

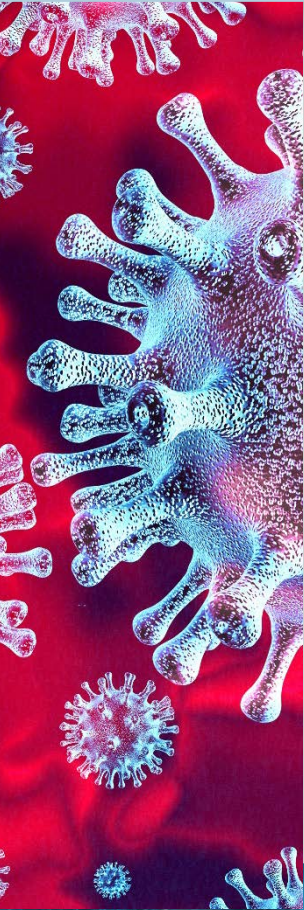
Coronavirus: Legal Aspects of the Public Health Response, and What Employers Should Be Doing Now

Audioconference

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ROPES & GRAY
March 5, 2020

AGENDA

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- A vertical strip on the left side of the slide features a microscopic image of coronavirus particles. The particles are depicted as spherical structures with prominent, irregular spikes extending from their surfaces. They are set against a dark, textured background with a color gradient from deep red at the top to black at the bottom.
- **Responding to a Public Health Crisis**
 - **Infectious Disease Control Measures**
 - **Considerations for Health Care Providers, Employers and Public Companies**

AGENDA



- **Responding to a Public Health Crisis**
- **Infectious Disease Control Measures**
- **Considerations for Health Care Providers, Employers and Public Companies**

ROADMAP



- **Responding to a Public Health Crisis**
- Infectious Disease Control Measures
- Considerations for Health Care Providers, Employers and Public Companies

- **Facts and Figures**
- Legal Authority for Federal, State and Local Responses

Facts and Figures

- The virus is named “SARS-CoV-2” and the disease it causes is named “coronavirus disease 2019” (abbreviated “COVID-19”).
 - The virus is a betacoronavirus, like MERS-CoV and SARS-CoV. Research suggests that all three originated in bats; with the spread for SARS-CoV-2 to humans still undetermined.
- **January 30, 2020** -- the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a “public health emergency of international concern” (“PHEIC”).
- **January 31, 2020** -- Health and Human Services (“HHS”) Secretary Alex M. Azar II declared a public health emergency (“PHE”) for the United States to aid the nation’s healthcare community in responding to COVID-19.

Facts and Figures

- U.S. Travel Restrictions
 - **February 2**: suspended entry of foreign nationals who have been in China within the past 14 days.
 - U.S. citizens, residents, and their immediate family members who have been in Hubei province and other parts of mainland China are allowed to enter, subject to health monitoring and possible quarantine for up to 14 days.
 - **February 29**: suspended entry of foreign nationals who have been in Iran within the past 14 days.

See <https://www.cdc.gov/coronavirus/2019-nCoV/summary.html>.

Facts and Figures

- CDC has issued the following travel guidance related to COVID-19:
 - **China** — Level 3, Avoid Nonessential Travel — *updated February 22*
 - **Hong Kong** — Level 1, Practice Usual Precautions — *issued February 19*
 - **Iran** — Level 3, Avoid Nonessential Travel — *updated February 28*
 - **Italy** — Level 3, Avoid Nonessential Travel — *updated February 28*
 - **Japan** — Level 2, Practice Enhanced Precautions — *updated February 22*
 - **South Korea** — Level 3, Avoid Nonessential Travel — *updated February 24*

See <https://www.cdc.gov/coronavirus/2019-nCoV/summary.html>.

