

Duane Morris®

[www.duanemorris.com](http://www.duanemorris.com)

# COVID-19 Risk and what can you do now?

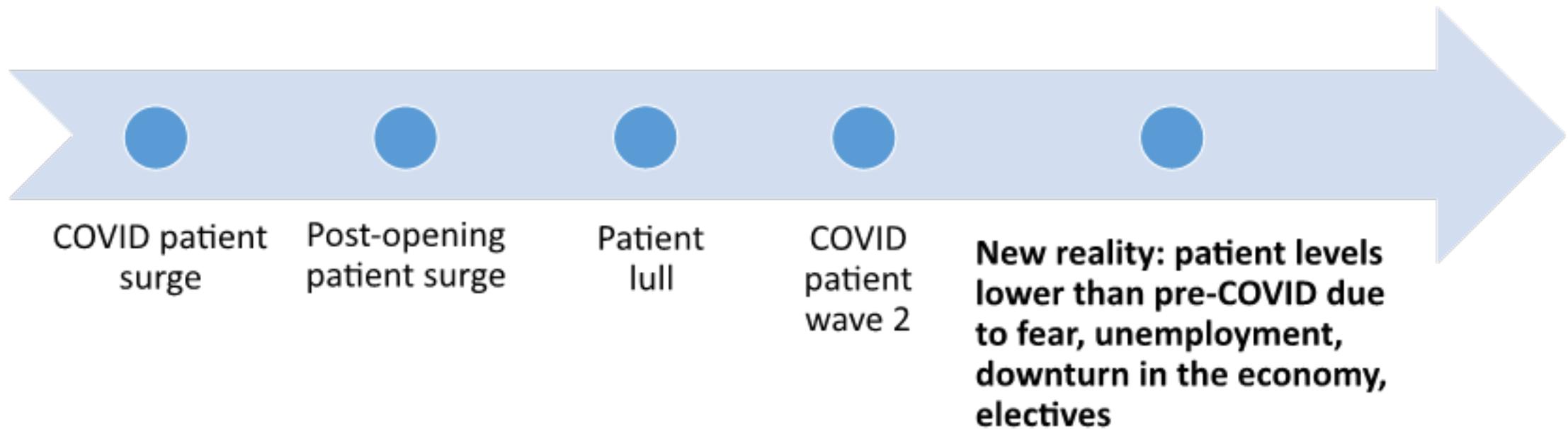
presented by

Delphine O'Rourke, Esq.

©2020 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris—Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Taiwan | Boston | Houston | Austin | Hanoi | Ho Chi Minh City | Shanghai | Atlanta | Baltimore  
Wilmington | Miami | Boca Raton | Pittsburgh | Newark | Las Vegas | Cherry Hill | Lake Tahoe | Myanmar | Oman | Duane Morris—Affiliate Offices | Mexico City | Sri Lanka | Duane Morris LLP—A Delaware limited liability partnership

# The Patient Waves



## State of Critical Care Pre-COVID-19 Outbreak

- **ICU Admissions:** More than 5 million patients are admitted annually to U.S. ICUs for intensive or invasive monitoring.
- **Technological Support:** The most common technological support is mechanical ventilation, required by 20%-40% of U.S. ICU admissions.
- **ICU Teams:** The multidisciplinary ICU team may consist of critical care nurses, APPs (nurse practitioners and physician assistants), intensivists, hospitalists, pharmacists, respiratory therapists, nutritionists, social workers, and other professionals.

# National Statistics Pre-COVID-19 Outbreak

924,107 acute care beds

---

96,596 ICU beds

---

5,256 American Hospital Association-registered community hospitals

---

51.4% of hospitals provide ICU services

---

*Society of Critical Care Management*, March 2020, <https://sccm.org/Blog/March-2020/United-States-Resource-Availability-for-COVID-19>

# COVID-19 Timeline in New Jersey

January 31, 2020

- **Public health emergency declared** for the United States for the 2019 Novel Coronavirus by Health and Human Services Secretary Alex Azar.

March 4, 2020

- **New Jersey's first confirmed cases** of COVID-19 reported.

March 9, 2020

- **Gov. Murphy declares state of emergency.**

March 10, 2020

- **New Jersey's first virus-related death reported.**

March 13, 2020

- **President Trump declares a National Emergency** by Proclamation Concerning the Novel Coronavirus Disease Outbreak.

