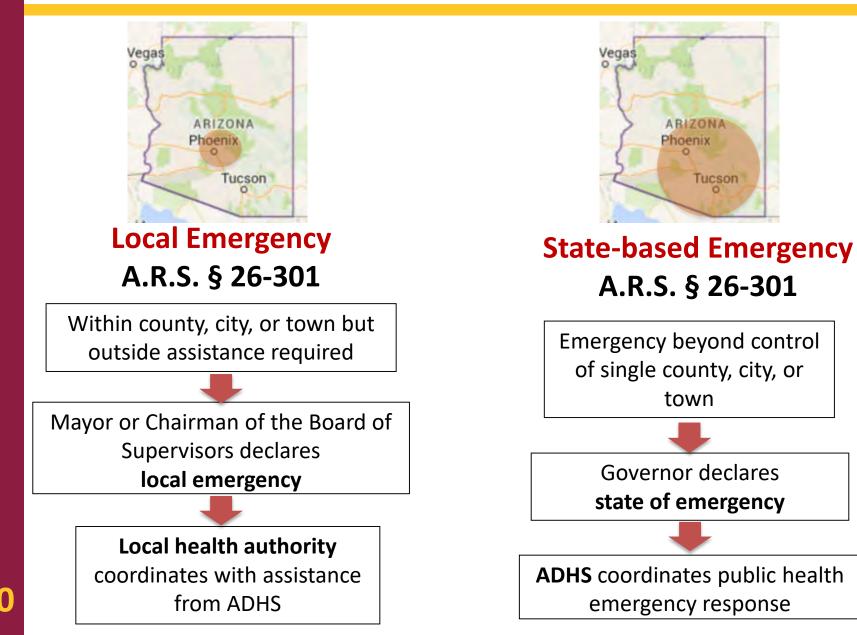
Arizona State Emergency

The **Emergency Declaration** provides the following tools to address the spread of COVID-19:

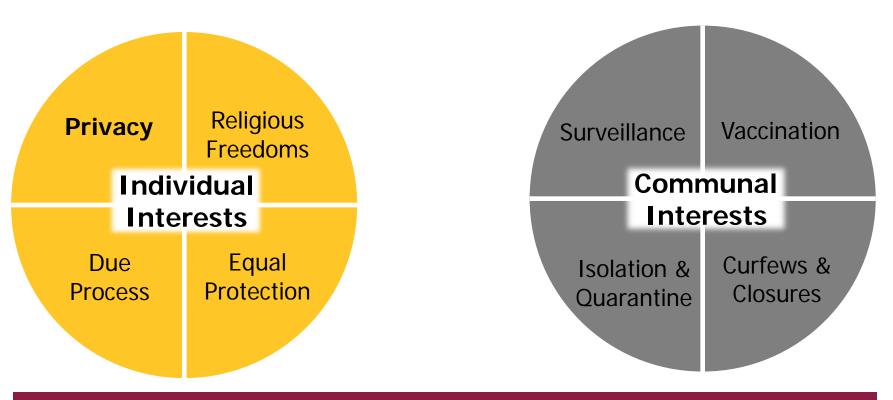
- Establishes the Arizona Department of Health Services (ADHS) as the entity responsible for coordinating all matters pertaining to the public health emergency response of the State.
- Allows ADHS to waive licensing requirements to provide health care officials with assistance in delivering services during times of heightened demand.
- Allows the state to access \$500,000 in emergency funds to aid in measures and resources to protect public health.
- Provides the state with **emergency procurement authority** to procure goods and services as needed to protect public health.



