

COVID-19

Emergency Legal Preparedness Primer

As of February 1, 2021

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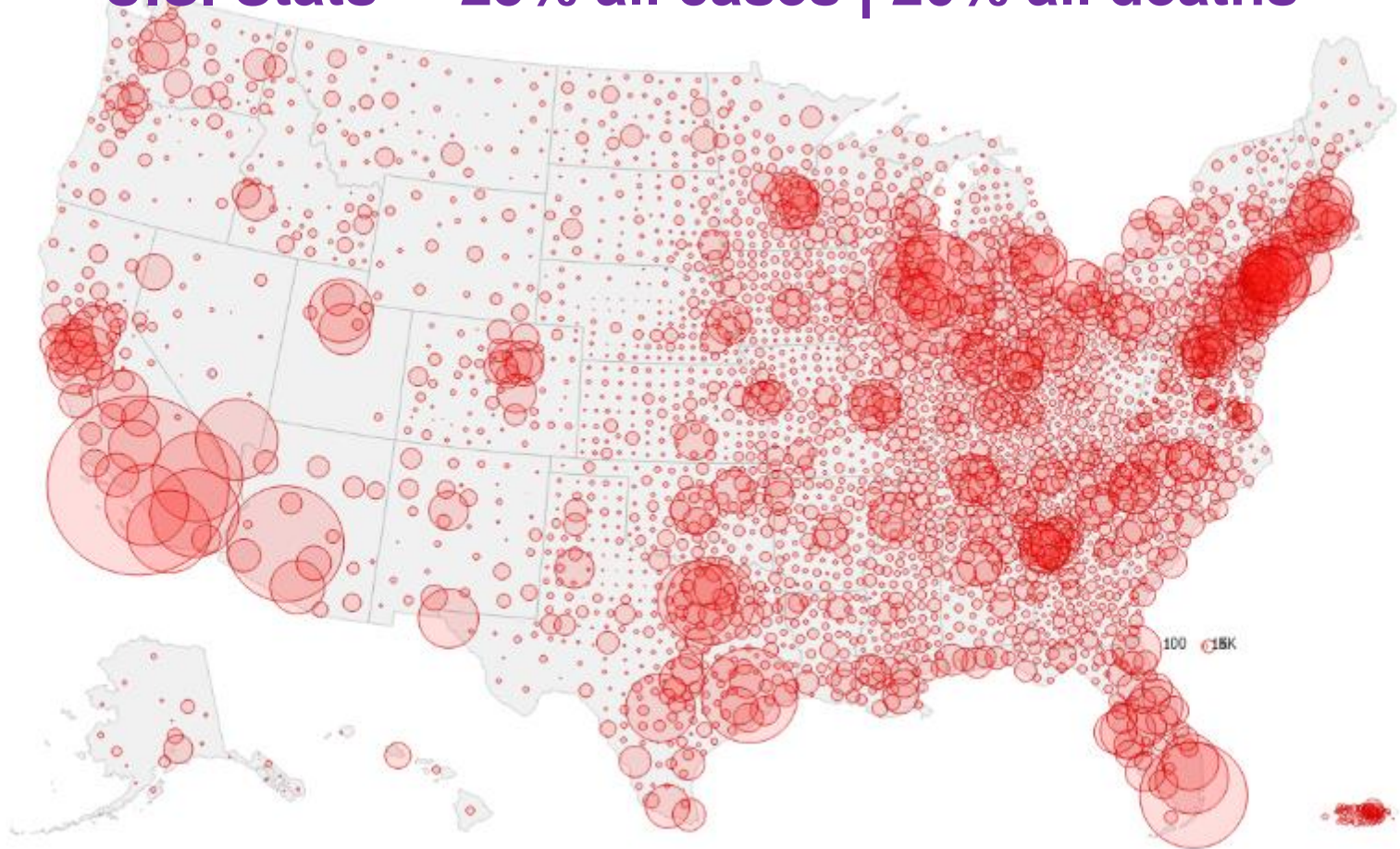
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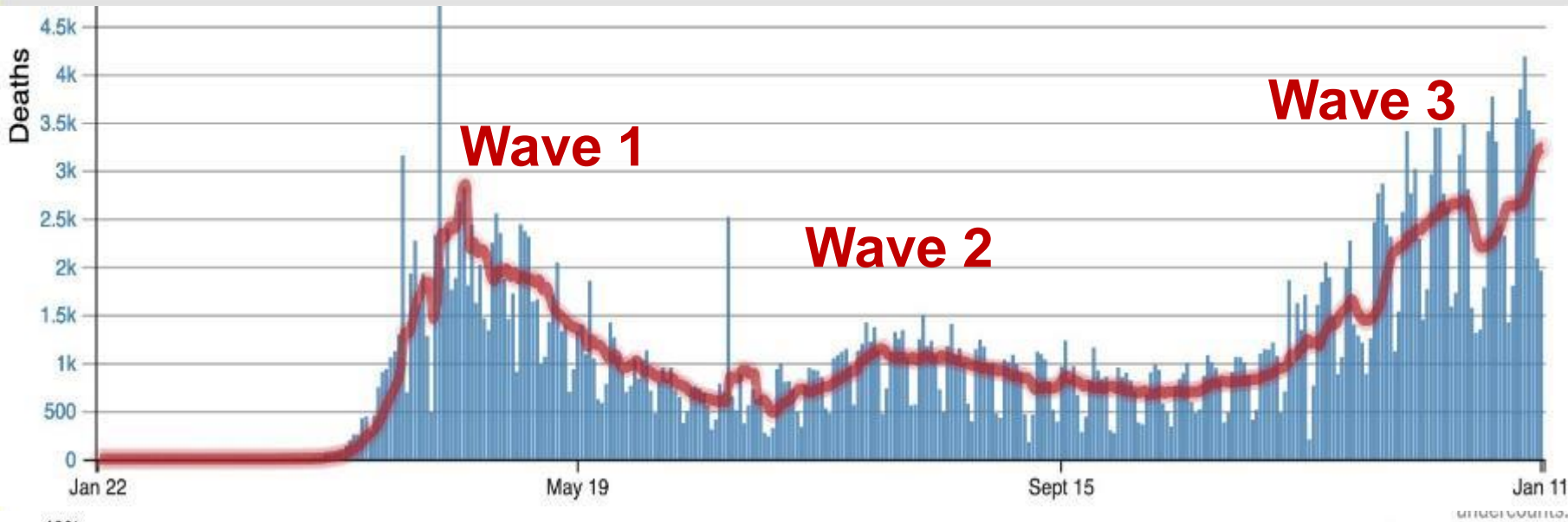
- COVID-19 Epi Trends**
- Emergency Legal Preparedness/
Response/Recovery**
- Constitutional & Other Challenges**
- Public Health Emergency Powers**
- Crisis Standards of Care**
- COVID-19 Vaccinations**
- National Strategic Response Plan**
- Additional Resources**

Global Cases 103 million | Deaths: 2.23 million

U.S. Cases 26.19 million | Deaths: 441,331

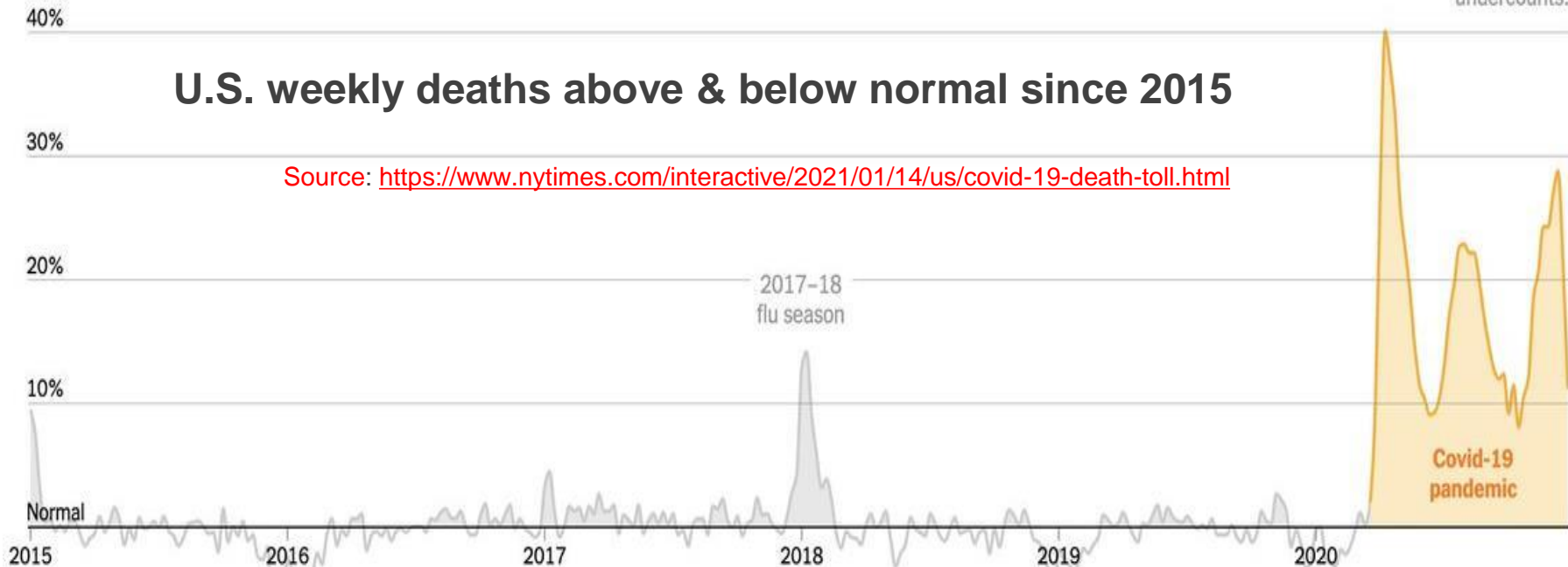
U.S. Stats 25% all cases | 20% all deaths