March 6-30, 2020

- **CMS Blanket Waivers:** In response to the Emergency Proclamation, the Centers for Medicare and Medicaid Services (CMS) issued a number of blanket waivers to ease certain requirements, effective March 1, 2020.

March 19, 2020

- **Governor Murphy orders a statewide shutdown** of all non-essential businesses.

# COVID-19 Timeline in New Jersey (continued)

April 2, 2020

- **Governor Murphy signs Executive Order providing civil immunity** for health care professionals responding to the COVID-19 crisis.

April 14, 2020

- **New Jersey passes immunity laws offering** expansive legal protections to health care providers and facilities retroactive to March 1, 2020.

May 15, 2020

- **Governor Murphy signs executive order to allow resumption of elective surgeries** and invasive procedures effective May 26.

May 18, 2020

- **Governor Murphy unveils a three stage reopening strategy.**

June 1, 2020

- **Gov. Murphy announced that stage 2 of reopening would resume on June 15<sup>th</sup>**

# What to expect from a litigation perspective?

- ***Increased Lawsuits***

- Experts are predicting ***a wave of potential lawsuits*** against health care providers, facilities, and health companies arising out of preparation and response to the COVID-19 pandemic.

- ***Triage Risk***

- Providers may face lawsuits related to actions taken in response, including decisions to allocate resources and deny care when those resources run short.

- ***Class action lawsuit***

- One has already been filed against PADOH, alleging PADOH engaged in a policy and practice of denying appropriate safeguards and care to nursing home residents.
  - *Gill v. Pa. Dep't of Health*, No. 20-cv-02038 (E.D. Pa. Apr. 28, 2020).

- ***Wrongful death lawsuit***

- One already filed against Life Care Center in Kirkland, Washington, by the family of a deceased resident.
- Seattle-area nursing home, one of the first known sites of the outbreak in the United States.

## Liability Lessons Learned Following Hurricane Katrina

In the aftermath of Hurricane Katrina, questions arose regarding the treatment of patients at **Memorial Medical Center**.

- ***Facility Issues:***
  - Due to flooding, the hospital lost electricity, was without sanitation, and was running out of food.
- ***Transportation Issues:***
  - Helicopters hired to assist in evacuation did not arrive in time, and several patients died while being moved.
- ***Toxicology tests showed presence of sedatives in deceased:***
  - After toxicology tests showed the presence of morphine and sedatives in a number of bodies recovered from the hospital, an investigation was conducted.

## Liability following Hurricane Katrina (continued)

- ***Criminal investigation and prosecution of Dr. Anna Pou:***
  - Dr. Anna Pou was arrested and charged with homicide, although ultimately a grand jury failed to indict Dr. Pou and charges were expunged.
- ***Immunity legislation:***
  - Dr. Pou later assisted in the passage of legislation in Louisiana providing immunity to health care providers during mass casualty situations.
- ***Settlement of class action:***
  - In 2011, Memorial's parent company, Tenet Healthcare Corp., agreed to pay \$25 million to settle a class action lawsuit by families of patients killed during the disaster, who alleged that the company had failed to adequately prepare for and respond to the disaster
- ***Additional civil lawsuits*** against Dr. Pou and other providers were settled.

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910)

## *Legislative intent:*

**“The enactment of this bill is to ensure that there are no impediments to providing medical treatment related to the COVID-2019 emergency and that all medical personnel supporting the COVID-19 response are granted immunity.”**

- Received a 30-2 vote in Senate, and 73-1-1 vote in the Assembly
- Retroactive to March 9, 2020

## New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- Covers all aspects of COVID-19 treatment/care by almost any person in the healthcare workforce
  - “Notwithstanding the provisions of any law, rule, or regulation to the contrary:
    - (1) a health care professional shall not be liable for civil damages for injury or death alleged to have been sustained as a result of an act or omission . . . **in the course of providing medical services in support of the State’s response to the outbreak of the coronavirus disease[.]”**

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Immunity law does not apply to:***
  - Acts or omissions constituting a crime, actual fraud, actual malice, gross negligence, recklessness, or willful misconduct.
  - Care and procedures performed by health care professionals unrelated to the COVID-19 emergency.
    - E.g., OB/GYN services, orthopedic procedures