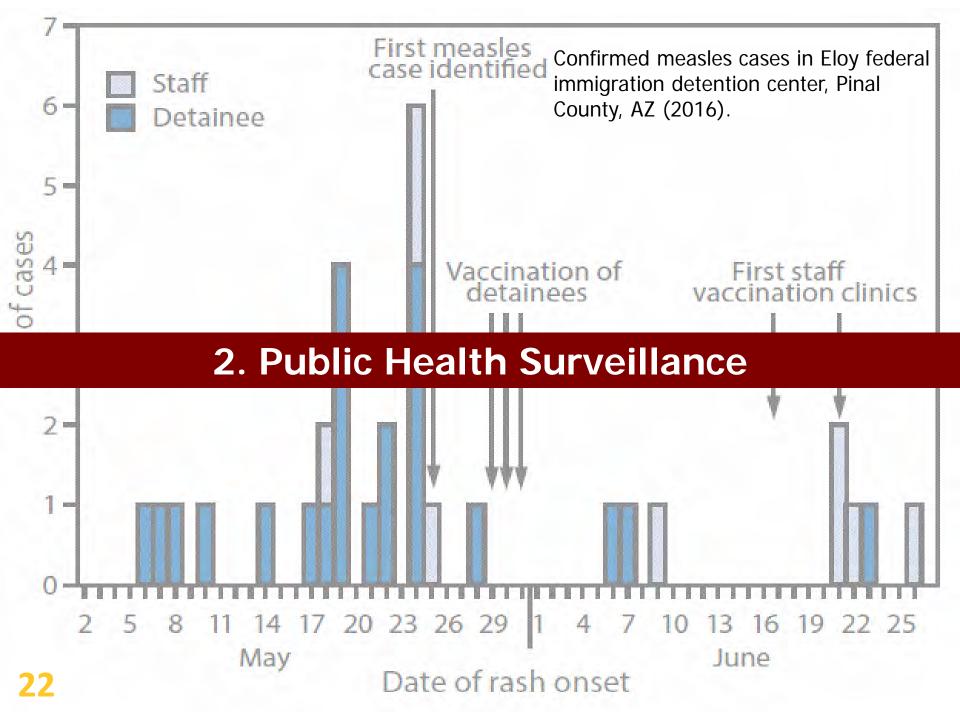
Emergency Coordination



Balancing Interests in Emergencies



State of Emergency



PHE Reporting Requirements

- Enhanced data reporting authority
 - State & local laws/practices may authorize tracking & surveillance of specific, additional conditions
- Expanded surveillance
 - Authorized explicitly in some state laws (or generally in others), this type of syndromic surveillance may include data related to school absences or over-the-counter medication sales

AZ Enhanced Surveillance Advisory

- A.R.S. § 36-782: Governor may issue an "enhanced surveillance advisory" upon a reasonable belief that an illness has been (or may be) caused by bioterrorism, epidemic, or pandemic disease.
- Surveillance advisory shall direct:
 - Persons & entities required to report;
 - Clinical syndromes to be reported;
 - Patient tracking;
 - Information sharing;
 - Specimen testing coordination.
- A.R.S. § 36-783: Health providers must report all cases of conditions specified in the advisory within 24 hours of identification.

Arizona Health Information Privacy

Arizona law covers the **confidentiality of patient records**

- A.R.S. § 12-2292.
 - All medical & payment records are privileged & confidential. A health provider may only disclose part or all of such records as:
 (1) authorized by state or federal law; or
 (2) via written authorization signed by the

patient or health care decision maker;

 Does <u>not</u> derail other federal or state laws governing the confidentiality of medical records & payment records.

HIPAA Privacy Rule

Covered entities may disclose **protected health information (PHI)** without individual authorization to state or local public health authorities:

- To prevent or control disease, injury or disability
- For disease reporting & public health surveillance
- To notify persons exposed to communicable diseases
- To prevent serious threats to persons or the public
- To address specific issues in declared emergencies

In a federally-declared **emergency** HHS may waive certain provisions of the HIPAA Privacy Rule.

Data Sharing & Privacy



Click on images to access

March 2020

COVID-19 & HIPAA Bulletin

Limited Waiver of HIPAA Sanctions and Penalties During a Nationwide Public Health Emergency

The Novel Coronavirus Disease (COVID-19) outbreak imposes additional challenges on health care providers. Often questions arise about the ability of entities covered by the HIPAA regulations to share information, including with friends and family, public health officials, and

COVID-19 and HIPAA: Disclosures to law enforcement, paramedics, other first responders and public health authorities

Does the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allow a covered entity to share the name or other identifying information of an individual who has been infected with, or exposed to, the virus SARS-CoV-2, or the disease caused by the virus, Coronavirus Disease 2019 (COVID-19), with law enforcement, paramedics, other first responders, and public health authorities without an individual's authorization?



3. Standard of Care



Shifting Standards of Care

Standard of Care

- Degree of care owed to patients by health providers in their respective discipline or class
- Generally refers to the duty owed by health providers to their patients depending on circumstances

Cooper v. VA Hospital Phoenix (2017): veteran awarded \$2.5 million when the U.S. magistrate court found that a failure to order more tests (despite certain abnormalities) breached SOC.

Crisis Standard of Care

- Specific circumstances & formal emergency declared justify substantial changes in the usual healthcare operations & level of care possible to deliver (IOM, 2009).
- Adapted standard of care to screen, assess & treat increasing numbers of patients when resources are scarce or limited.

