Disaster Preparedness & Response: Here, There & Everywhere

- From the hospital parking lot to the town center. From the school campus, the vacation resort, and the night club. From the Zika virus to lone shooters. From floods to fires. From hurricanes and earthquakes to terrorist attacks. Healthcare entities, local and state governments, emergency service agencies, community partners, and—especially lawyers, need to be alert, informed and prepared all day, every day. This panel is devoted to exploring all types of unplanned incidents and accidents, the responses to them, and any legal issues that may arise at the Federal, State/County, and Local levels. Acts of nature or intended aberrant behavior, much of what can and should be done—is already known. Too often, however, that knowledge comes from experience; which is usually the unintended consequence of a "surprise."
Panelists:

Moderator: Noel Christian Pace, Esq., MHA, FACHE, Vice Chair, American Bar Association’s Health Law Section’s Public Health & Policy Interest Group

Panelist: Gregory Sunshine, JD, Public Health Analyst, Chenega Professional & Technical Services, LLC, Public Health Law Program, Office for State, Tribal, Local and Territorial Support

Panelist: Scott Cormier, Vice President, Emergency Management, Environment of Care and Safety, Medxcel Facilities Management
Legal Preparedness at the Intersection of Public Health and Healthcare

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Chenega Professional & Technical Services, LLC
Public Health Law Program
Office for State, Tribal, Local and Territorial Support

Disaster Preparedness: Here, There, and Everywhere for the ABA Health Law Section’s Public Health & Policy Interest Group
May 2, 2017
CDC’s Public Health Law Program (PHLP)

- What we do
  - Advance the use of law as a public health tool
- How we do it
  - Training and workforce development
  - Legal epidemiology
- Whom we serve
  - CDC programs and state, tribal, local, and territorial communities
  - You!
CDC–PHLP Disclaimer

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Always seek the advice of an attorney or other qualified professional with any questions you may have regarding a legal matter.
Presentation Overview

- Importance of legal preparedness for healthcare: potential sources of liability
- Public health investigations and implications for healthcare
- Liability protection for countermeasure distribution: the story of *Parker v. St. Lawrence* and the PREP Act
- Conclusion
Importance of legal preparedness for healthcare: potential sources of liability
Failure to Prepare as a Source of Potential Liability

- Cases suggest that failure to prepare for foreseeable public health threats and disasters could result in accusations of liability from:
  - Patients and the public
  - Employees of the health care facility
Preparedness Liability from Patients and the Public

Potential sources of liability:

- Duty to Plan and/or Comply with Plan
  - Husband v. Tenet Health Systems Mem'l Med. Ctr., Inc., 16 So. 3d 1220 (La. App. 4 Cir. 8/12/09)
    - Patients, family members, visitors, staff, and employees of Memorial Medical Center in New Orleans brought class action against the hospital for damages stemming from hospital evacuation after Hurricane Katrina
    - Holding:
      The Fourth Circuit of the Court of Appeals of Louisiana upheld trial court certification of the class because the allegation that the hospital’s failure to have a “sufficient emergency plan, negligently caused the injuries to the class members, all of whom were on [the hospital’s] premises during Hurricane Katrina and its aftermath” satisfied the commonality and typicality certification requirements.
Preparedness Liability from Patients and the Public

Potential sources of liability:

- Duty to Follow ICS
    - Widow of volunteer firefighter sued county and the fire control coordinator after her husband was killed in line of duty
  - Holding:
    New York State appellate court found the National Incident Management System-Incident Command System “may form the predicate for liability” under state law because it “‘mandates a reasonably defined and precedentially developed standard of care,’ and does not require the trier of fact to ‘second-guess [a firefighter's] split-second weighing of choices.’
Preparedness Liability from Patients and the Public

Potential sources of liability:

- **Americans with Disabilities Act (ADA)**
    - Court held city had violated state disability laws and the ADA for not considering persons with disabilities in city emergency plans
    - Jury found city had not adequately prepared for persons with disabilities in the city’s disaster response planning
Public health investigations and implications for healthcare
Disease Investigation

To control the spread of diseases, health authorities must determine who has been exposed

- *Where do public health authorities get power to investigate disease?*
Disease Investigation

State public health authority to investigate diseases can be broad:

  
  • “(a) The department shall investigate the causes of communicable disease and methods of prevention.
  
