



**BARCLAY DAMON** LLP

***Propelling New York  
Forward: Liability and  
Immunity in the Age of  
Coronavirus***

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# Agenda

- » NYS Immunity and Exceptions
- » Federal Immunity Declarations
- » Health Care Facility Notification Requirements
- » Pending Litigations and Other State and Federal Investigations
- » Other States' Immunity Laws
- » Provider Precautions to Avoid Pitfalls



# **COVID-19: NYS Immunity**



# COVID-19: NYS Immunity

## » **Article 30-D of the NY Public Health Law**

- » As long as certain criteria are met, immunity is granted to health care facilities and professionals from civil or criminal liability for any harm or damages alleged as a result of the treatment, prevention, or diagnosis of COVID-19.
- » Retroactive to governor's March 7 emergency declaration
- » Ends whenever the state of emergency declared by Governor Cuomo is lifted

# COVID-19: NYS Immunity Criteria

## » Immunity applies as long as:

- › The health care facility or health care professional is arranging for or providing health care services pursuant to a COVID-19 emergency rule or otherwise in accordance with applicable law
- › The act or omission occurs in the course of arranging for or providing health care services, and the treatment of the individual is impacted by the health care facility's or health care professional's decisions or activities in response to or as a result of the COVID-19 outbreak and in support of the state's directives
- › The health care services are provided in good faith



# COVID-19: Limits on NYS Immunity

- » **Willful or intentional criminal misconduct, gross negligence, reckless misconduct, or intentional infliction of harm**
  - › Decisions resulting from a resource or staffing shortage won't fall within this exception



# COVID-19: NYS Immunity and Other Statutes

## » **Public Health Law § 2801-d**

- › Private right of action by residential health care facility residents, including nursing homes

## » **CPLR Article 16**

- » Gross negligence standard



# COVID-19: NYS Immunity Insights

- » **Does the EDTPA supersede other NYS statutes like PHL § 2801-d?**
  - › “Notwithstanding any law to the contrary ...”
  - › Exception: Willful or intentional misconduct or gross negligence
    - › Note: Also the standard for punitive damages under PHL § 2801-d



# COVID-19: Efforts to Repeal NYS Immunity

- » Assemblymen Ron Kim and Dan Quart sponsor a bill that seeks to repeal the immunities provided under the EDTPA
  - › Argue the gross negligence standard is an extraordinarily high bar that insulates nursing home administrators and executives from liability and results in “zero accountability”

*\*Source: <https://www.law360.com/articles/1275101/ny-bill-would-repeal-covid-19-immunity-for-nursing-homes>*



# **COVID-19: Federal Immunity Declarations**



# COVID-19: PREP Act

- » PREP Act declaration made by HHS secretary on January 31, 2020
- » Immunizes a covered person from legal liability for all claims for loss relating to the administration or use of a covered countermeasure

# COVID-19: PREP Act (cont'd.)

## » Immunity breaks down into four elements

1. Individual or entity must be a “covered person”
2. Legal claim must be for a “loss”
3. The loss must have a “causal relationship” with the administration or use of a covered countermeasure
4. The medical product that caused the loss must be a “covered countermeasure”

# COVID-19: PREP Act (cont'd.)

## » “Covered persons”

- › The United States
- › Manufacturers and distributors of covered countermeasures
- › Program planners
- › Qualified persons who prescribe, administer, or dispense covered countermeasures (including licensed health professionals)

# COVID-19: PREP Act (cont'd.)

## » All claims for loss

- › Loss is broadly defined and includes:
  - Death
  - Physical, mental, or emotional injury; illness; disability; or condition
  - Fear of injury, including medical monitoring costs
  - Loss of or damage to property, including business interruption loss



# COVID-19: PREP Act (cont'd.)

- » **Causal relationship to the administration and use of a covered countermeasure**
  - » Immunity applies to any claim for loss that has “a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use” of a covered countermeasure



# COVID-19: PREP Act (cont'd.)

- » **Medical product at issue must be a “covered countermeasure”**
  - › Three general types of countermeasures
    1. A qualified “pandemic or epidemic product”
      - › To diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic that is FDA approved, licensed, or authorized
    2. A “security countermeasure”
    3. A drug, biological product, or device that the US Food and Drug Administration has authorized for emergency use