U.S. weekly deaths above & below normal since 2015

Source: <https://www.nytimes.com/interactive/2021/01/14/us/covid-19-death-toll.html>



81%
of deaths in
persons
ages 65+

66,000+
deaths of
persons ages
64 & under

54%
of deaths
among males

2.8x*
number of
deaths
among
Blacks

2.8x*
number of
deaths
among
Hispanics

2.6x*
number of
deaths
among Native
Americans

* Compared to White/Non-Hispanics persons



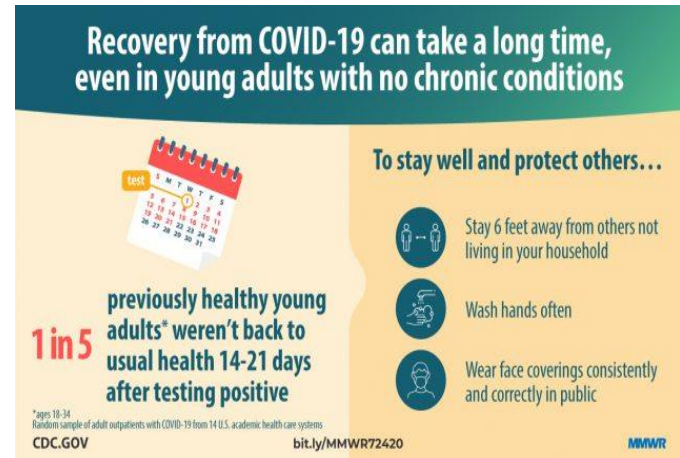
Asymptomatic persons could account for 40-45% of infections spread



Multiple vaccines are authorized for use; others remain in Phase III clinical trials






Antibodies may be insufficient to ward off additional infections



Recovery from COVID-19 can take a long time, even in young adults with no chronic conditions

1 in 5 previously healthy young adults* weren't back to usual health 14-21 days after testing positive

To stay well and protect others...

-  Stay 6 feet away from others not living in your household
-  Wash hands often
-  Wear face coverings consistently and correctly in public

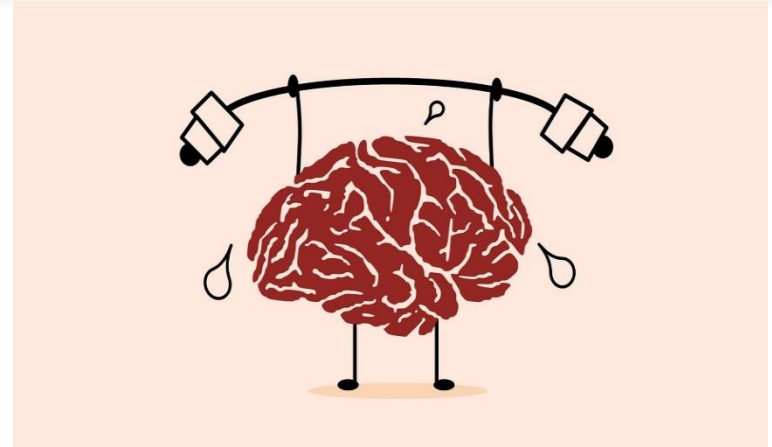
*ages 18-24
Random sample of adult outpatients with COVID-19 from 14 U.S. academic health care systems
CDC.GOV bit.ly/MMWR72420 MMWR

COVID-19 can cause milder outpatient illnesses among young adults & others

Epi & Medical Trends II



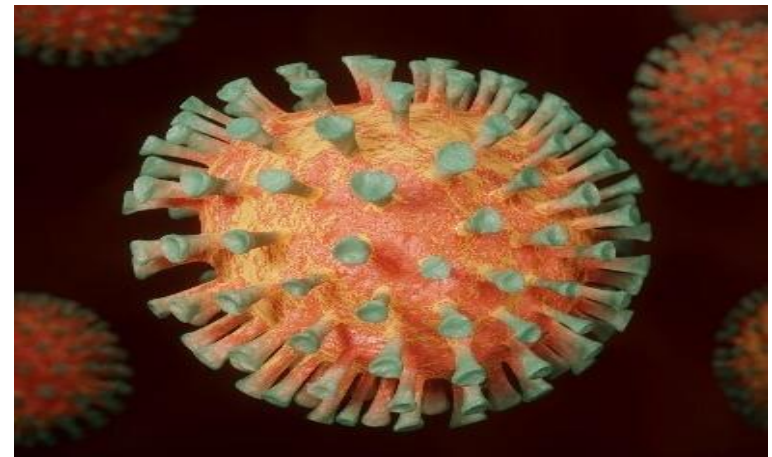
“Long haul COVID” cases extend over months



Evidence is emerging of impacts of COVID infection on mental health

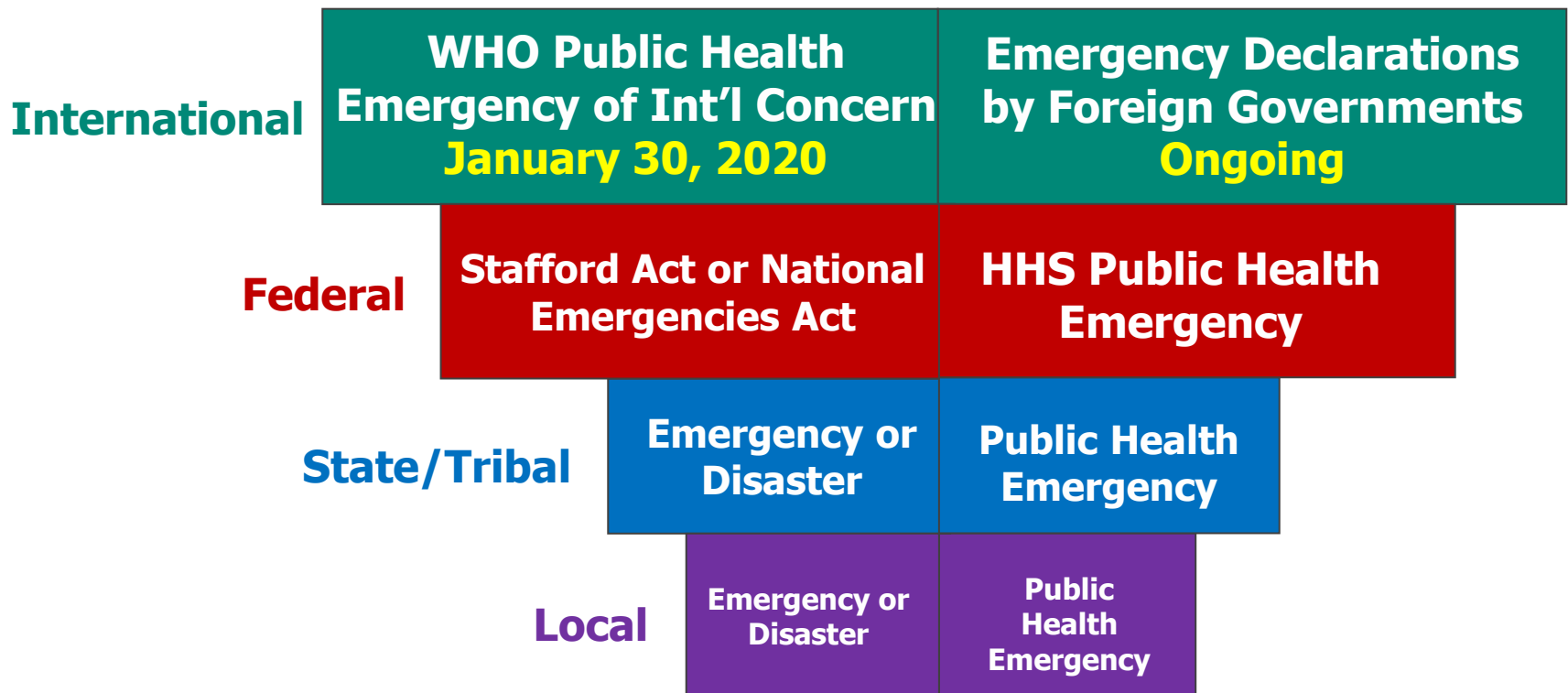


“Super spreader” events entail extensive risks for affected persons



Viral variants challenge existing infection rates and vaccines

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



Jan. 31: HHS Sec. Alex Azar declares national **public health emergency** effective as of Jan. 27, 2020 (and since renewed on 3 subsequent occasions).