Facts and Figures

CDC Reporting (March 4, 2020) (updated daily, but *undercount*; refer to states):

- Total cases: 80 [159]
- Total deaths: 9 [11]
- States reporting cases: 13

Vaccine and Drug Development underway:

- *Phase 1 vaccine trial*, multisite, with estimated 3-4 months duration, 45 subjects. (NIH/NIAID funded); Phase 2 thereafter, 1-1.5 years.
- *Phase 2 drug trial*, single site, with estimated multi-year duration, using approved drug (NIH/NIAID funded)

See <https://clinicaltrials.gov/ct2/show/NCT04283461?term=mRNA-1273&draw=2&rank=1>; <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-remdesivir-treat-covid-19-begins>

ROADMAP



- **Responding to a Public Health Crisis**
- Infectious Disease Control Measures
- Considerations for Health Care Providers, Employers and Public Companies

- Facts and Figures
- Legal Authority for Federal, State and Local Responses

Headlines About Preparedness for COVID-19

COVID-19

Chicago Officials, Medical Professionals Detail Plans to Combat Coronavirus

New York City could spend \$1 million a day on coronavirus response, Chuck Schumer warns

If the coronavirus hits America, who's responsible for protecting you?

Judge Extends Temporary Order To Block Plan To Move Coronavirus Patients To OC Facility

Pence To Lead Coronavirus Response, But Trump Says He's Not A Czar

Metro Atlanta schools prepare for potential coronavirus outbreak

How Federal Agencies Are Responding to the New Coronavirus Outbreak

The government can quarantine you for coronavirus, and there's almost nothing you can do about it

Representatives of Coronavirus Task Force Brief Governors at NGA

Pa. is preparing for coronavirus as CDC warns spread in U.S. may be 'inevitable'

Hawaii officials urge preparing 14-day emergency kit in case of coronavirus outbreak

Don't Send Them Here: Local Officials Resist Plans to House Coronavirus Patients

White House Asks Congress for Billions to Fight Coronavirus

Legal Landscape

Federal Law

- Federal agencies' limited authorities to prevent spread of infectious disease
 - Quarantine, Isolation, Surveillance and Contact Tracing –
 - Containment at U.S. Borders;
 - Centers for Disease Control (CDC); advisory to states
- Testing kits and drug or vaccine approval
 - Approval to market, Emergency Use Authorization, Food and Drug Administration (FDA)
- Vaccine and drug development research
 - Grant/contract funding from National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID), and Biomedical Advanced Research and Development Authority (BARDA)

State and Local Law, Tribal and Territorial Partners

- States implement most surveillance and controls under police powers

Legal Authority: Federal Law

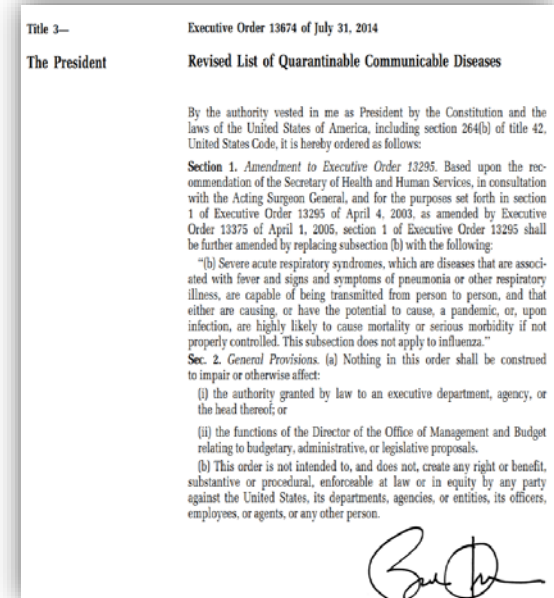
- **Statutory: Public Health Service Act, § 361 (42 USC §§ 264-272), *CONTROL OF COMMUNICABLE DISEASES***
 - **Long history and tradition of protecting against disease at national border and deferring to states to exercise police power**
 - **Strengthened in recent years** as part of wider strategy to limit the entry and spread of communicable diseases into the U.S. and among the states.
 - Pandemic and All-Hazards Preparedness Act (PAHPA) (2006)
 - Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) (2013)
 - Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) (2019)
 - Authority for carrying out these functions has been delegated to the **Centers for Disease Control and Prevention** (“CDC”).
 - Statute authorizes fines “of not more than \$1,000 or by imprisonment for not more than one year, or both” for violations.