Crisis Standards of Care



Steps Healthcare Facilities Can Take Now to Prepare for Coronavirus Disease 2019 (COVID-19)

Practical, Ethical, and Legal **Challenges Underlying Crisis** Standards of Care

Click on article image to access

James G. Hodge, Jr., Dan Hanfling, and Tia P. Powell

Addressing critical questions is complicated by changing legal dynamics during crises. Emergency powers depend on the type and duration of governmental declarations, which, in turn, may advance or impede CSC implementation.

Crisis Standards of Care

A Systems Framework for Catastrophic Disaster Response

Arizona CSC Plan



"During a PHE, the State Disaster Medical Advisory Committee convenes to develop incident-specific priorities & guidance for the delivery of health care & use of scarce medical resources. This guidance may address:

- Triage for emergency medical services;
- Primary, secondary & tertiary triage for health care facilities;
- Expanded scopes of practice as approved by regulatory authorities;
- Priorities for medical resources including space, staff & supplies;
- Considerations for health care access, including hospitals, out-of-hospital facilities & alternate care sites.

CSC Legal Issues

Issue	Description			
Surge capacity	Meeting legal requirements to treat existing & forthcoming patients			
Enhanced surveillance	Maintaining mechanisms for reporting, testing & screening			
Patients with disabilities	Providing accommodations consistent with relevant legal & ethical protections			
Scarcity	Facilitating processes for determining allocation of limited resources			
Expanded scope of practice	Coordinating personnel (employees, contractors, volunteers) to provide services			



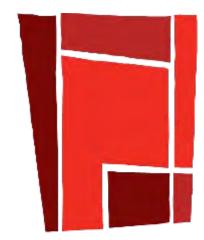
4. Scope of Practice



Arizona Emergency Authority

A.R.S. § 36-787(A)(7)

During a declared PHE, ADHS is authorized to temporarily alter professional licensure requirements to facilitate emergency responses



ARIZONA DEPARTMENT OF HEALTH SERVICES

Mutual Aid Assistance

Interstate: Emergency Management Assistance Compact (EMAC)

- Legislatively-authorized contract among all states for sharing personnel & other resources
- Triggered by state declaration of emergency + request for assistance

Intrastate

- State mutual aid legislation
- Formal mutual aid agreements between local governments
- Less formal mutual aid agreements for routine cooperation
- Interjurisdictional resolutions

Tribal Nations

 Mutual aid agreements between tribes & state/local health departments can facilitate the sharing of personnel and other resources

Volunteer Registration Programs

State Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) Local Medical Reserve Corps (MRC)

MRC Programs Assist with VHPs:

ESAR-VHP Programs Verify VHPs:

- Identification
- Credentials
- Licenses (including reciprocity)
- Accreditations
- Hospital privileges

- Approval
- Credentialing (via ESAR-VHP)
- Training
- Screening (background checks, medical assessments)

Hospital Privileges

General Privileges

- Authority granted to a physician by a hospital governing board to provide patient care
- Limited by the individual's professional license, experience & competence

Poston v. UA Medical Center (2014): Surgeon specializing in robotic coronary bypass settled with hospital that suspended his privileges when peer review committee deemed him an imminent threat to patients.

Emergency Privileges

- May be granted by a hospital governing board or CEO in declared emergencies regardless of a physician's regular assignment or status
- Alternatively, temporary privileges may be granted to a VHP to provide health services for a limited period

Dispensing Medicines & Drugs

Routine

- Only state-licensed pharmacists, interns & other licensed practitioners (MDs, DOs, PAs, RNPs), may dispense prescription drugs & devices
- State or county public health facilities may dispense without a prescription if storage, safety, labeling & recordkeeping requirements are met

Emergency

- Pharmacists & practitioners licensed in other states (participating as VHPs) may be permitted to dispense drugs or devices
- Other VHPs may dispense if licensing requirements are temporarily waived or scopes of practice are altered



5. Vaccination & Treatment



Arizona Vaccination & Treatment Mandates

A.R.S. § 36-787(C):

- During declared states of emergency, the Governor, in consultation with ADHS' director, may mandate medical examinations for persons exposed to a contagious disease.
- In emergencies involving threats of smallpox, plague, viral hemorrhagic fevers (e.g., Ebola), or other highly contagious/fatal disease, the Governor may mandate vaccination or treatment of persons infected, exposed, or reasonably believed to have been exposed to the harm-causing agent.