- Encourages interjurisdictional coordination
- Allows waivers of specific federal laws
- Authorizes real-time countermeasures through emergency use authorizations
- Supports social distancing measures

Federal Emergencies/Invocations

**HHS Public
Health
Emergency**

**Jan.
31**

**HHS
PREP
Act
Declara-
tion**

**Feb.
4**

**Stafford
Act
Emergency**

**Mar.
13**

**National
Emer-
gencies
Act**

**Mar.
13**

**Defense
Production
Act**

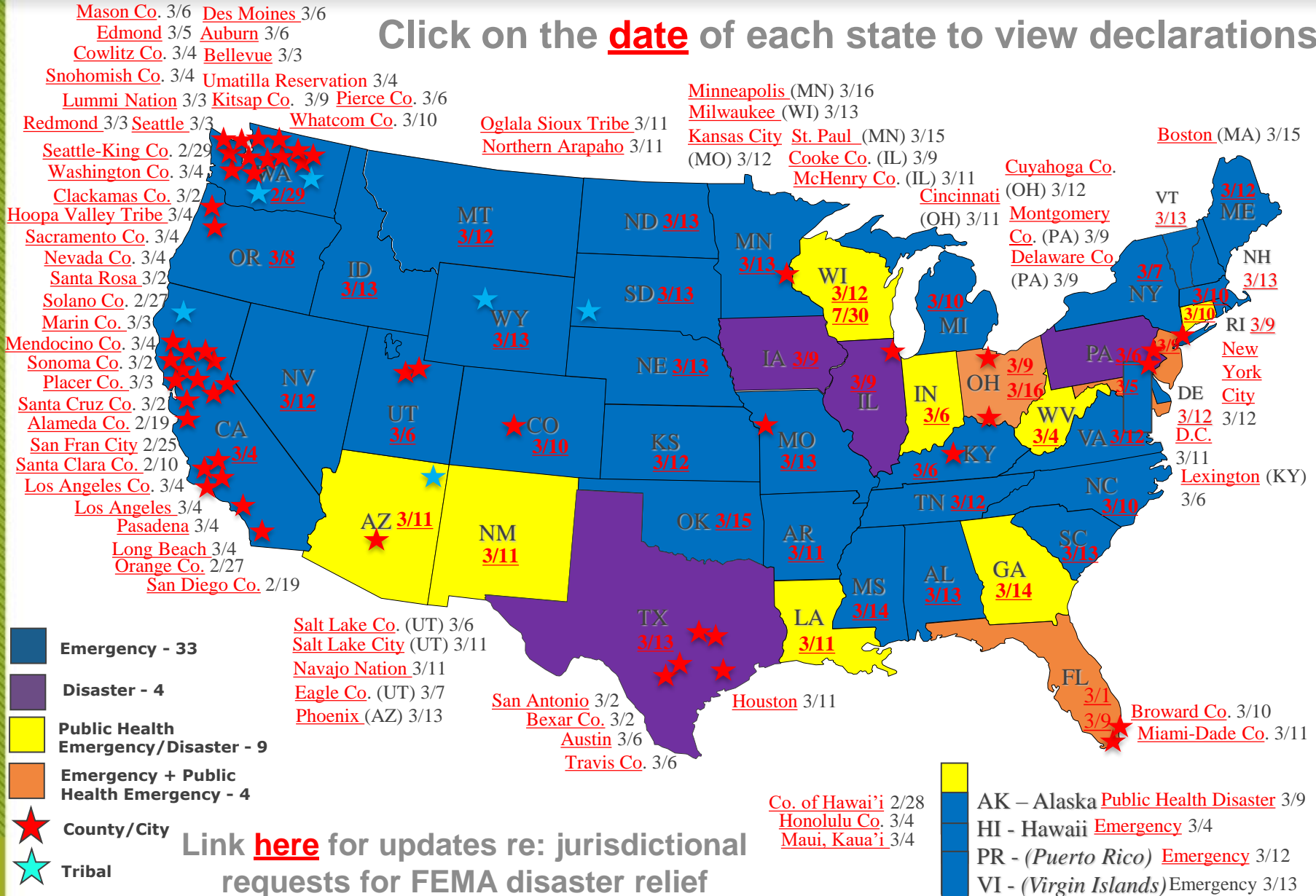
**Mar.
20**



FEMA

COVID State & Select Tribal/Local Emergency Declarations

Click on the **date** of each state to view declarations

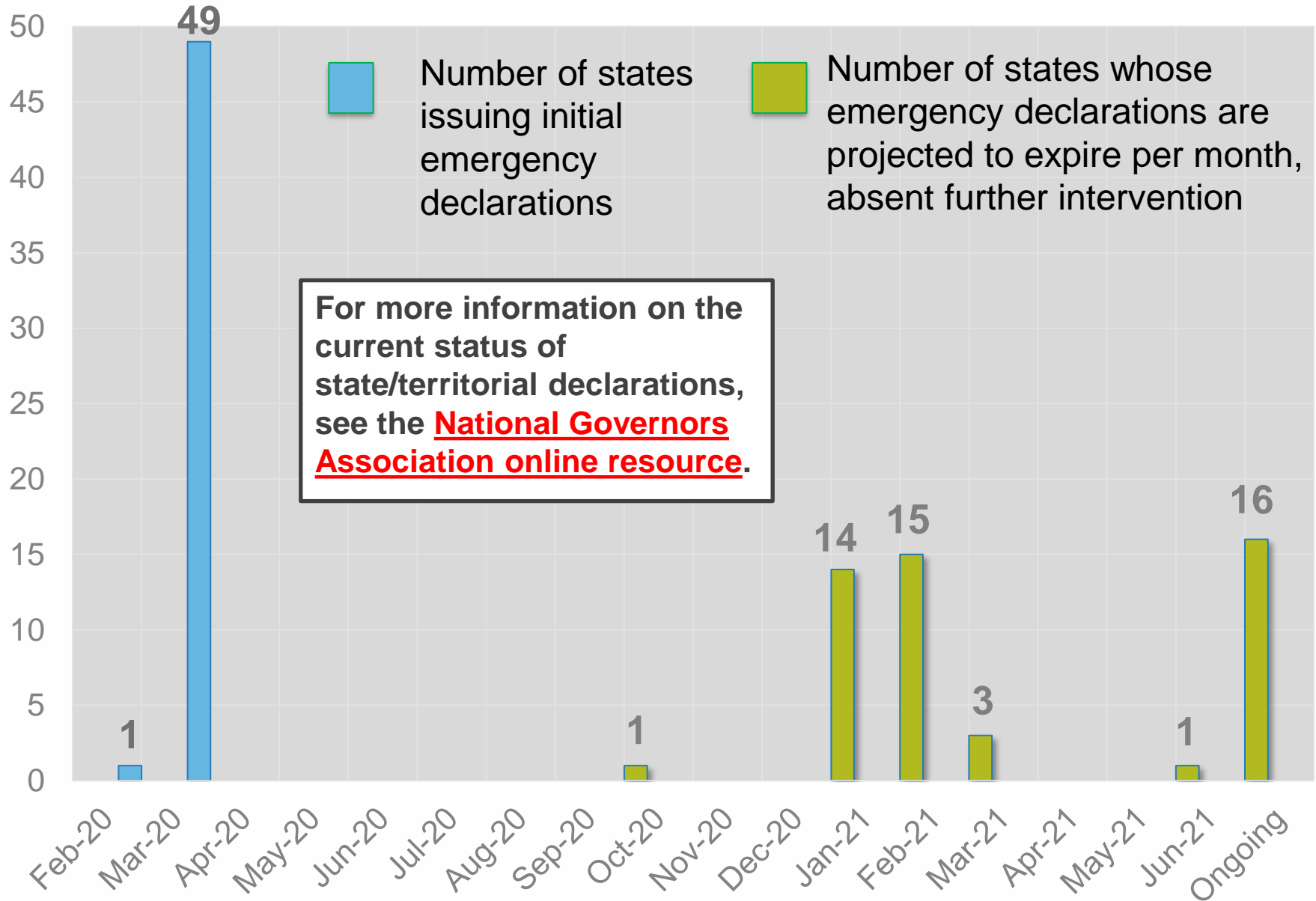


Select State Emergency Powers Explicitly Invoked by Declarations

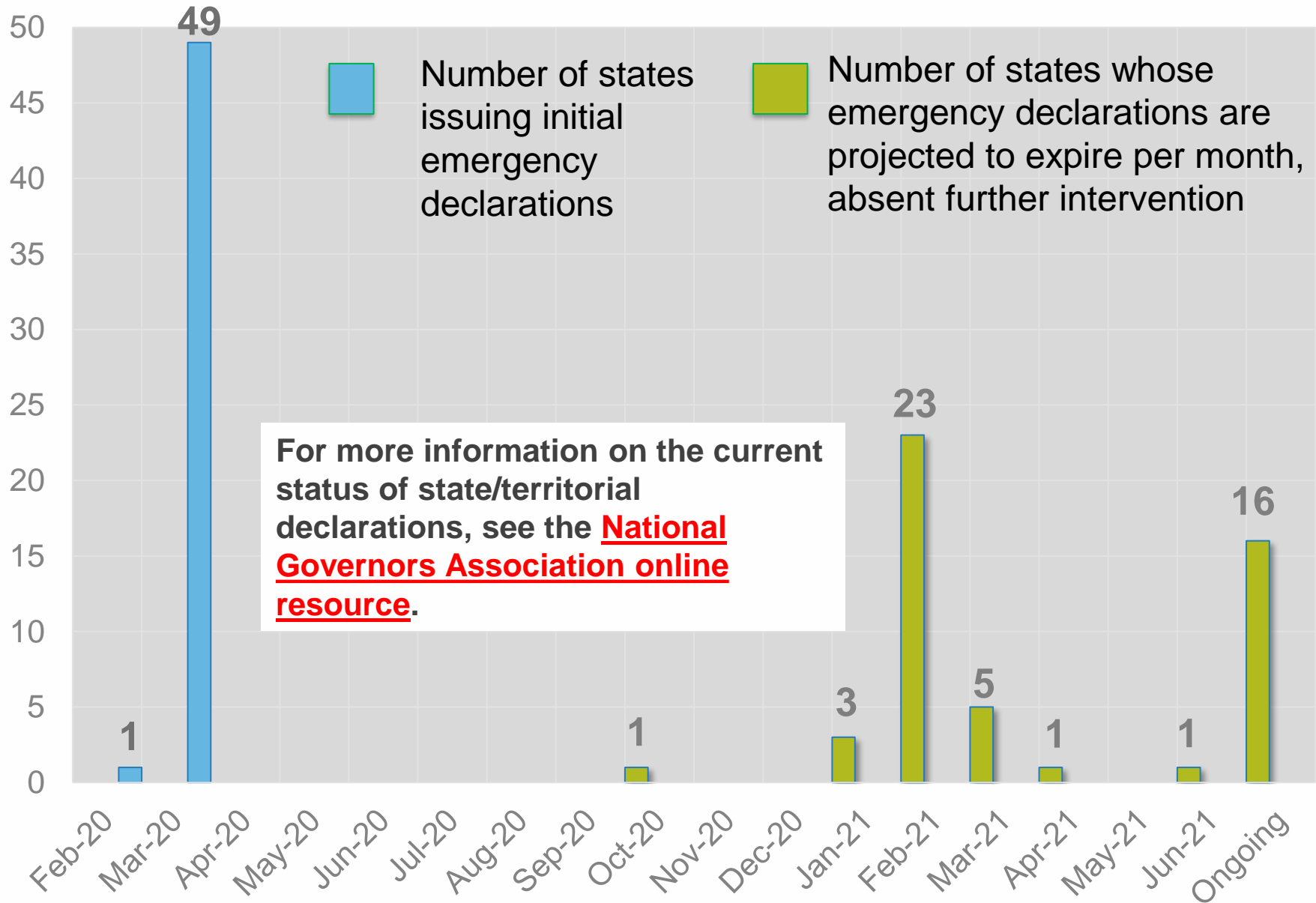
Note: this table tracks select, express authorities referenced via state emergency declarations ([link](#) on each state acronym for access). *Additional emergency powers may be authorized under state law through which the declarations are issued.*