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Covered health care professionals includes any:***
  - physician
  - physician assistant
  - registered nurse
  - advanced practice nurse
  - licensed practical nurse
  - emergency medical technician
  - mobile intensive care paramedic

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Health care facilities and health care systems***

Not liable for civil damages for injury or death alleged to have been sustained as a result of:

- an act or omission by one or more of its agents, officers, employees, servants, representatives or volunteers, **if, and to the extent, such [individual] is immune from liability.**

## New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Acts or omissions “undertaken in good faith”***
  - Civil immunity also extends to acts and omissions “undertaken in good faith” by providers and the facilities/health systems that employ them to support the COVID-19 relief effort that would otherwise fall outside the scope of the provider’s license.
  - ***Except*** if such acts and omissions otherwise constitute “a crime, actual fraud, actual malice, gross negligence, recklessness, or willful misconduct[.]”

## New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Civil immunity also applies to telemedicine:***
  - care provided through telemedicine and other technologically driven methods of care being utilized extensively during this crisis due to social distancing measures aimed at curbing the spread of the virus.

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Allocation of scarce medical resources***
  - Insulates providers/facilities from both civil and criminal liability for deaths or injuries sustained as a consequence of decisions about the allocation of mechanical ventilators or what the law calls “other scarce medical resources” that are in limited supply and high demand during a public health emergency.
  - However, the immunity is **only** applicable if the facility or health system adopts and adheres to a “**scarce critical resource allocation policy.**”

# New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Scarce critical resource allocation policy:***
  - Guidelines for the creation of scarce critical resource allocation policies were previously promulgated by New Jersey Department of Health Commissioner Perscichilli on April 11, 2020.
  - The state of New Jersey has adopted what has become known as the “University of Pittsburgh Model Policy,” which was created after a decade-long research project at the University.

NJ DOH Guidelines for creation of scarce critical resource allocation policies available at <https://nj.gov/health/legal/covid19/FinalAllocationPolicy4.11.20v2%20.pdf>

Univ. Pitt. Model Policy available at <https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now>

## New Jersey's COVID-19 Immunity Law (S-2333/A-3910) (continued)

- ***Duration: until state of emergency rescinded***
  - The immunities granted pursuant to the statute extend until the New Jersey state of emergency and public health emergency declarations by Governor Murphy are ended.

# COVID-19 Risk Exposure and Immunity

## Medical Malpractice

- Ordinary negligence, gross negligence

## Crisis standards of care

- Appropriately triggered, process, when on and off

## Triage protocols/policies

- Rigorous adherence, documentation, evolution of education

## Reopening of elective surgeries

- NJ requirements, facilities, infection control, delayed diagnosis, delayed treatment, fraud and abuse

## COVID-19 Risk Exposure and Immunity (continued)

**HIPAA breaches**

**OSHA: failure to provide a safe workplace environment**

**Employment claims**

**Discrimination**

**NLRB**

**Contract disputes with third parties**

**Insurance claims**

**Payment disputes with payors and patients**

# COVID-19 Risk Exposure and Immunity

Government funds including The CARES Act, FEMA, PEMA, PPE

Violation of federal and state laws and regulations during COVID – consideration of Section 1135 blanket waivers, Section 1135 individual waivers, state waivers

Violation of federal and state laws and regulations in post-national emergency state

CMS is pushing forward with price transparency – “COVID pricing”

# The waivers will come to an end.

## ***End date:***

- Waivers granted under section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

## ***EMTALA and HIPAA Waivers***

- Waivers for EMTALA (for public health emergencies that do not involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol.
- Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic-related public health emergency.

## ***Only applies to Federal requirements***

- The 1135 waiver authority applies only to Federal requirements and does not apply to State requirements for licensure or conditions of participation.

# Return to Workplace

## Return to Work Certification

- ***Employee Survey:***
  - For employees returning to work from furlough, layoff or self-quarantine due to COVID-19, employers should, and may be required to, request that employees state whether, within the prior 14 days, they were diagnosed with COVID-19, experienced symptoms of COVID-19, came in close contact with someone who was diagnosed with or experienced symptoms of COVID-19 or engaged in any travel.
- ***Identification:***
  - Employers should consider implementing a return to work certification to identify these circumstances.