Constitutional Considerations

A.R.S. § 36-787(F):

During a state of emergency, unless the public's health is endangered, ADHS may not:

- impose a mode of treatment on any person; or
- require treatment contrary to one's religious concepts

so long as sanitary or preventive measures & quarantine laws are complied with.

Emergency Use Authorizations



- Emergency Use Authorizations (EUAs) permit the use of unapproved medical drugs or devices during a federally-declared state of emergency if:
 - Serious or life-threatening disease or condition
 - Unapproved product appears **potentially effective** to diagnose/treat/prevent
 - Known & potential benefits outweigh risks
 - Lack of adequate & available approved alternatives
 - Necessary & appropriate use conditions are established

Emergency Use Authorizations



Jan. 27, 2020: FDA Announces Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures

Emergency Use Authorization of Medical Products and Related Authorities

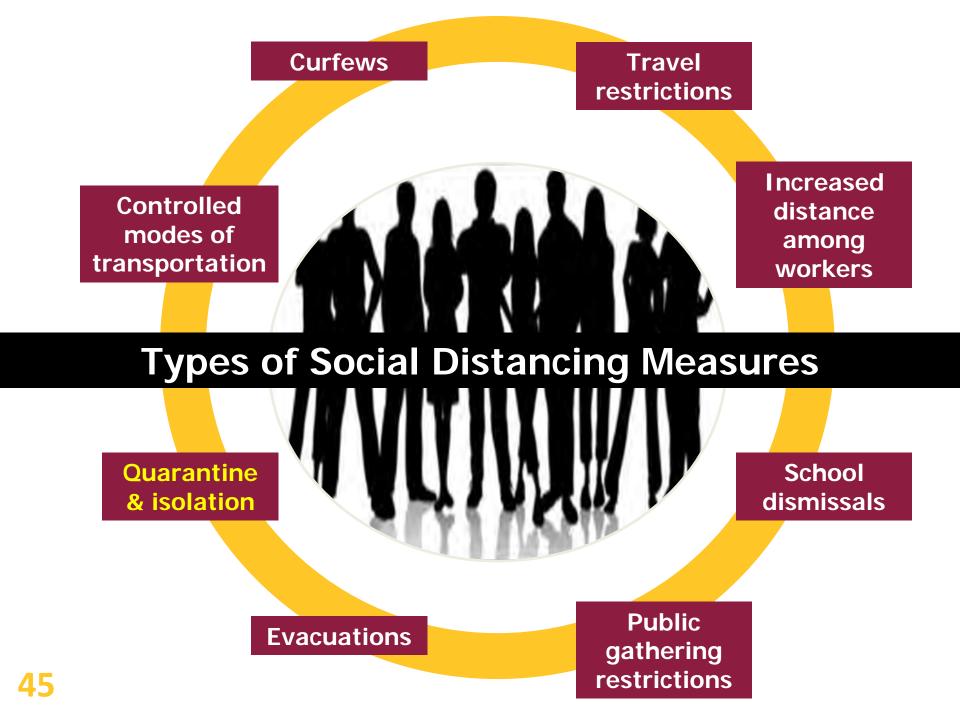
Guidance for Industry and Other Stakeholders

U.S. Department of Health and Human Services Feed and Drug Administration Office of the Countissioner Office of the Chief Scientist Office of Counterterrorism and Emerging Threats Feb. 4, 2020: FDA grants EUA for CDC's COVID-19 Real-Time PCR Diagnostic Panel.



6. Social Distancing Powers





Quarantine & Isolation Illustrated

A.R.S. § 36-787



Separation from others of persons who are exposed to a contagious condition prior to knowing if such persons may be ill or contagious

Isolation

Separation from others of persons known to be infected with a contagious condition

Individual exposed to contagion

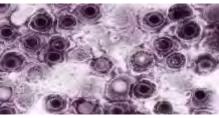
Contagious Diseases Subject to Q & I

Yes



Viral Hemorrhagic Fever A.A.C. § R9-6-390

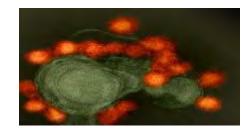
No



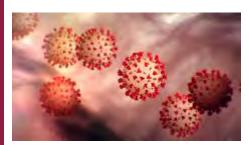
HIV/AIDS



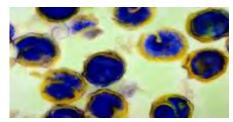
Active Tuberculosis A.A.C. § R9-6-380



Zika virus



Emerging or Exotic Disease A.A.C. § R9-6-327



Chlamydia

Federal Social Distancing Authority

March 21, 2017: new regulations strengthen CDC's authority to:

- conduct disease prevention measures at airports, seaports, bus terminals & other transportation hubs.
- subject travelers to observation, questioning, review of health & travel records or (in some cases) medical exams.
- issue orders for apprehension, isolation, quarantine, or conditional release of individuals reasonably believed to have a "quarantinable condition."
- keep infected individuals from travelling (with exceptions) without a federal travel permit.





