HALL BOOTH SMITH, PC
“Serving to Achieve Excellence”

Propel Insurance COVID-19 Program
Working Together: Responding to COVID-19
About Hall Booth Smith, P.C.

- Hall Booth Smith, P.C. (HBS) is a full-service law firm established in 1989. We have offices strategically located throughout Georgia, Alabama, Florida, North Carolina, South Carolina, Tennessee, New Jersey, and New York. HBS prides itself on providing knowledgeable, proactive, client-specific counsel to individuals, domestic and international corporations, state and federal agencies, and nonprofit organizations.

- HBS has a recognized National Practice on handling complex high exposure cases.

- HBS has delivered quality legal services in a variety of practice areas for over 30 years. Experience across legal disciplines combined with a focus on the unique business or personal requirements of the client is the hallmark of the firm. Our clients receive the attention, expertise, and cost-effectiveness of a smaller law firm with a full-service and strong regional presence typical of a large law firm.

- At HBS, our mission is: “To ethically and professionally serve our clients by providing the highest quality legal representation in a personally satisfying firm environment.”

- At HBS, our promise is: “Serving to Achieve Excellence”
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*Serving to Achieve Excellence*  
[WWW.HALLBOOTHSMITH.COM](http://WWW.HALLBOOTHSMITH.COM)
HBS Coronavirus Task Force

• Highly experienced attorneys with diverse skill sets, knowledge and expertise across disciplines most affected by coronavirus pandemic including medical malpractice, employment, liability, regulatory and insurance.

• Experience handling COVID-19 claims asserted against senior living providers across the country.

• 1000’s of hours developing tools and strategies
HBS Coronavirus Task Force

• Help clients establish best practices and protocols for handling the myriad issues that unexpectedly arise each day.

• Provide guidance on reviewing the legal implications of decisions that are made and documenting actions that are taken. We help gather and preserve valuable evidence that can protect their interests and help build a strong and sound defense, should litigation occur in the future.

• Our Coronavirus Task Force represents healthcare facilities and long-term care centers, physicians, nurses and other professionals who will likely face lawsuits in the coming months and years alleging misdiagnosis, negligent diagnosis, negligent care, wrongful death and other high-exposure claims.
HBS Coronavirus Task Force

• Our Coronavirus Task Force also supports clients in day-to-day business needs, emerging issues and unexpected challenges that arise when workforces are suddenly working from home for extended periods of time, including cybersecurity issues, file access, data storage and security, and best practices for minimizing exposure and risk during this global crisis.
WHAT IS THE PREP ACT?
WHAT IMMUNITY DOES IT PROVIDE?
HOW DOES THIS APPLY TO AGING SERVICES PROVIDERS?

WHICH STATES HAVE IMMUNITY ORDERS?
HOW CAN YOU BE PROACTIVE IN YOUR DEFENSE?
WHAT CAN YOU EXPECT TO SEE IN LITIGATION?
FEDERAL IMMUNITY:
What is the PREP Act and How does it apply?
The PREP Act was enacted in 2005 by Congress. The PREP Act authorizes the Secretary of the US Department of Health and Human Services to issue a PREP Act declaration in response to a public health emergency.

The PREP Act authorizes the Secretary of Health and Human Services (HHS) to declare that certain “covered persons” are immune from liability (i.e., loss sounding in tort or contract) for taking certain “covered countermeasures” that are necessary to combat a public-health emergency such as COVID-19.

On March 10, 2020, Secretary of HHS Alex Azar issued such a PREP Act declaration, effective February 4, 2020 (“Declaration”).
The PREP Act Declaration: Basic Elements

Elements of PREP Immunity:

• “Claim for loss”

• “Covered Person”

• “Use” or “Administration” (“Recommended Activity”)
  • Also: manufacturing, development, testing, production, and distribution

• “Covered Countermeasure”

• Causal nexus between the activity and the claim
Immunity includes:

- Any claim, under federal or state law, for loss that has a causal relationship with the administration to or use by an individual covered by a countermeasure.

- A loss is defined to include: death, personal injury, emotional injury, property damage, business interruption and fear of personal injury.

- The protection is very broad and applies “without regard to the date of the occurrence, presentation or discovery of the loss.” With few exceptions.

- Immunity from liability under the PREP Act is not available for death or serious physical injury caused by willful misconduct.
Who is a “COVERED PERSON”? 