Emergency Powers	A	A	A	C	C	C	D	F	H	I	I	I	K	L	M	M	M	M	N	N	N	N	O	O	P	R	T	V	U	W	W	W		
	K	Z	R	A	O	T	E	L	I	L	N	A	Y	A	E	D	A	I	J	M	Y	C	H	R	A	I	N	A	T	A	V	I		
Altered Contracts Procurements		■		■					■	■				■	■				■	■	■	■	■		■	■		■						
Emergency Plans ICS	■			■	■			■		■		■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Funding Resource Allocation	■	■							■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■			■	■	■	■			
Intrastate Coordination	■	■	■	■	■	■			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Isolation Quarantine	■	■			■	■		■						■								■												
Licensure Reciprocity	■			■					■												■	■	■				■							
Price Controls re: Gouging	■			■					■					■						■			■	■	■		■	■				■	■	
Surveillance Reporting	■			■				■															■											
Testing Screening Treatment	■				■										■				■		■	■	■	■	■		■							
Travel Restrictions			■	■		■		■						■					■				■	■										
Waivers Suspensions	■	■	■		■									■					■	■	■	■		■	■	■	■	■	■				■	

Emergency Declaration Initial Timing & Projected Expiration by Month (2020-2021)



Emergency Declaration Initial Timing & Projected Expiration by Month (2020-2021)



- ❑ **1,565** COVID-related bills introduced at the federal level (as of 11/16/20) according to GovTrack. com— (42 enacted, either in-full or by incorporation)
- ❑ **3,333** COVID-related state bills (as of 11/16/20) according to NCSL — 902 adopted
- ❑ Thousands more local ordinances proposed/enacted nationally (**2,720** reported by NLC through 8/20/20)



Families First



Mar. 18: Families First Coronavirus Response Act

- Private health plans must provide \$0 cost coverage for COVID-19 tests
- Temporarily increases federal portion of Medicaid
- Requires 14 days of paid sick leave for certain employees

CARES Act



Mar. 27: CARES Act

- Largest stimulus package in history
- Requires insurance providers to cover COVID-19 testing, vaccines & preventative services
- Protects volunteer HCWs from liability
- Authorizes PHI disclosure with written patient consent

PPP & HEA



Apr. 24: Paycheck Protection Program & Healthcare Enhancement Act

- Additional funding for hospitals & HCPs
- Supports testing & contact tracing efforts
- Requires governors to submit 2020 testing plan
- HHS Secretary must report on testing, cases & deaths

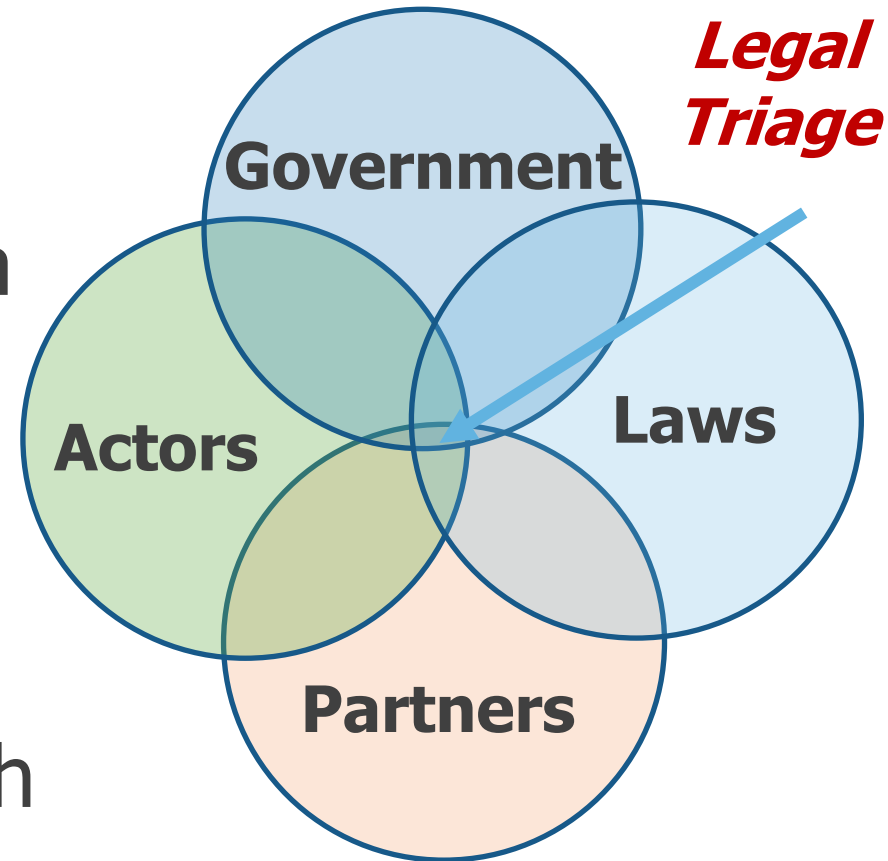


Dec. 27: President Trump signs \$2.3 trillion CAA 2021

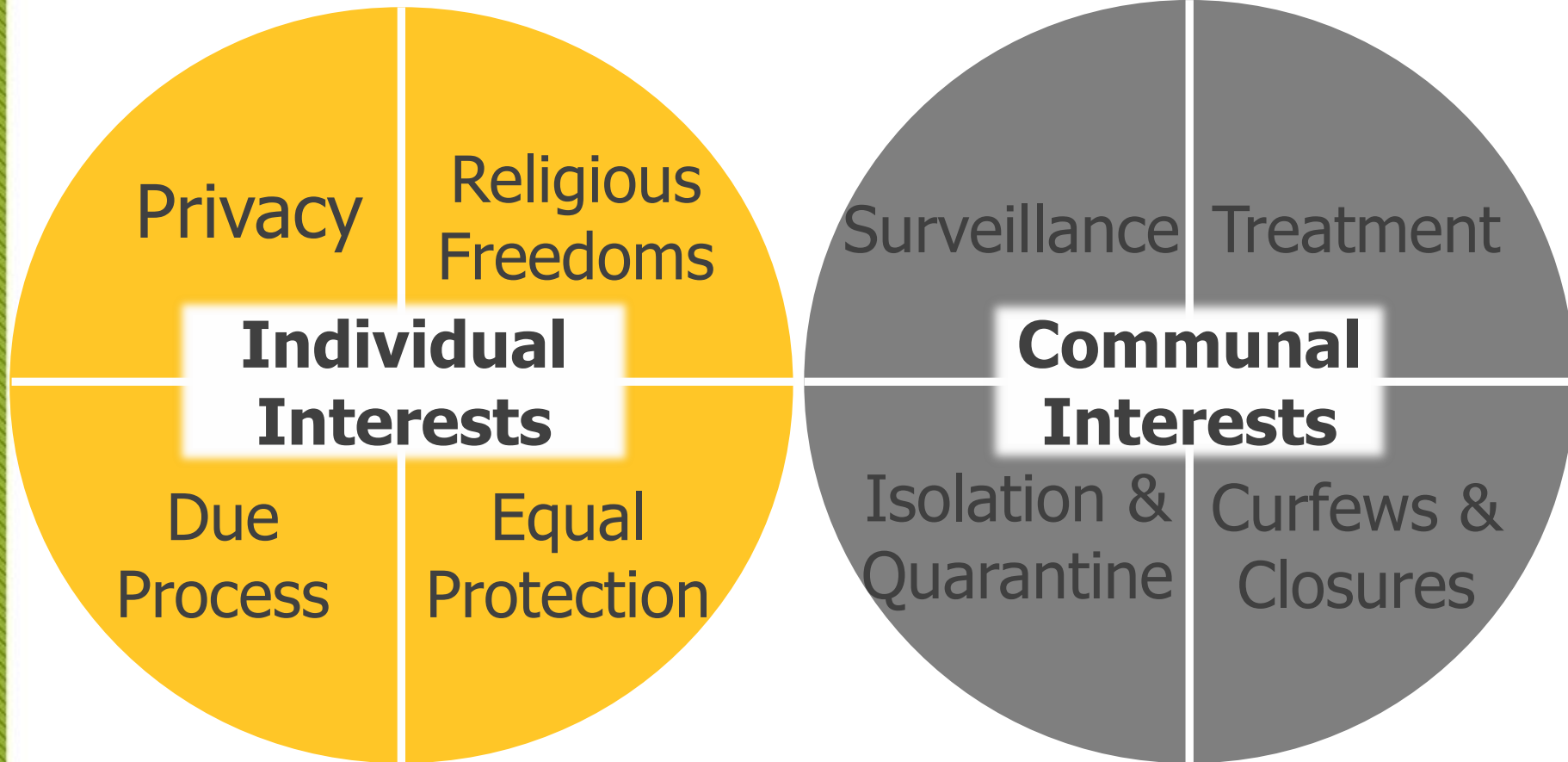
(largest stimulus package in history):