Federal Quarantine & Isolation In Practice



Jan. 31, 2020: CDC Director Robert Redfield orders a 14-day quarantine of nearly 200 persons arriving at a U.S. military base in California 2 days prior on an evacuation flight from Wuhan, China.

As of February 10, 2020, 4 additional flights amassing more than 800 Americans are under quarantine at 4 military bases.



Feb. 17, 2020: CDC quarantines 2 flights of over 300 Americans returning from the Diamond Princess cruise ship (in Yokohama, Japan) at Travis and Lackland Airforce Bases.

Feb. 19, 2020: U.S. Daegu Army Base in South Korea imposes a selfquarantine of U.S. troop members attending a local church linked to COVID-19 infections.

Arizona Quarantine and Isolation Authorities

Option 1 A.R.S. § 36-136 ADHS General Authorities (including Q and I)

Option 2 A.R.S. § 36-624 ADHS/County Routine Q and I Authorities

Option 3 A.R.S. § 36-789 Emergency Q and I

AZ Quarantine & Isolation Laws: Non-emergency

- Generalized Q & I Authority: A.R.S. § 36-136
 - ADHS Director may prescribe measures for controlling communicable and preventable diseases, including by isolation or quarantine.
 - Could adopt by reference emergency procedures for judicial review as noted in A.R.S. § 36-789.
- Explicit Q & I Authority: A.R.S. § 36-624
 - After investigation, if it is determined that a communicable disease exists a local health department may take isolation and quarantine measures consistent with ADHS rules and A.R.S. §§ 36-788, 36-789.
 - The local health department shall **immediately notify** ADHS of the existence and nature of the disease and response measures.

Reporting Requirements A.A.C. § R9-6-302

Local health agency confirms existence of potential or actual contagious disease



May implement isolation/quarantine measures affecting private individuals



Agency must notify **ADHS** of any quarantine measures taken

ARIZONA DEPARTMENT OF HEALTH SERVICES

Isolation & Quarantine - Emergency A.R.S. § 36-789



Acknowledgment: Aubrey Joy Corcoran, JD, MPH, AZ AG's Office

Additional Due Process for Q & I A.R.S. § 36-789





Court shall appoint counsel at government expense Court may consolidate individual claims into groups



Constitutional Considerations



Judicial Review of Agency Actions A.R.S. § 36-789

- 1. Original hearing on quarantine petition
- Quarantined or isolated persons may apply to the court for a "show cause" order from agency why they may not be released
- They may also apply for a hearing regarding treatment and conditions of quarantine or isolation
- 4. Petitions for **habeas corpus** are always a possibility

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7. Control of Property



Government Takings

5th Amendment requires government to pay just compensation to owners of property that the government "takes."

- applies in ordinary time & emergencies
- exception: destruction by necessity



<u>Takings in PA</u>: In *Friends of Danny DeVito v. Wolf*, the PA S. Ct determined that temporary closures of non-essential businesses under the Governor's emergency orders did not constitute a taking. Plaintiffs have sought review via the U.S. Supreme Court.

Nuisance Abatement

- When private uses of land or other property may harm community health, routine powers allow state & local officials to enter & inspect the property, remove offending issues, or condemn the property.
- A.R.S. § 36-601(A): "nuisances dangerous to public health" subject to cease & desist orders, include:
 - Populous places constituting breeding grounds for disease-carrying rodents or insects;
 - Presence of bedbugs, lice, or mites in places offering sleeping accommodations to the public; or
 - Contamination of public drinking waters.

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Tonopah, AZ: in Aug 2017, local businesses & neighbors sued a farm operation alleging its pollution, odors & flies are a nuisance.



Reimbursement/Compensation

Nuisance Abatement

 No compensation for property owners is required



Takings

- A.R.S. § 35-192: liabilities & expenses incurred to meet & mitigate contingencies in declared emergencies may be paid as claims against the state from unrestricted funds.
- Stafford Act, 42 U.S.C. § 5121, et seq.: FEMA may reimburse costs incurred by state/local governments or individuals in emergencies.