- Not limited to individuals.
- “Program planners”
  - a person or entity involved in planning, administering, or supervising programs for distribution of a countermeasure
  - A “private sector employer” – such as a provider of aging services – can be a program planner
- “Qualified persons”
  - licensed health care professionals or other individuals authorized to prescribe, administer, or dispense covered countermeasures under the law of the state in which the covered countermeasure is prescribed.
  - Officials, agents and employees of any of these entities or persons
The PREP Act
Declaration:
Covered
Countermeasures

What are “Covered Countermeasures”?

• Any drug, biological product, diagnostic, or device used to treat, diagnose, cure, prevent, or mitigate COVID-19.
Examples of “covered countermeasures” found in Assisted Living:

- Personal Protective Equipment
  - Surgical Masks (non-N95); Respirators (N95); Gloves; Gowns; Face Shields
- OTC Hand Sanitizer
- COVID Tests
- CPAP Machines & Ventilators
- Therapeutic Drugs: Hydroxychloroquine (before June 15, 2020—EUA ended) and Remdesivir
- Protective Barrier Enclosures & Airway Management Isolation chambers
- Decontamination/Sterilization Systems (but not disinfectants, generally)
What is "Administration“?
• physical provision of countermeasures to recipients;

• activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients;

• management and operation of countermeasure programs;

• management and operation of locations for purposes of distributing and dispensing countermeasures.
### The PREP Act: Prior Declarations

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/26/07</td>
<td>Avian Influenza A (H5N1)</td>
</tr>
<tr>
<td>10/1/08</td>
<td>Anthrax</td>
</tr>
<tr>
<td>10/10/08</td>
<td>Avian Influenza A – Specific Drugs</td>
</tr>
<tr>
<td>10/10/08</td>
<td>Botulism; Acute Radiation Syndrome; Smallpox; More Avian Influenza Strands</td>
</tr>
<tr>
<td>12/17/08</td>
<td>Avian Influenza – Respiratory Devices</td>
</tr>
<tr>
<td>9/28/09</td>
<td>H1N1</td>
</tr>
<tr>
<td>12/3/14</td>
<td>Ebola Virus – Specific Vaccines</td>
</tr>
<tr>
<td>4/9/15</td>
<td>Ebola Virus – Specific Therapeutics</td>
</tr>
<tr>
<td>2/6/17</td>
<td>Zika Virus – Specific Vaccine Types</td>
</tr>
<tr>
<td>5/4/17</td>
<td>Nerve Agent/Insecticide</td>
</tr>
<tr>
<td>8/1/18</td>
<td>Zika Virus – Other Specific Vaccine Types</td>
</tr>
</tbody>
</table>
Comparing PREP Act Declarations

PREP Act

Influenza A/H1N1

Covid-19

Ebola

Anthrax
<table>
<thead>
<tr>
<th>COVID-19 Declarations</th>
<th>Influenza A/H1N1 Declarations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Includes PPE and many other products, not just vaccines.</td>
<td>Does not include PPE outside of Personal Respiratory Protection Devices (March 2015).</td>
</tr>
</tbody>
</table>
| Does not focus on vaccines, but on using products to test for, treat, and prevent the spread of COVID-19. | Primary focus is antivirals and vaccines  
*Example: Published as "The Declaration for the Use of the PREP Act for H1N1 Vaccines"* |
| Does not include specific vaccines (as none are presently available to contain the virus.) | Specifically listed the vaccines that were covered under the Declarations.                    |
| Issued to address the concerns and progression of the novel coronavirus.              | Limited to influenza (and orthopox) viruses brought on by animal borne illness.              |
State Limited Liability Orders
States with Immunity
Executive Orders / Legislation

- Immunity
- No Immunity
Q: Do state immunities still apply in federal court?

**Answer:** Yes. If the state immunities are broader than PREP, they are not preempted. They can also be raised in federal court.
Q: What if we have an arbitration agreement?

**Answer:** You can assert the PREP Act during Arbitration.

- However, remember that arbitration may be final and binding.

**How?** Remove case from state court to federal court. Seek to compel arbitration with first responsive pleading (otherwise you risk waiver of right to remove).