# Return to Workplace (continued)

## Return to Work Survey

- A ***voluntary*** return to work survey may help employers understand ongoing challenges that employees may face as they return to work.
- ***Information privacy:***
  - Because employers must comply with anti-discrimination laws, employers who implement such voluntary surveys (which may involve child care needs, health concerns, status of any COVID-19 diagnosis or symptoms, or work commute) must be careful about how such information is stored and used and who has access to it.
- ***Consult:***
  - Employers should consult counsel before implementing such surveys given the risks associated with such inquiries.

# Return to Workplace

## Employee/Contractor Reporting of Circumstances Form

- To help maintain a healthy and safe workplace, employees who report to work in-person or contractors who enter the workplace must know to whom they should report if they are diagnosed with COVID-19 or experience symptoms of COVID-19 before, during or after work, and what situations and symptoms to look out for regarding COVID-19.
- Consider making available to employees and contractors a form to self-monitor for symptoms or report a diagnosis of COVID-19.
- CDC's updated Guidance suggests conducting daily health checks, hazard assessment of workplace, improving building ventilation system, social distancing and face covering policies.

# Supply Chain Impact

## President Trump signed Executive Order to Prevent and Punish Hoarding and Fraud

- Authority to take action to prevent “[t]he hoarding and price gouging of critical supplies needed to combat the Coronavirus”. White House Fact Sheets: March 23, 2020
- In scope: hoarding unnecessary quantities of items for the purpose of selling them above fair market value
- Authorized under the Defense Production Act

## Supply Chain Impact (continued)

- President Trump delegated to the U.S. Department of Health and Human Services (HHS) the authority to designate:
  - (1) scarce resources; and
  - (2) resources, the supply of which, would be threatened by hoarding

# Fraud

- ***Potential for fraud/scams:***
  - DOJ warned against fraudulent offers to sell respiratory masks and other medical devices, include sales of large amounts of PPE.
    - An Atlanta man was arrested after misrepresenting to the Department of Veterans Affairs that he could obtain over 125 million 3M masks, worth \$750 million, from domestic factories.
  - The FBI issued an alert warning that hackers have targeted the government and other healthcare industry buyers attempting to purchase PPE with business email compromise (BEC) scams.

## Much needed supplies

- Health systems and hospitals contracted with a variety of third parties to purchase much-needed PPE.
- Already circumstances where health systems were defrauded, received defective or otherwise non-compliant products and/or financial disputes including masks, ventilators, drugs
- Attorney General's office has established a process for reporting problematic vendors

## Physician contracting

- Regulatory compliance – within scope of Stark Law waiver
- Reconciliation of employed physician compensation models and contractual arrangements
- Reconciliation of financial arrangements with independent physicians – patient surges, reallocation of physicians, lack of patient volume due to closure of elective surgeries and procedures
- Termination of employed physicians
- Revising arrangements, as necessary

## Lessons Learning....

- ❑ Deploy your known tools and strategies
- ❑ Prepare for civil lawsuits with third party entities
- ❑ Prepare for audits, inspections, and investigations
- ❑ Prepare for criminal investigations brought by government agencies
- ❑ Education, drills, changing landscape during non-patient surge periods of time
- ❑ Insurance – anticipate additional coverage
- ❑ Complete patient records with detail on COVID-19 treatment (medical malpractice, funding, agency audits etc.)

## Lessons Learning.... (continued)

- ❑ Due diligence before payment of any monies for PPE and other critical equipment; inventory PPE and other essential supplies and document any attempts to obtain.
- ❑ Eligibility for funds: eligibility, attestation, detailed accounting and specific cost centers to allow pivoting and return of funds, if necessary, and False Claims Act and/or criminal charges
- ❑ Meaningful communication with providers, employees, patients and community: TRUST, pulse on what's "really going on," policy v. practice

## Lessons Learning.... (continued)

- ❑ If you are going to have a “HOTLINE”, make sure it is fully operational it creates an expectation of expediency
- ❑ “Healthcare Heroes” fade as time goes by
- ❑ Emotional connection v. transactional relationship
- ❑ Your reality versus the general experience, particularly in 2 plus years when the cases will be filed/tried
- ❑ CARE for STAFF: patient and family ambassadors, angry staff member that whispers “this should have never happened”; care, feeding, wholistic approach, unions, class actions

# Discussion . . .