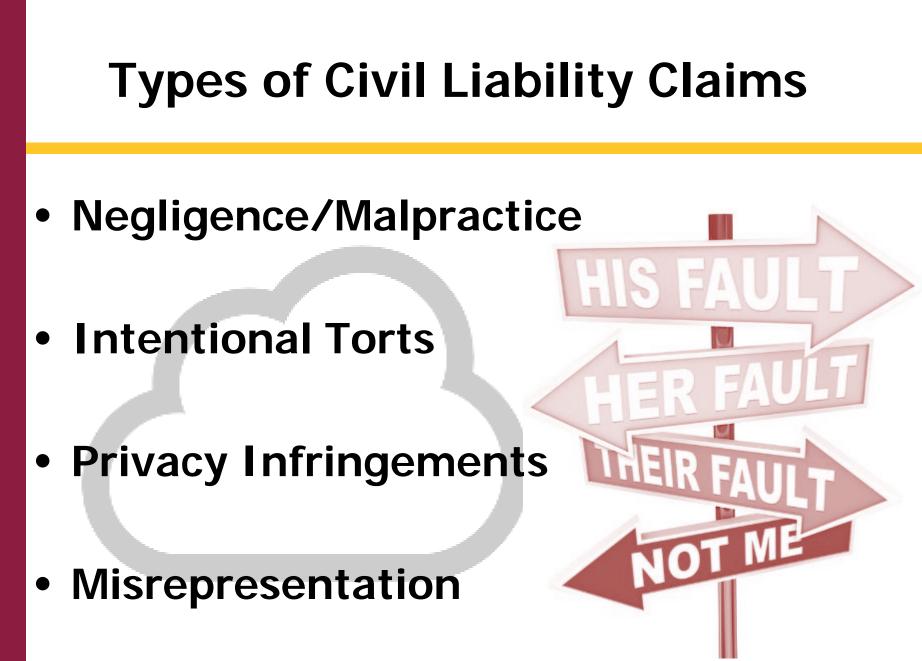


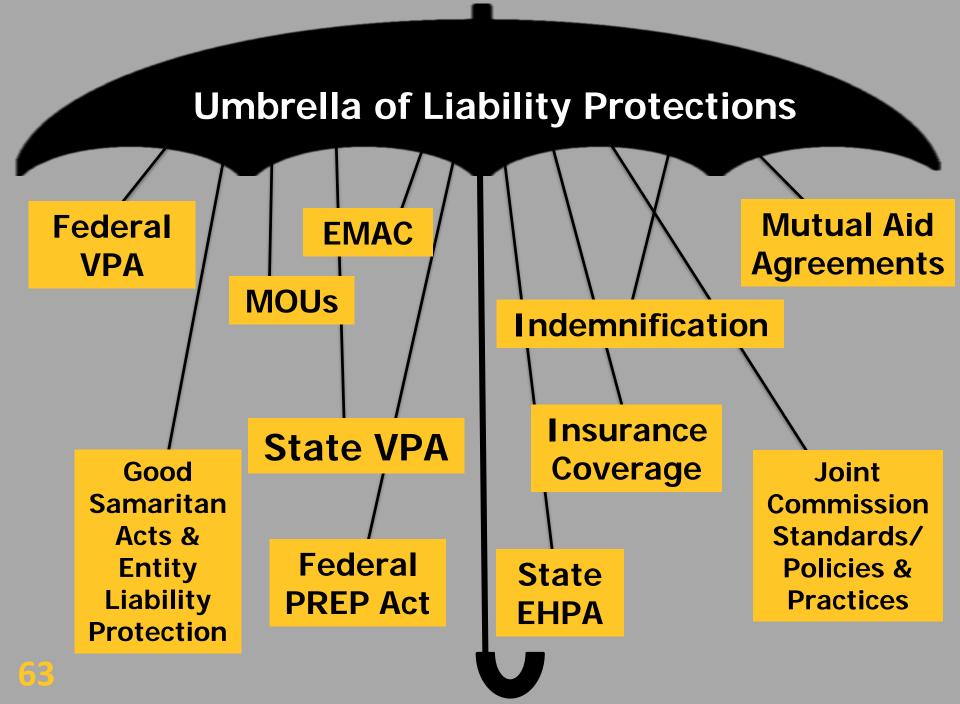




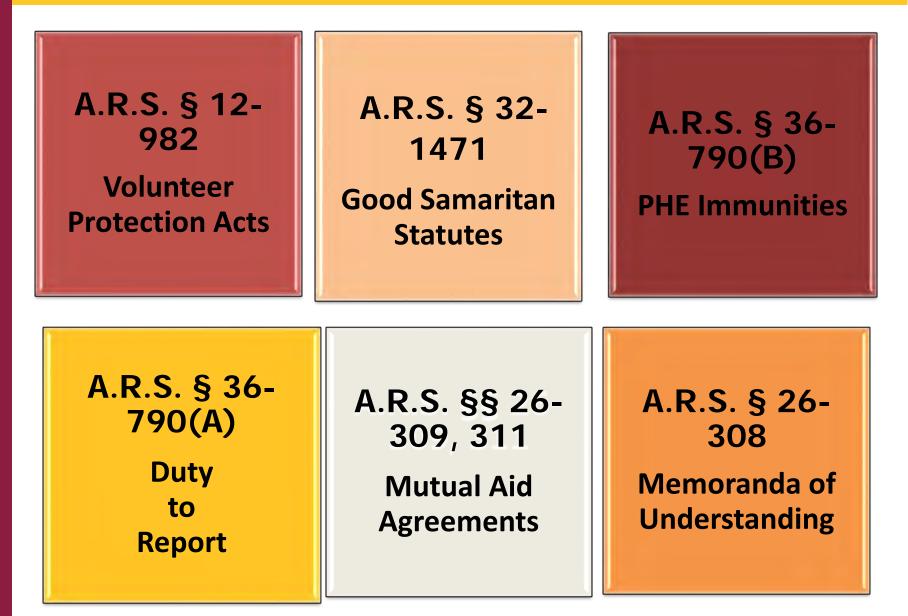
8. Liability







Arizona Liability Protections



Workers Compensation

Non-Emergency

- Workers compensation programs & laws protect employees injured or killed at work
- Simple rule: *if you get hurt at work, your employer pays regardless of who is actually at fault*

Emergency

 In declared emergencies, application of this simple rule gets murky due to the limited extent of workers compensation coverage for employees acting outside their typical setting & VHPs