See <https://www.phe.gov/Preparedness/legal/pahpa/Pages/default.aspx>

Legal Authority: Federal Law

- **Regulatory**: 42 CFR Parts 70 and 71
 - Implement federal quarantine authority across states (part 70) and into the states (part 71)
 - Authorized to detain, medically examine, and release persons arriving into the United States and traveling between states who are suspected of carrying these communicable diseases
- **Executive Order 13295** (last updated: July 31, 2014)
 - List of Quarantinable Communicable Diseases

See EO 13674: Revised List of Quarantinable Communicable Diseases



CDC Quarantine Regulation

- **2017 Final Rule** (82 Fed. Reg. 6890 (Jan. 19, 2017))
 - Amended the domestic (interstate) and foreign quarantine regulations to improve the CDC's ability to protect against communicable diseases while ensuring due process.
 - Modernized text and refines definitions, increased non-invasive public health intervention measures (e.g., traveler health screening, commercial flight illness/death reporting, electronic monitoring of people under conditional release orders).
 - Required HHS/CDC to explain reasons for quarantine/isolation orders, set administrative processes for appeal and a mandatory reassessment of such orders.
 - Did not authorize compulsory medical testing, vaccination, or medical treatment without prior informed consent.
 - Required CDC to advise individuals subject to medical examinations that such examinations will be conducted by an authorized health worker and with prior informed consent.
 - Included due process protections for individuals subject to public health orders, including a right to counsel for indigent individuals.

CDC Quarantine Rule – Policy and Updates

- **CDC policy statement**: “CDC exercises its authority for isolation and quarantine “consistent with principles of using the least restrictive means to protect the public’s health.” In other words, “CDC will attempt to obtain voluntary compliance with public health measures and explore options such as the appropriateness of a home environment if quarantine or isolation is necessary.” (emphasis added).
- **2020 Final Rule** (85 Fed. Reg. 7874 (Feb. 12, 2020))
 - A direct response to COVID-19 to improve the CDC’s ability to identify and evaluate those who may have been exposed.
 - Requires airlines to collect, and provide to CDC, certain data regarding passengers and crew arriving from foreign countries to enable contact tracing.

See <https://www.cdc.gov/quarantine/qa-final-rule-communicable-diseases.html>

Sources of Legal Authority: State, Tribal, Local

States' authority derives from their police powers (e.g., to protect the health, safety, and welfare of persons within their borders.)

- States can enact laws to enforce the use of isolation and quarantine, or delegate authority to municipalities and counties.
- In most states, breaking a quarantine order is a criminal misdemeanor.
- State and local laws can vary greatly.
 - For example, in some states, local health authorities directly implement state law for quarantine or isolation, subject to judicial review, while others require court orders to detain an individual.

Tribes also have police power authority to take actions that promote the health, safety, and welfare of tribal members. Tribal health authorities may enforce their own isolation and quarantine laws within tribal lands, if such laws exist.

See <https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html>

State Quarantine & Isolation Law: CA

Summary	Enumerated Police Powers (Examples)
<p>California empowers health officers to “take all necessary steps to prevent the spread of a contagious disease.” The statutes provide for very specific police powers.¹</p>	<ul style="list-style-type: none">▪ Establish and maintain places of quarantine or isolation.▪ Access all health care providers, suppliers and other entities’ inventories of critical medical supplies and equipment.▪ Destroy items that are an imminent menace to public health.

¹ Cal. Health & Safety Code §§ 120100-120305.

State Quarantine & Isolation Law: MA

Summary	Enumerated Police Powers (Examples)
<p>Massachusetts requires its board of health to provide assistance to and regulate a place of outbreak. MA statutes are broad and appear to be somewhat outdated.¹</p>	<ul style="list-style-type: none"><li data-bbox="908 349 1835 567">■ The board may remove people as necessary from the location of an outbreak. The sick may be removed to a hospital as long as their health is not endangered; the healthy may be removed from their neighborhoods.<li data-bbox="908 622 1835 709">■ Quarantined or isolated wage earners shall receive compensation up to \$2 per working day.