Consider pros/cons of removal on case-by-case basis.
Anticipated Claims
• The plaintiffs’ bar will attempt to circumvent the scope of the immunity provided by targeting their efforts on alleged claims of negligent care and treatment of residents as being unrelated to COVID-19.
Anticipated Claims

• Failure to prevent/mitigate spread of infection
  • Failure to limit visitors/vendors/employees
  • Failure to screen/test
  • Lack of PPE
  • Failure to have proper infectious disease protocol

• Failure to warn/notify

• Failure to recognize changes in condition

• Failure to report changes in condition

• Failure to provide appropriate and timely care
Anticipated Claims

• Failure to communicate infection rates to residents of assisted living communities.

• Failure to develop and implement effective cohorting plans for assisted living communities.

• Failure to prevent non-COVID injuries (pressure injuries, falls, medication error) due to understaffing.

• Violations of Resident Rights
  • Visitors, isolation, dignity, etc.
COVID-19: Prepare Defenses Proactively
COVID – Prepared for future litigation

• Maintain a Timeline*:
  • Dates and Responses to Changing Guidance/Recommendations.
  • Note when visitations were restricted, vitals started, testing began, social distancing enforced, etc.
  • Policy/Procedure changes
  • Family communication

• Work with leadership in your communities to document the “day in the life” of a caregiver during the COVID-19 emergency.

• Demonstrate the positive steps your community has taken to meet a crisis standard of care.
COVID – Be prepared for future litigation

• Consolidate and Retain Pertinent Documentation.
  • Redistribution of Staff
  • Administrative Actions to procure PPE and Testing
  • Caregiver Training and Meetings
  • Disinfection of Community
  • Communication to staff/resident/family
  • Infectious disease safety measures
  • Policies and procedures

• Identify a custodian.
COVID – Be prepared for future litigation

• Third party vendor issues
• Communication with physician and resident/responsible party about changes
COVID – Be prepared for future litigation

- Identify key witnesses in the organization who participated in the community/facility response to act as expert witnesses in future cases.
  - Prepare
  - Document
  - Preserve
Consider including general documentation in every chart:

“Please note that this care is given at a time of national public health emergency due to the pandemic caused by COVID-19 (Novel Coronavirus). As a result, it is acknowledged and understood that the spread of COVID-19 within our communities places an incomprehensible strain on our providers, hospital systems and the resources, equipment, beds, treatment options, and services available in support of patient care.

It is further acknowledged and understood that the community, during the COVID-19 pandemic, endeavors to remain operational and provide care to all residents commensurable with the resources available and existing at that time. Further, it is acknowledged that the transmittable risks, treatment process and diagnosis are novel without well-defined guidelines.

It is further acknowledged due to the novel and emergency nature of this pandemic, care is provided utilizing the best judgment and currently known practices, within the limitation of resources.”
Hall Booth Smith National COVID Defense Counsel
Defense Strategy Roadmap (Generally...)

- Assess the case:
  - Does this case meet the PREP Act Criteria? What state immunities/defenses apply?
- Pick your forum:
  - Do I want to be in Federal or State Court? Strategic Cost/Benefit Analysis.
- Removal
- Compel Arbitration
- Move to Dismiss
- Engage in Discovery
- Motion for Summary Judgment
HBS National COVID-19 Defense Counsel

• Facility-by-facility basis:
  • Assisting facility pre-suit in preparing defenses.

• Case-by-case basis.
  • Provide expertise in COVID-19-related litigation working as primary counsel or with other local defense counsel to present a unified defense strategy.
  • Advise and consult in developing defense strategy.
  • Prepare pleadings specific to each case.
General Programs Offered

Phase 1-A – Federal PREP Act Immunity

- Develop and Implement a consistent PREP Act defense strategy to be used in all matters.

- Includes:
  - Comprehensive White Paper
  - Notice of Removal to Federal Court
  - Motions Templates: Dismissal, Summary Judgement, Application for Higher Standards, etc.
  - Discovery Templates
  - Affirmative Defenses
General Programs Offered

Phase 1-B – State-Based Immunity

• Develop and Implement a state-specific defense strategies in all matters. Including states with immunity and without immunity provisions.

• Includes:
  • Comprehensive White Paper
  • Motions Templates: Dismissal, Summary Judgement, Application for Higher Standards, etc.
  • Discovery Templates
  • Affirmative Defenses
Conclusion

Questions, Answers and Responses.