9. Emergency Ethics



Routine Ethics vs. PHE Ethics





Principles of Public health PHE bioethics ethics ethics

Core PHE Ethics

- Stewardship
- Transparency
- Soundness
- Duty to Care
- Proportionality
- Accountability
- Reciprocity
- Fairness

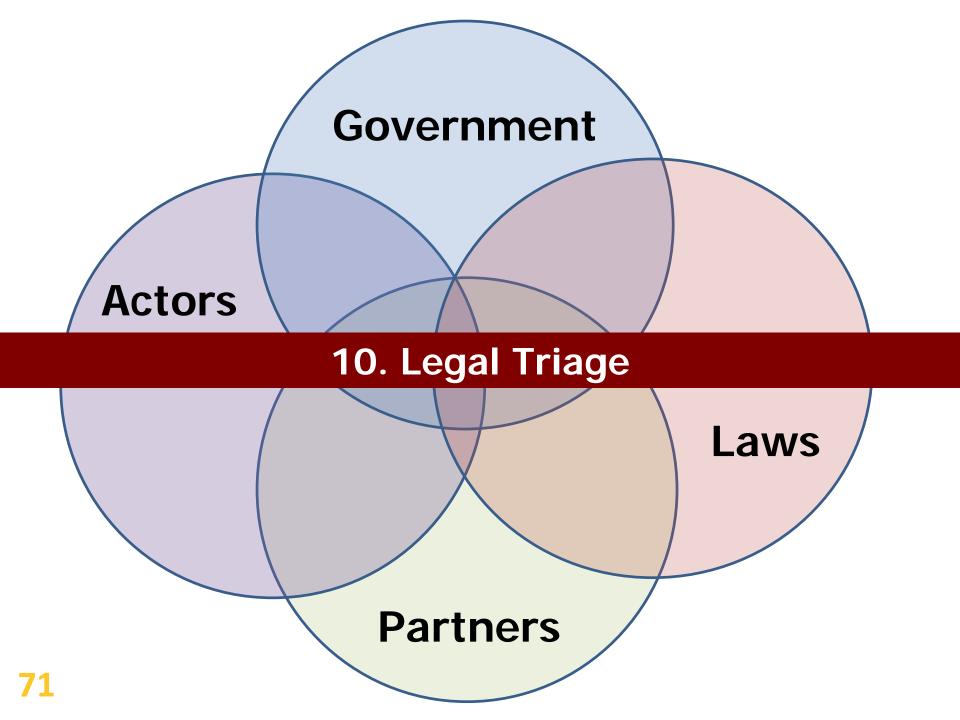
Reciprocity

- Health providers facing disproportionate risks or burdens in PHEs for the benefit of the community are entitled to receive additional support.
- Those who perform essential emergency functions may be prioritized for protective measures in limited supply where possible.