- Provides \$900 billion in stimulus relief for COVID-19 & \$1.4 trillion omnibus spending bill for 2021's federal fiscal year
- Supplements CARES ACT Paycheck Protection Program with additional \$284.5 billion for PPP loans
- Expands Medicare access to mental health services via telehealth
- Mitigates cuts to physician payments & provides \$3 billion in increased physician services
- Establishes a new Rural Emergency Hospital Medicare designation

Legal Triage: efforts of legal actors & others during declared emergencies to build a favorable legal environment by prioritizing issues & solutions facilitating legitimate public health responses



Balancing Individual & Communal Interests

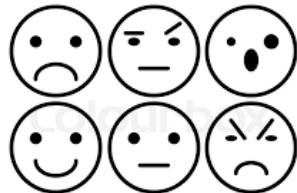


Emergency Preparedness & Response

Select Structural & Rights-based Constitutional Issues



Separation of Powers



Freedom of Expression



Equal Protection



Federalism



Freedom of Assembly



Right to Travel



Supremacy



Freedom of Religion



Right to Bear Arms



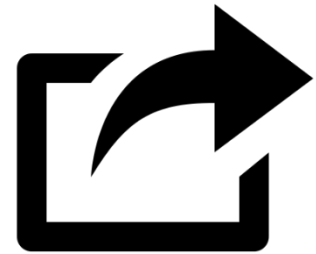
Preemption



Due Process



Cruel & Unusual Punishment



Judicial Deference



Right to Privacy



Takings



Screening & Testing

March 3: VP Pence: “**Any American can be tested . . . subject to doctor’s orders.**”

March 21: Some health officials restrict coronavirus testing to HCWs & hospitalized persons, **saying “the battle to contain the virus is lost [as we move] into a new phase of the pandemic response.”**

April 11: CMS issues guidance requiring insurers to cover diagnostic testing & related services with **no patient cost-sharing.**

April 19: Antibody tests key to reopening country are in high demand, yet tests’ **availability** & **inaccuracies** raise alarms.

May 7: AZ Gov. Ducey **withdraws access** by university researchers to select health data for in-state surveillance, then reverses decision.

January 11, 2021: More than **260 million** COVID-19 tests have been conducted in the U.S.



Contact Tracing

- Contact tracing - efforts typically led by public health agents to ascertain specific contacts of persons infected with COVID-19 & notify them of potential exposure & seek testing.
- States are hiring thousands for contact tracing activities within health agencies
- Apple & Google released Bluetooth technology on April 10 that sends automatic alerts to persons in range of COVID + persons, raising privacy concerns
- New bill signed into law in Kansas on June 8 restricts contact tracing to voluntary participants, provides strong confidentiality protections & extensively limits liability.



Click on images to access

December 18, 2020



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

HIPAA, Health Information Exchanges, and Disclosures of
Protected Health Information for Public Health Purposes

OCR Issues Guidance on HIPAA, Health
Information Exchanges, and Disclosures of
Protected Health Information for Public Health
Purposes

Today, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) issued guidance on how the Health Insurance Portability and Accountability Act of 1996 (HIPAA) permits covered entities and their business associates to use health information exchanges (HIEs) to disclose protected health information (PHI) for the public health activities of a public health authority (PHA).

**For additional expert analyses & guidance, contact Denise Chrysler,
JD and colleagues at the [Network–MidStates Region](#)**

Face Mask Requirements



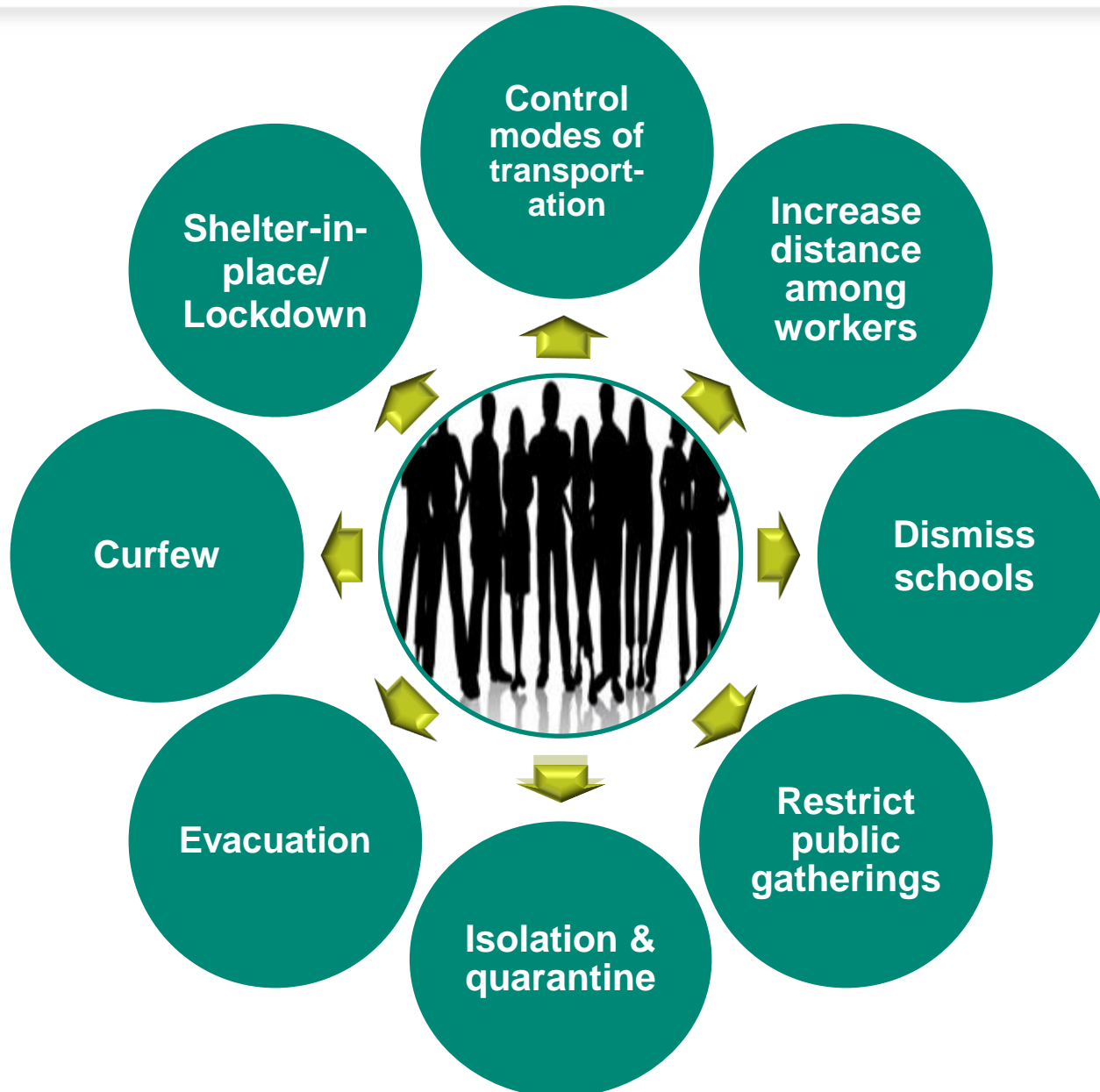
- Localities in 43 states & territories require face masks to be worn by employees, customers, or others in public.
- July 7: Freedom Foundation files lawsuit challenging the constitutionality of WA state mask mandate. On July 27, it sues Oregon re: its mask mandate.
- July 10: Judge rejects FL lawsuit challenging the constitutionality of Orange County's mask requirement.
- Aug. 13: GA Governor Kemp announces his office is dropping its case against the City of Atlanta re: its mask requirement.
- Aug. 13: Future President Joe Biden calls on states to craft face mask requirements.
- Aug. 20: NY Gov. Cuomo admits mask requirement should have been issued months earlier.

Sept. 2: CDC Director Dr. Robert Redfield signs declaration **temporarily halting evictions.**

- Order bans evictions of residential renters earning less than \$99k annually (\$198k jointly) through December 2020.
- Qualifying renters must present written declaration testifying to their circumstances to landlords
- Landlords who defy the moratorium may face criminal penalties
- CDC cites its authority under the [Public Health Service Act § 361\(42 U.S.C. 264\)](#) & an emergency action taken under [42 C.F.R. 70.2](#), “measures in the event of inadequate local control.”
- **Oct. 29:** U.S. District Court of Georgia - Atlanta Division affirms CDC’s eviction order.