# COVID-19: PREP Act (cont'd.)

## » **Sole exception to PREP Act immunity**

- › When a covered person proximately causes death or serious physical injury to another person through willful misconduct
  - Meaning the covered person acted:
    1. Intentionally to achieve a wrongful purpose
    2. Knowingly without legal or factual justification
    3. In disregard of a known or obvious risk that's so great as to make it highly probable that the harm will outweigh the benefit



# COVID-19: Section 1135 Waivers

- » Adopted to allow hospitals, laboratories, nursing homes, hospice, psychiatric hospitals, critical access hospitals, and other regulated organizations and facilities to provide timely and quality care to those in need

# COVID-19: Section 1135 Waivers (cont'd.)

## » **Waivers may impact:**

- › Requirements that physicians and other health care professionals be licensed in the state in which they are providing services as long as they have equivalent licensing in another state, subject to any applicable state laws governing licensure
- › Stark self-referral transactions
- › Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers
- › Program participation, conditions of participation, and other certification requirements
- › Preapproval requirements

*\*Source: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>*



# **COVID-19: Federal and NYS Health Care Facility Notification Requirements**





# COVID-19: NYS Notification Requirements

- » **April 16:** Executive Order 202.18 requiring nursing and adult-care homes to report COVID-19 cases to family members and next of kin within 24 hours of a positive test result or COVID-19-related death
- » **April 17:** Executive Order 202.19 providing for penalties for a facility's failure to provide the required notifications



## COVID-19: Federal Notification Requirements

- » **April 30:** Federal government imposed new reporting obligations on nursing homes
- » Among other things, nursing homes are required to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility.
- » Notifications must comply with existing privacy regulations and must **not** include any PHI.

# COVID-19: Nursing Homes

## » Nursing homes

- › March 3: DOJ's National Nursing Home Initiative
- › April 10: Soldier's Home investigation
- › April 23: Joint investigation of nursing homes announced by DOH and OAG in New York State
- › April 30: CMS announces independent Commission to conduct assessment of nursing homes' response to COVID-19
- › May 5: Violations found in DOH-operated nursing homes



# COVID-19: Nursing Homes (cont'd.)



- » April 22: “It’s their patient ... and their patient that they’re getting paid to take care of now contracts the COVID virus. OK. Now you have to take care of that patient ... with the COVID virus...”

# COVID-19: Nursing Homes (cont'd.)

**The Washington Post**  
*Democracy Dies in Darkness*

## Investigations


**Major nursing home chain violated federal standards meant to stop spread of disease even after start of covid-19, records show**

# COVID-19: Nursing Homes (cont'd.)



## Man sues Brooklyn nursing home for failing to protect dead father from COVID

- » <https://nypost.com/2020/05/26/man-sues-brooklyn-nursing-home-where-father-died-from-coronavirus/>



# COVID-19: Nursing Homes (cont'd.)

## » **Nursing home statistics**

- › As of June 22: 6,250 confirmed or presumed COVID-19 deaths in New York State
- › As of June 2: Survey of nursing homes released by CMS reveals almost 26,000 COVID-19 resident deaths nationwide

# COVID-19: Nursing Homes (cont'd.)

- » May 10: Governor Cuomo issued Executive Order 202.30, reversing the state's nursing home admission and readmission policy for hospital patients.
  - › Prohibits hospitals from discharging any patient to a nursing home unless the operator or administrator first certifies it's able to properly care for the patient
  - › Nursing homes and adult-care facilities must test all personnel at least twice per week
  - › Penalties: \$2,000 per violation per day and \$10,000 per day for subsequent violations

# COVID-19: Nursing Homes (cont'd.)

## THE WALL STREET JOURNAL.

English Edition ▾ | May 18, 2020 | Print Edition | Video

U.S.

### New York Sent Recovering Coronavirus Patients to Nursing Homes: 'It Was a Fatal Error'

The state reversed its policy after mounting criticism and deaths. The mandate is part of broader scrutiny of weaknesses at long-term care facilities that have made them hot spots for Covid-19.