Fairness

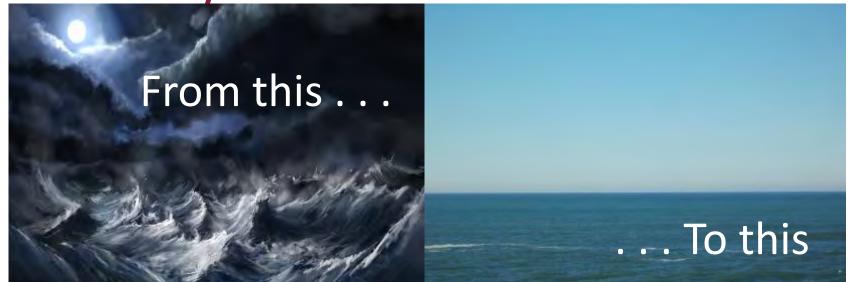
- In PHEs, similarly-situated individuals & groups should be treated alike.
- Health care/public health responses & allocations of scarce resources may not be based on factors unrelated to health status or emergency response needs. Focus on:

✓ consistency
 ✓ medical need & prognosis
 ✓ justice
 ✓ privacy



Legal Triage - Defined

Efforts among legal actors & others to build a favorable legal environment in emergencies by prioritizing issues & solutions facilitating legitimate public health responses



Addressing Real-Time Legal Issues

solutions

Identify

legal

issues

In responding to PHEs, legal & public health actors must work together in real time to:

> Explain legal conclusions Develop legal

Collaborate with public & private sector partners

Assess, apply & monitor changing legal norms **Temporary Waivers**

Federal laws concerning programs like Medicare or Medicaid may be altered or waived temporarily in emergencies to facilitate treatment & prevent the spread of contagious diseases

Emergency Waivers

Mar. 13: HHS Sec. Azar issues §1135 national waivers re:

- EMTALA sanctions for patient relocation purposes
- HIPAA Privacy Rule regulations (for limited duration)
- In-state licensure requirements for health care workers
- Participation restrictions on Medicare, Medicaid, SCHIP
- Medicare Advantage payment limitations
- Stark Law sanctions

<u>April 15</u>: CMS updates waivers for health care providers re:

- Telemedicine provisions, facilitating Medicare services
- Physical environments to allow care in non-hospital settings during surge
- Patient rights surrounding access to medical records, visitation & seclusion

Key Take Aways & Resources

Take Aways 1

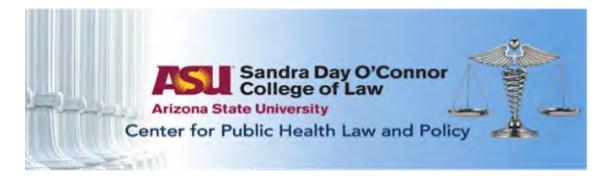
#	Торіс	Message
1	Emergency declarations	Emergency declarations at multiple levels of government change the legal landscape of public health authority.
2	Public health surveillance	Federal & state laws provide for enhanced surveillance & reporting authority during PHEs to detect/prevent threats.
3	Standard of care	Heightened PHE circumstances can shift operations & levels of care owed to patients to maximize use of resources.
4	Scope of practice	State authorities may temporarily alter professional licensure requirements during PHEs to facilitate responses.
5	Vaccination & treatment	PHEs broaden governmental powers to require & administer medical therapies, drugs & devices.

Take Aways 2

#	Торіс	Message
6	Social distancing powers	Governments must balance civil liberties & other rights in preventing the spread of contagious diseases.
7	Control of property	Routine & emergency powers permit government control of individual property for public safety.
8	Liability	Federal & state laws provide numerous liability protections for responders & VHPs during emergencies.
9	Emergency ethics	PHE ethics diverge from bioethics or public health ethics to facilitate emergency responses.
10	Legal triage	Legal & public health actors must align to assess & address real-time legal issues.
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Key Resources 1







Ideas. Experience. Practical answers.

Conclusion & Acknowledgments

- Special thanks to Claudia M. Reeves & Erica N. White at ASU's Center for Public Health Law & Policy for their contributions
- Contact James G. Hodge, Jr. with questions, comments, or requests for more information at:

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