Social Distancing Measures



Justifying Social Distancing



Assess Epi



Assure Mobilization



Acquire PPE



Find Treatments



Develop Vaccines



Save Lives

Quarantine & Isolation

Quarantine

Separation from others of people exposed to a contagious condition prior to knowing if they may be ill or contagious

Isolation

Separation from others of people who are known to be infected, or capable of infecting others, with a contagious condition

Best Practices



Safe, hygienic premises



Monitoring & care



Basic necessities



Means of communication



Least restrictive means



Termination

Closures & Cancellations



Places of Worship



Employers



Schools & Universities



Events



Sports



Festivals



Mar. 29: Curfew order extending across Navajo Nation requires all persons (w/some exceptions) to stay home from 8:00 p.m. - 5:00 a.m., 7 days a week.

May 5: Gallup, NM imposes strict confinement measures via use of “riot act” authorities allowed by NM Gov. Grisham.

Aug. 19: Puerto Rico Gov. Wanda Vazquez imposes “Sunday” lockdown (in addition to weekly 10 pm – 5 am curfew).

Jan. 20: Arizona state court judge voids Pima County’s 10:00 p.m. curfew as violation of state law.

Guidance as of 3/15/2020

[Click on image to access](#)

March 15, 2020: White House and CDC recommend no in-person events consisting of **10 or more people throughout the U.S. until April 30.**

Jan. 8, 2021: CDC guidance states “The size of an event or gathering should be determined based on **state, local, territorial or tribal safety laws and regulations.”**



Flight Bans



Immigration Activities



Foreign Work Visas



Border Crossings



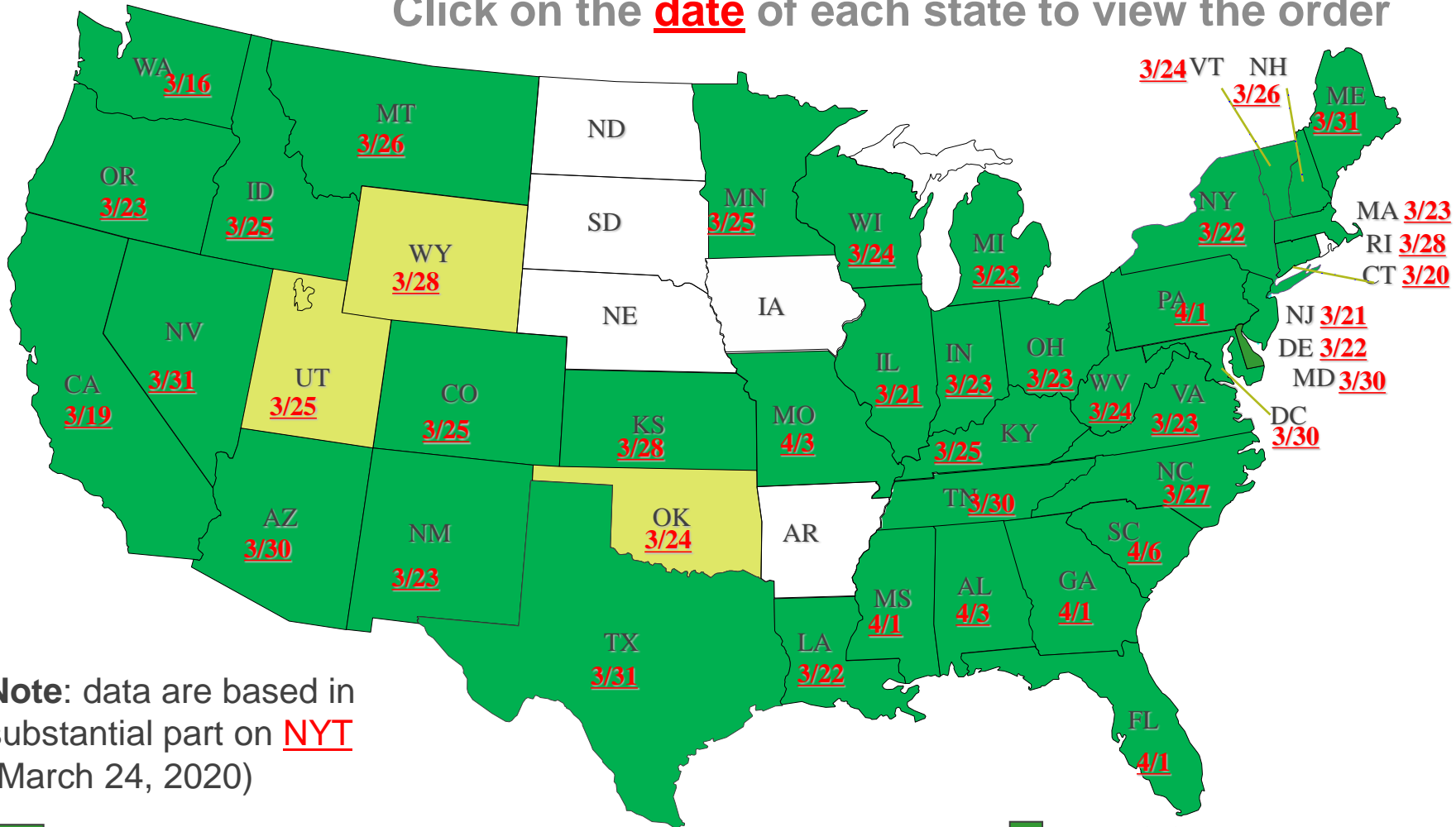
State Quarantines



Closures

State Shelter-In-Place or Stay Home Orders

Click on the **date** of each state to view the order



Note: data are based in substantial part on [NYT](#) (March 24, 2020)

Shelter-in-Place or Stay Home Orders – 43 states

Shelter-in-Place or Stay Home Orders – 3 partial states

AK – Alaska **4/1**

HI – Hawaii **3/23**

PR - (Puerto Rico)

VI - (U.S. Virgin Islands)

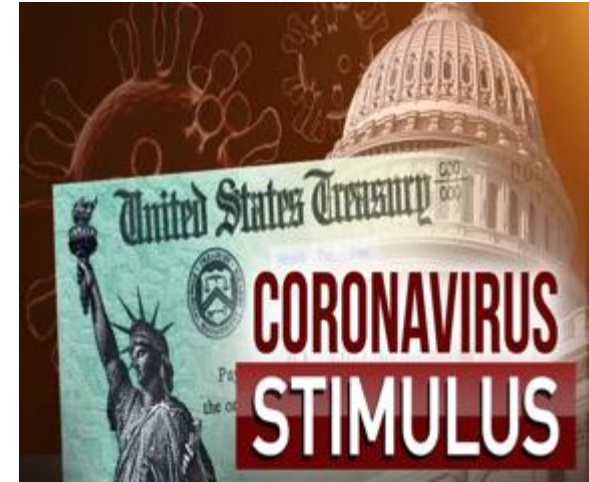
Collateral Consequences



Unemployment



Business Failures



Government Bailouts



Active Protests



Mental Health



Lost Lives



April 16: White House releases guidelines for “Opening Up America Again,” a 3 phased approach for state/local officials to consider. States must first meet **regional gating criteria:**

- Downward trajectory of COVID illnesses reported w/in 14 days
- Downward trajectory of cases or positive tests w/in 14 days
- Hospitals must treat all patients outside CSC or implementation of a “robust reporting system”

April 21: U.S. Attorney General William Barr instructs U.S. Attorneys to litigate against states failing to comply with national re-opening strategies

Re-opening Phases

Phase 1

- Vulnerable individuals shelter-in-place
- Practice social distancing & avoid socializing in groups >10
- Employers should encourage telework & most businesses remain closed

Phase 2

- Resume non-essential travel
- Schools, gyms & bars may re-open

Phase 3

- Vulnerable individuals may resume public interactions, with social distancing
- Large venues may reopen