¹ *Mass. Gen. Laws ch. 111 § 105*

State Quarantine & Isolation Law: IL

Summary

Illinois grants its Dept. of Public Health “supreme authority over declaring new or modifying existing quarantines.” It specifically empowers local, municipal and county authorities the power to quarantine. However, the Dept. may take direct action in a locality if local authorities fail to act with all expenses to be paid by the locality.¹

Enumerated Police Powers (Examples)

- Usually quarantine or isolation of people or a place requires consent or a court order; however, if the Dept. deems immediate action necessary (which it must later demonstrate by clear and convincing evidence), it may act without consent or a court order.
- The Dept. may quarantine or isolate people who refuse testing or treatment, but persons subject to quarantine or isolation have the right to counsel and shall be given written notice.

¹ Ill. Rev. Stat. ch. 20 § 2305/2.

Local Quarantine & Isolation Law: NYC

Summary	Enumerated Police Powers (Examples)
<p>New York City empowers its Department of Health and Mental Hygiene to “take such action as may become necessary to assure the maintenance of public health, the prevention of disease, or the safety of the City and its residents.”¹</p>	<ul style="list-style-type: none">■ Physicians, people in charge of health care providers, shelters or other group facilities, and educational settings have a duty to isolate any “case, carrier, suspect case or suspect carrier” of an enumerated list of contagious diseases.■ Isolated or quarantined individuals may be ordered to remain at home “under such conditions and for such duration as the department may specify to prevent transmission of the disease to others.”■ People are prohibited from engaging in acts that are likely to spread disease.

¹ *New York City Public Health Code § 11.17*

State Variation in Quarantine Laws

“Fewer than half of state laws even include right to counsel during a quarantine, and many fewer have written protections for being able to choose a medical provider or receive compensation for damages that may occur. While half of the states have granted explicit police powers to enforce public health actions during a quarantine, half do not. And only twenty percent provide any employment protection for individuals forced to stay away from work for the betterment of society. More worrisome, less than half of the states have language in their laws and regulations related to providing safe and humane quarantines.”

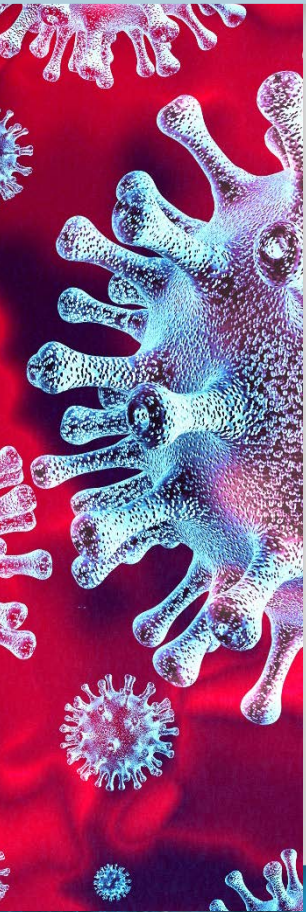
– Rebecca Katz (2018)

The Relationship Between State, Local and Federal Authority is Complex

“Given the variation in due process rights in connection with quarantine, which may be afforded under federal and state law, one can foresee the possibility of considerable conflict.” - Felice Batlan

“When it comes to the exercise of isolation and quarantine powers, reality tends to be messier than the conceptual realm. Public health officials need clear lines of authority in emergency situations . . . Unfortunately, confusion about which level of government should take the lead often occurs, thus spotlight[ing the] difficulties federalism poses for public health.” - David P. Fidler, Lawrence O. Gostin, and Howard Markel

ROADMAP



- Responding to a Public Health Crisis
 - **Infectious Disease Control Measures**
 - Considerations for Health Care Providers, Employers and Public Companies
- From Disease Reporting to Quarantine

Infectious Disease Control Measures

- Range of Public Health Interventions:
 - Public education and disinformation control
 - Disease reporting by providers to local and state health departments
 - Clinical inquiries and contact tracing
 - Mandatory examinations and lab testing
 - Offering of treatment
 - Mandatory treatment
 - Quarantine/isolation