# COVID-19: Nursing Homes (cont'd.)



**Cuomo says no one should be prosecuted for coronavirus deaths in New York, including those in nursing homes**

# COVID-19: Nursing Homes (cont'd.)

- » **June 1:** CMS announces “performance-based” funding requirement tied to the CARES Act supplemental grants
  - › Enhancement of penalties for non-compliance with infection control to provider greater accountability
  - › States that haven’t completed 100 percent of the focused infection control surveys will be required to submit a corrective action plan for completion within 30 days
  - › If after 30 days surveys aren’t completed in 100 percent of nursing homes, CARES Act allocation may be reduced by 10 percent
  - › Subsequent 30-day extensions could result in an additional 5-percent reduction
  - › Funds will be redistributed to those States that completed 100 percent of the surveys by July 31

\*Source: <https://www.cms.gov/files/document/qso-20-31-all.pdf>



# COVID-19: Nursing Homes (cont'd.)

- » **June 23:** NYS Senator Jim Tedisco introduced legislation that would form a state panel to investigate the more than 6,000 COVID-19-related deaths that occurred in nursing homes.
- » The panel would investigate the governor's March 25 executive order barring testing of COVID-19 for those being admitted or returning to nursing homes.
  - *\*Source: <https://cbs6albany.com/news/coronavirus/legislation-calls-for-bi-partisan-review-of-covid-19-response-in-ny-nursing-homes>*



# COVID-19: OPWDD Providers

## » Access to residential facilities

- › Providers implement policies against family and home visits as well as offsite programming
- › OPWDD oversight: Surveys and other investigative activities (Mental H. L. § 16.11)
  - › Unfettered discretion
- › Provider penalties and sanctions (Mental H. L. § 16.17)

# COVID-19: OPWDD Group Homes


## CBS6 Investigates: Call for policy changes, nearly 2,000 COVID cases in OPWDD group homes

by Anne McCloy | Thursday, May 14th 2020


AA



- » <https://cbs6albany.com/news/coronavirus/cbs6-investigates-call-for-policy-changes-nearly-2000-covid-cases-in-opwdd-group-homes>



# **COVID-19: Pending Litigations and Other Investigations**





# COVID-19: Pending Litigations

## » **April 20: New York State Nurses Association**

- › Three lawsuits filed in state and federal courts against hospitals and NYS Department of Health
  - Allegations that the DOH neglected its statutory duties and nurses were forced to work while experiencing symptoms or awaiting test results, not provided with testing, and rationing of PPE



# COVID-19: Pending Litigations

- » **May 4: Residents of Queens Adult Care Center filed a class-action lawsuit in the EDNY alleging violations of the ADA**
  - › Operators' failure to take proper precautions against COVID-19, including proper screening and testing of employees and residents



# **COVID-19: Other States' Immunity Laws**

# COVID-19: Other States' Immunity Laws

- » At least 14 other states have granted some form of immunity to nursing homes and long-term care facilities from liability during the COVID-19 pandemic.
  - » States include: Alabama, Arizona, Connecticut, Georgia, Illinois, Kentucky, Massachusetts, Michigan, Mississippi, New Jersey, Nevada, Rhode Island, Vermont, and Wisconsin

\*Source: <https://www.abajournal.com/news/article/at-least-15-states-grant-lawsuit-protection-to-long-term-care-facilities-during-pandemic>



# COVID-19: Other States' Immunity Laws (cont'd.)

- » Critics of immunity statutes maintain that nursing homes and other facilities should be held accountable for deficiencies, such as staffing shortages and poor infection control, which were reportedly problems before the onset of the pandemic.



# **COVID-19: Provider Precautions to Avoid Pitfalls**



# COVID-19: Provider Precautions

- » Documented and measured steps to avoid federal or state anti-discrimination and anti-fraud liability
- » Risk of False Claims Act liability
  - › Substandard nursing care to residents
- » Claims under federal law and NYS immunity
- » Compliance
  - › Thoroughly document services received by all residents and patients

# Questions?



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