Re-opening Efforts



Essential Business



Light Retail



Schools/Colleges



Bars

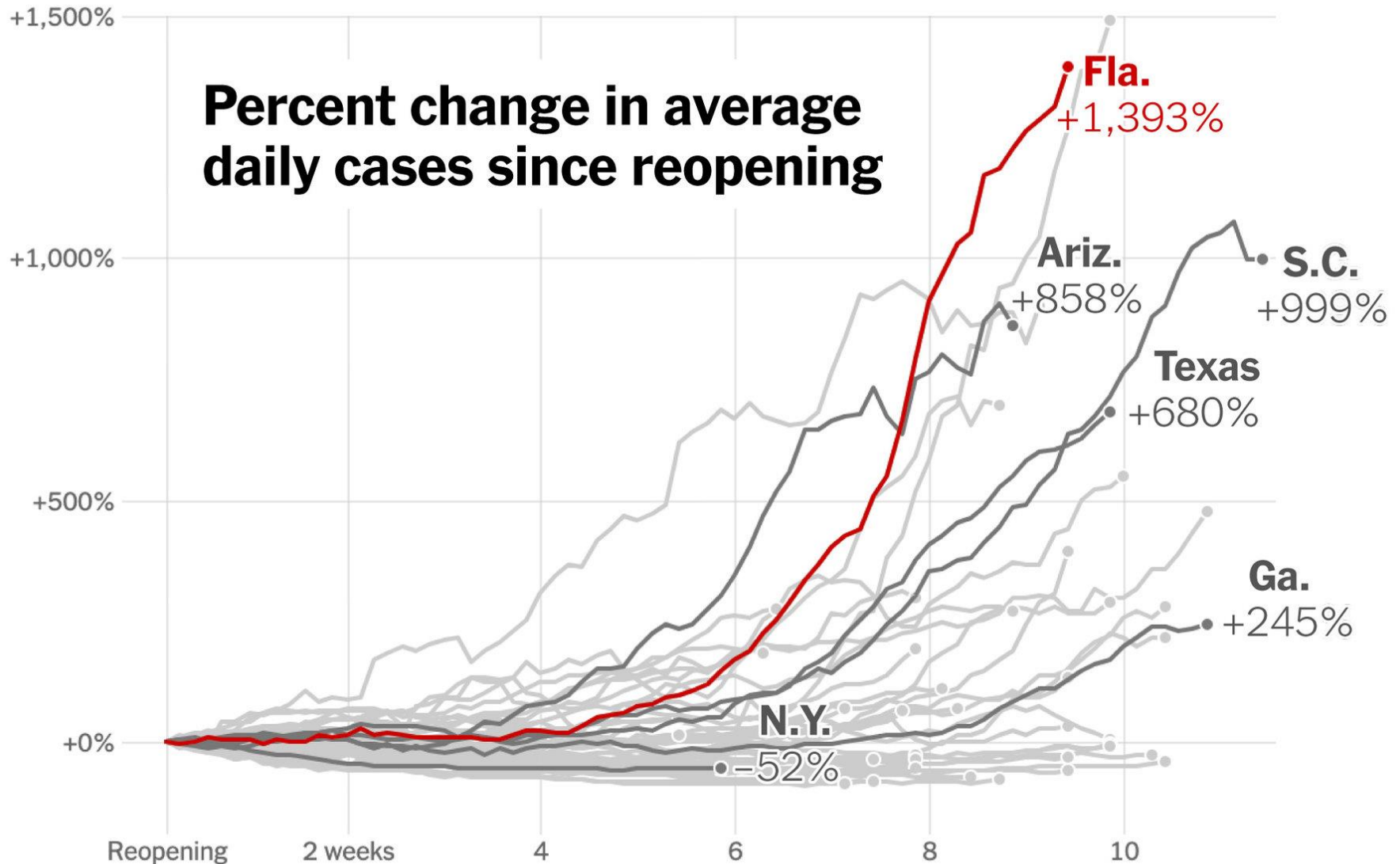


Gyms



Restaurants

Re-opening Infection Rates



Source: [New York Times](#)

**Substantial change in usual
healthcare operations & level of
care due to a pervasive or
catastrophic disaster.**

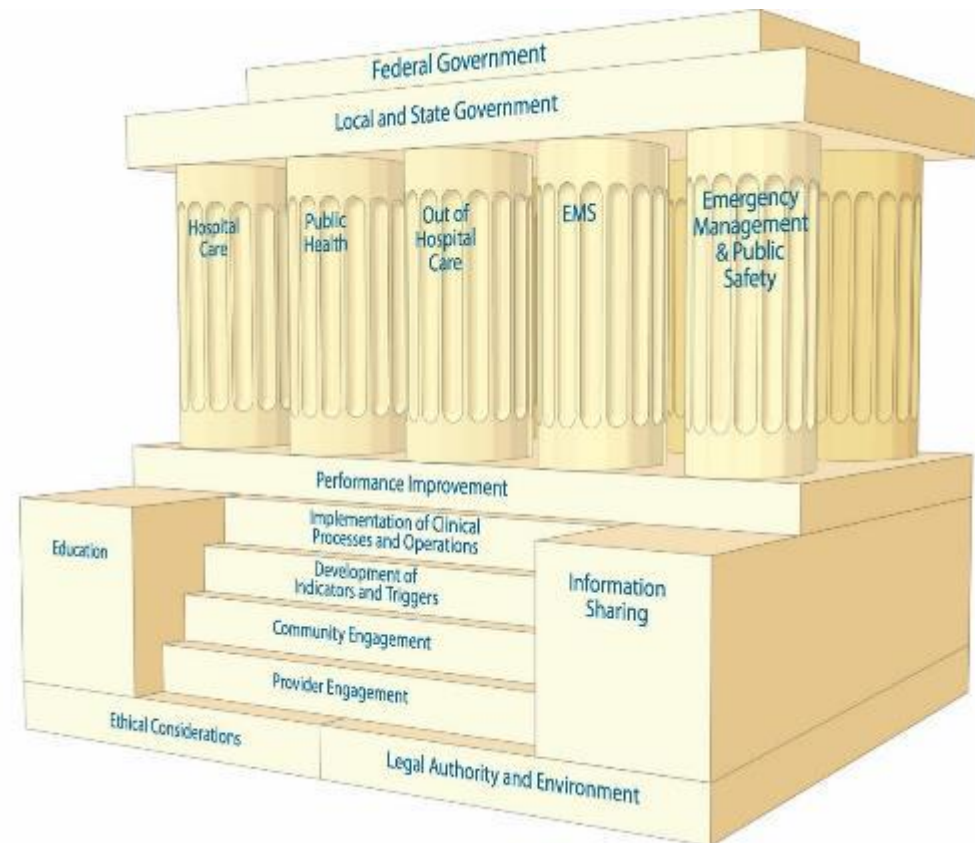
Crisis Standards of Care

A Systems Framework for
Catastrophic Disaster Response

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

- Allocation
- Patient's Rights
- Reimbursement
- Licensure
- Scope of Practice
- Civil Rights
- Documentation
- Uniformity
- **Liability**



2 Paths Re: CSC Liability Claims

Increasing:

- Patient #s
- Patient needs
- Risks



*Path 1 - Follow the Evolving
Standard of Care*



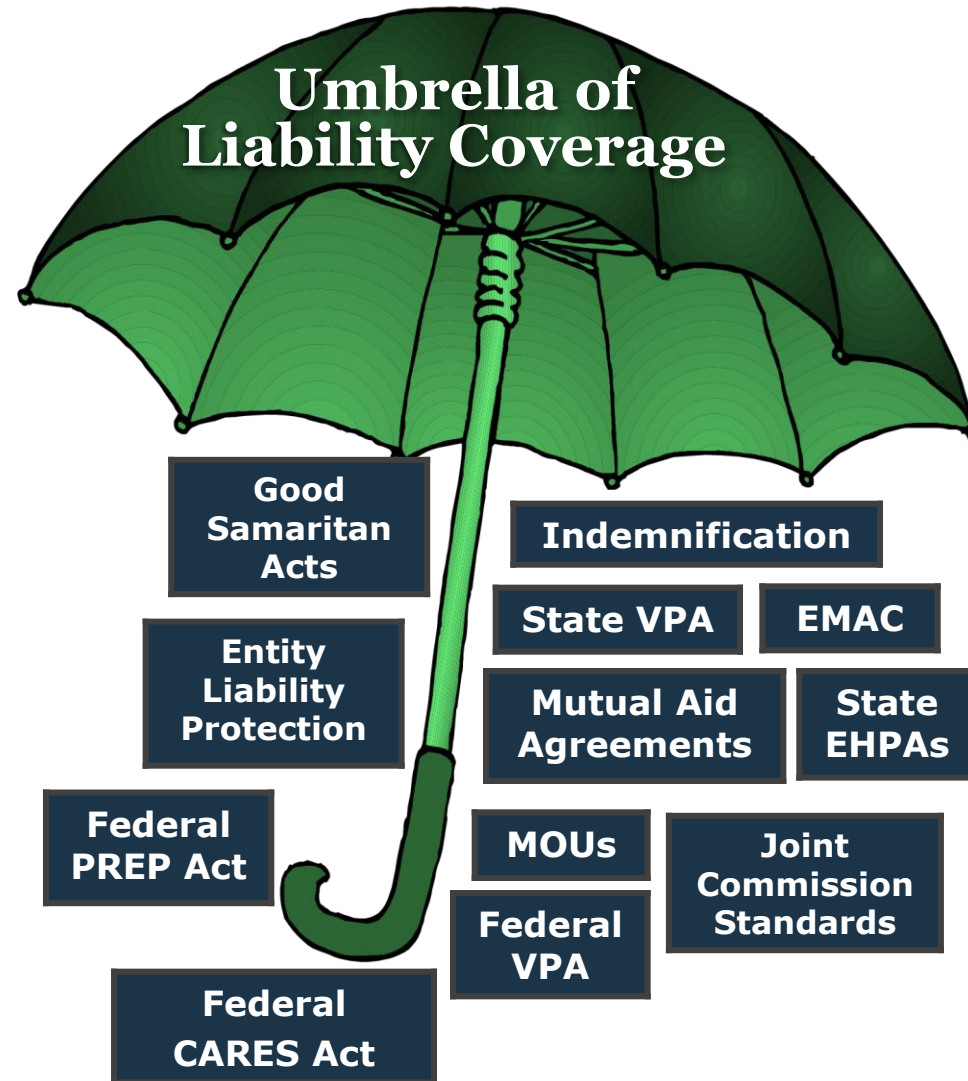
**Path 2 - Provide Enhanced Liability Protections
for HCWs & Entities** 

Lessening:

- HCWs
- Volunteers
- ICU beds
- PPE



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



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

Alleviating licensure & scope of practice concerns through SOP expansions or reciprocity can ameliorate shortages

5

Shifting standards of care do not belie general legal duties or additional CSC duties owed to patients

6

Documenting decisions lawfully and transparently implicates CSC shifts internally and externally