Quarantine v. Isolation

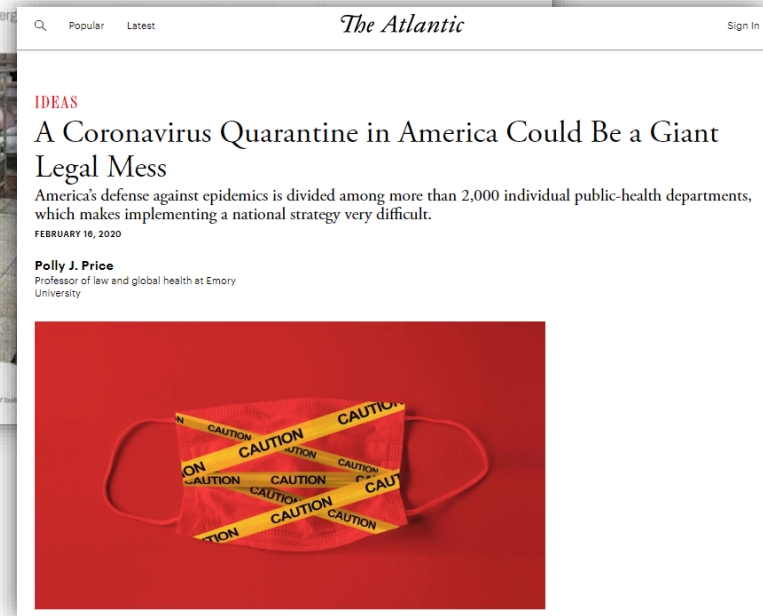
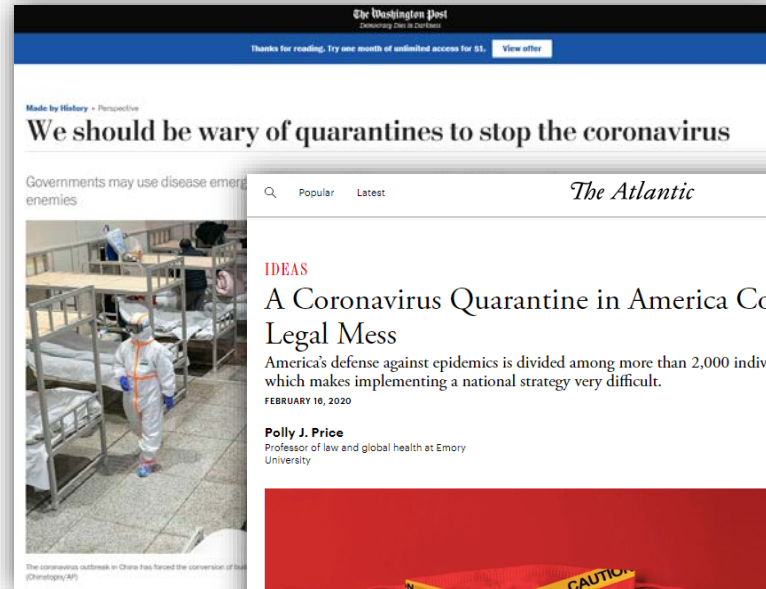
- Quarantine separates and restricts the movement of people who were exposed to a contagious disease to see if they become sick
- Isolation separates sick people with a quarantinable communicable disease from people who are not sick.



Yellow Fever Quarantine Camps

Quarantine: Balancing Individual Rights and Community Needs

- Emergency health measures like quarantine, isolation and contact tracing necessitate a balancing of the rights of individuals with the needs of the community.



Court Challenges to Quarantine

- **Dormant Commerce Clause**: *Gibbons v. Ogden* (1824); *Francaise de Navigation a Vapeur v. Louisiana State Board of Health* (1902)
- **Equal Protection**: *Wong Wai v. Williamson* (1900); *Jew Ho v. Williamson* (1900)
- **Recent Cases**: *United States v. Shinnick* (1963); *Hickox v. Christie* (2007)



Potential Quarantine Issues

- The rights of states and cities to refuse quarantine facility placements.
- Government responsibility to provide for the care of people in voluntary home-quarantine situations.
- Eminent domain powers if the government requisitions private facilities for quarantine purposes.