7

Manifold liability protections help assure HCWs, volunteers, and entities can implement CSC

8

Mitigation of legal risks entails advance planning, real-time interventions & commitment to sound process/ethics



National Academies Vaccine Allocation Guidance

Phase 1

- High-risk workers in health care facilities
- First responders
- People of all ages with comorbid & underlying conditions at *significantly* higher risk
- Older adults living in congregate settings

Phase 2

- Critical risk workers
- Teachers & school staff
- People of all ages with comorbid & underlying conditions at *moderately* higher risk
- All other older adults
- People in homeless shelters & prisons

Phase 3

- Children
- Young adults
- Workers in essential industries

Phase 4

- Everyone else living in the US

The National Academies of
SCIENCES • ENGINEERING • MEDICINE



2

Extending doses



State and local allocations



Federalizing vaccine delivery



Prospective deaths and injuries

Core Legal Issues Regarding COVID-19 Vaccine Allocation

1

Relevance of Emergency Declarations

2

Legal Challenges to the Allocation Scheme

3

FDA Approval and EUA Authorization Process

4

Federal Authority over State, Tribal, & Local Governments

5

State Mandates to Vaccinate

6

Employer Mandates

7

Vaccine Exemptions

8

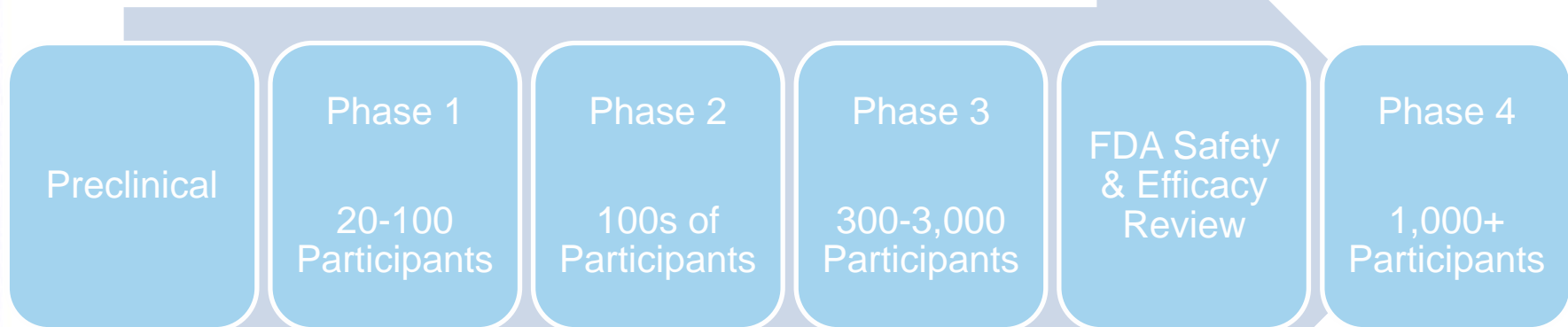
Informed Consent

9

Liability Protections for Providers & Entities

10

Compensation for Injuries Resulting from Vaccination



Emergency Use Authorization (EUA): FDA evaluates evidence available, balancing known risks with known benefits, to determine whether the product “may be effective” and subsequently authorized.

Biden-Harris Administration National Response Efforts

“There are moments in history when more is asked of us as Americans. We are in that moment now and history will measure whether we were up to a task. *Beating this pandemic will be one of the most difficult operational challenges we have ever faced as a nation.*” Jan. 21, 2021



Day 1: January 20, 2021:

- Appoint national COVID-19 Response Coordinator
- Create Safer Federal Workforce Task Force
- Issue mask “challenge” & federal mandate
- Allow delays in student loan payment
- Extend restrictions on home evictions/foreclosures
- Seek \$1.9 trillion COVID-19 relief legislation
- Re-engage with the World Health Organization & global priorities

Days 2-10:

- Introduce National Strategic Plan
- Set public health standards based in science & best practices
- Restructure federal response efforts globally & domestically
- Deliver economic relief to families bearing the brunt of the crisis

Days 11-100:

- Coordinate with state, territorial tribal & local governments to sync social distancing & mask requirements nationally
- 100 million+ vaccine shots to Americans
- Open 100 FEMA-supported vaccination centers



[Jeffrey Zients](#)

Objectives & Duties:

- Reduce disparities in COVID-19 response & treatment
- Coordinate efforts to produce & distribute PPE, vaccines, tests & other response supplies
- Ensure continuity of educational & other services for kids & elementary/secondary students
- Coordinate with state, tribal, territorial & local authorities

The Task Force shall guide heads of agencies on multiple subjects related to the federal workforce:



Testing methodologies & protocols



Case investigation & contact tracing



Requirements & limitations on physical distancing



Enhanced structures to support telework

Federal Agency Coordination

Right click on each image to link to COVID-19 sites



NATIONAL STRATEGY FOR THE COVID-19 RESPONSE AND PANDEMIC PREPAREDNESS

JANUARY 2021

National Strategic Plan – 6 Primary Domestic Goals

“We can and will beat COVID-19. America deserves a response to the COVID-19 pandemic that is ***driven by science, data, and public health — not politics.***”

1.
Restore trust
with Americans

2.
Comprehensive
vaccination
campaign

3.
Mitigate spread
through public
health standards

4.
Expand
emergency relief
via DPA

5.
Reopen schools,
business &
travel

6.
Equity across
racial, ethnic &
rural/urban lines

“To rebuild the trust of the American people, the National Strategy will signal ***clear public leadership and a commitment to a robust whole-of-government response*** that puts science first.”

A.
National COVID-19
response structure
driven by science &
equity

B.
Conduct regular
science-based
public briefings

C.
Publicly share data
around key
response indicators

D.
Lead science-first
public health
campaigns

Goal 2. Vaccination Campaign

“The [U.S.] will spare no effort to ensure Americans can get vaccinated quickly, effectively, and equitably. The federal government will execute an aggressive vaccination strategy, focusing on the immediate actions necessary to convert vaccines into vaccinations. . . .”

A.
Ensure the
availability of safe,
effective vaccines

B.
Accelerate vaccine
administration to
people &
communities

C.
Create new venues
for people to be
vaccinated

D.
Focus on hard-to-
reach & high-risk
populations

E.
Expand range of
providers & assure
they are
compensated

F.
Monitor vaccine
safety & efficacy

Goal 3. Mitigate Spread

“A ***comprehensive national public health effort to control the virus*** — even after the vaccination program ramps up — will be critical to saving lives and restoring economic activity.”

A.
National mask mandate
& “challenges” to state,
tribal & local
governments

B.
Establish COVID-19
Pandemic Testing
Board to unify
approaches

C.
Effectively distribute
tests & expand access
to testing, especially
among schools

D.
Seek new treatments
& therapeutics

E.
Empower CDC to
develop actionable,
evidentiary guidance
based on new data

F.
Expand U.S. public
health workforce &
increase clinical care
capacity

Goal 4. Defense Production Act

“It’s past time to fix America’s COVID-response supply shortage problems for good. The [U.S.] will immediately address urgent supply gaps, . . . while also steering the distribution of supplies to areas [of] greatest need.”

A.

Increase emergency funding to states & bolster FEMA’s response efforts

B.

Fill major supply shortfalls via the Defense Production Act

C.

Develop a new Pandemic Supply Chain Resilience Strategy

D.

Improve distribution, expand availability, & control pricing of critical materials

“At the same time that the [U.S.] takes immediate steps to achieve an overall decrease in COVID-19 spread, it will also support *the safe operation of schools, businesses, and travel.*”

A.
Implement a national strategy to safely reopen schools

B.
Fund safe operations at child care centers & at-home providers

C.
Support equitable reopenings & operations at colleges

D.
Protect workers via OSHA & other federal safety guidelines

E.
Provide guidance & support to safely open commerce & small businesses

F.
Promote safe travel domestically & abroad

“The COVID-19 pandemic has exposed & exacerbated severe & pervasive health inequities among communities defined by race, ethnicity, geography, disability, sexual orientation, gender identity & other factors.”

A.
Establish a COVID-19 Health Equity Task Force

B.
Ramp up data collection & reporting for at-risk populations

C.
Ensure equitable access to critical PPE, tests, therapies & vaccines

D.
Expand access to high quality health care

E.
Enhance the “social service safety net” to meet basic needs

F.
Address risks for persons in congregate settings

Goal 7. Restore U.S. leadership globally



The Assistant to the President for National Security Affairs (APNSA) shall convene the National Security Council (NSC) Principals Committee for guidance regarding:

- Preparing & responding to biological threats
- Identifying, monitoring & preparing for emerging pandemic threats
- Assessing secondary or tertiary effects of COVID-19
- Intersection of COVID-19 responses & other national security priorities
- Re-engaging with the World Health Organization

Major Strategic Changes in Approach



Responsibility
for:

- *Testing*
- *Screening*
- *Masks*
- *Vaccination*
- *Treatments*
- *Travel/Opening*

Shared
with:

- *Science*
- *Guidance*
- *Data*
- *Best Practices*
- *Funding*

In return
for:

Shifts
to:





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[Latest Resources](#)

[Federal Public Health Emergencies](#)

[Social Distancing Powers](#)

[Liability of Health Care Workers and Entities](#)

[Hospital Emergency Legal Preparedness](#)

[State and Local Preparedness](#)

[Emergency Declarations and Powers](#)

[Mental and Behavioral Health Preparedness](#)

[Model Emergency Laws](#)

[Emerging Threats Preparedness and Response](#)

[Crisis Standards of Care](#)

[Public Health Emergency Ethics](#)

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