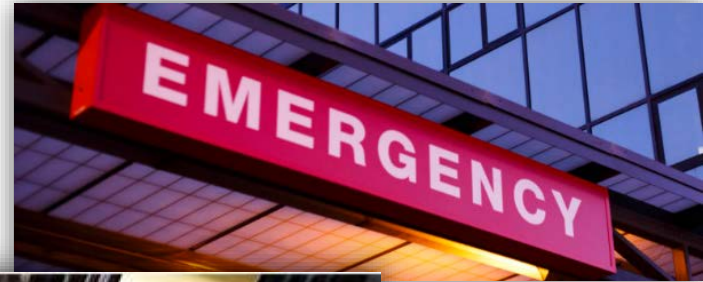
ROADMAP



- Responding to a Public Health Crisis
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 - **Considerations for Health Care Providers, Employers and Public Companies**
- **Legal, Employment and Disclosure Issues**

Legal Issues for Health Care Providers

- Liability for Insufficient Emergency Preparedness
- EMTALA Obligations
- Staffing Shortages
 - Provider Credentialing
- Government Authority over Health Care Institutions
- HIPAA Compliance
- Other Laws and Regulations
 - OSHA, Joint Commission



Legal Issues for Health Care Providers

- Diagnostics
- Clinical Trials
- Telehealth and Remote Care
 - Payment
 - Civil Monetary Penalties Law (“CMPL”)
- Considerations under Payor Risk Deals
 - Medicare Shared Savings Program (“MSSP”)
- Considerations for Teaching Programs



Legal Issues for Employers

■ Managing Employee Travel

- Monitor travel alerts issued by U.S. State Dept. and CDC.
- Restrict non-essential travel to high-risk areas.
- In accordance with CDC guidance, ask employees returning from high-risk areas to work remotely.



Legal Issues for Employers

- **What if an Employee Shows Symptoms?**

- Visibly ill employees can be instructed to stay away from the workplace and/or work remotely.
- Sick leave laws and company policies may require employees to be paid for time out of the office. Many employers are paying during self-quarantine, regardless of requirements.
- Consult counsel before requiring employees to submit to illness-related inquiries or screening.



Legal Issues for Employers

- **Key Employment Laws Implicated by COVID-19**
 - Anti-discrimination laws – Assess risks among employees based on objective non-discriminatory factors such as recent travel.
 - Disability Accommodations – Medical testing and inquiries implicate the Americans with Disabilities Act (ADA) and analogous state and local laws. Consider reasonable accommodations for disabilities.
 - OSHA – The Occupational Safety and Health Act (OSHA) requires employers to provide a safe working environment, including protections against “recognized hazards.”

Legal Issues for Employers

- **Key Employment Laws Implicated by COVID-19 (Continued)**



- Sick Leave Laws and FMLA – Various federal, state, and local laws provide protections for employees who are unable to work due to illness, the illness of a family member, or a workplace shutdown.
- Wage and Hour Laws – Employee absences due to illness, quarantine, or temporary shutdowns may implicate federal, state, and local wage and hour laws relating to permissible salary deductions and reporting pay.

Steps Employers Can Take Now

- Educate employees on developments in WHO and CDC guidance.
- Instruct symptomatic employees to stay away from the workplace.
- Provide sanitizing/hand-washing stations and regularly clean facilities.
- Appoint a Human Resources representative as a central resource.
- Consider preparing an internal workplace response plan.
- Consider cancelling non-essential meetings and/or company gatherings.



Practical Points to Think About

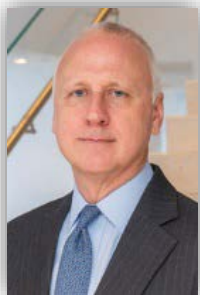
- Responses to employees who are nervous about reporting to the workplace.
- Responses to disruptions not covered by medical leave laws/policies:
 - School closures
 - Mass transit disruptions
- Responses to confirmed cases and/or exposure.

Legal Issues for Public Companies

- SEC Guidance on Financial Reporting & Disclosures
 - Potential relief for filing deadlines.
 - Importance of accurate disclosures.
- Best Practices for Disclosures
 - Clear explanation of how company may be affected.
 - Should be specifically tailored to business—not vague.
 - Discussion of timing and mitigation.



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