  • ...(c) The department may investigate the existence of communicable disease in the state to determine the nature and extent of the disease and to formulate and evaluate the control measures used to protect the public health. A person shall provide records and other information to the department on request according to the department's written instructions.”
Disease Investigation

This power can come with broad implementation authorities:

- Mandatory testing


    “(b) The secretary of health and environment is authorized to issue such orders and adopt rules and regulations as may be medically necessary and reasonable to prevent the spread and dissemination of diseases injurious to the public health, including but not limited to, providing for the testing for such diseases[.]”
Disease Investigation

This power can also include access to health information:

- Required disclosures under state disease investigation laws
  
  - *Md. Code Ann., Health General §18-904*

    “(b) [T]he Secretary may by order, directive, or regulation:
    (1) Require a health care provider or other person to report information to the Secretary or other public official [;]
    (2) Obtain access to information in the possession of a health care provider[;]
    (3) Require or authorize a health care provider to disclose information to an agency of the federal, State, or local government or another health care provider;”
How do required disclosures interact with patient privacy protections?

HIPAA privacy rule exception

- 45 C.F.R. § 164.512(b)(1). Uses and disclosures for which an authorization or opportunity to agree or object is not required.
  - A covered entity may use or disclose protected health information to:
  - “(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease...including, but not limited to, the reporting of disease... and the conduct of public health surveillance, public health investigations, and public health interventions;”

Per HHS guidance, covered entities may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the public health purpose

How do required disclosures interact with patient privacy protections?

Protection of disease investigation information

- Va. Code Ann. § 32.1-36(F)(2). Reports by physicians and laboratory directors
  
  “[A reportable disease] report submitted pursuant to this subsection shall be confidential and shall not be a public record pursuant to the [Virginia] Freedom of Information Act[.]

  The Department shall cooperate with and may share information submitted to it pursuant to this subsection with the United States Centers for Disease Control and Prevention, and state and federal law-enforcement agencies in any investigation involving the release, theft or loss of a dangerous microbe or pathogen required to be reported under this subsection.”

- “The Commissioner or his designee shall preserve the anonymity of each patient and practitioner of the healing arts whose records are examined[,] except that the Commissioner, in his sole discretion, may divulge the identity of such patients and practitioners if pertinent to an investigation, research or study. Any person to whom such identities are divulged shall preserve their anonymity.”
Liability protection for countermeasure distribution: the story of *Parker v. St. Lawrence* and the PREP Act
The 2009 H1N1 Influenza Outbreak

- Through CDC, HHS issued guidance for establishing School-Located Vaccination Clinics

School-Located Vaccination Planning Materials and Templates

September 13, 2009, 2:45 AM ET

These documents were designed to provide information for planning and conducting school-located 2009 H1N1 influenza vaccination clinics that target school-aged children enrolled in school and potentially other groups in the community. The targeted audience for these materials is primarily state and local public health department immunization and preparedness staff who are responsible for carrying out 2009 H1N1 influenza vaccination, but also education officials, school nurses, and others who are interested in planning and carrying out such activities.

School-Located 2009 H1N1 Influenza Vaccination (SLV): Information for Planners
The H1N1 Response in St. Lawrence County, NY

- On April 26, 2009, the New York State Department of Health informed the St. Lawrence County Department of Health that it would participate in a national program to distribute the H1N1 vaccine
  - The program included vaccinating students at local schools during the school day
To administer the vaccines, the St. Lawrence County Health Department hired 6 retired nurses to conduct the vaccinations at all of the elementary schools in the county.

Lisbon Central School’s vaccination clinic was scheduled for December 3, 2009.
The H1N1 Response in St. Lawrence County, NY

- Prior to the clinic, parents were sent consent and medical screening forms

<table>
<thead>
<tr>
<th>2009 H1N1 Influenza Vaccine Consent Form</th>
</tr>
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<tbody>
<tr>
<td><strong>Section 1: Information about Child to Receive Vaccine (please print)</strong></td>
</tr>
<tr>
<td><strong>STUDENT’S NAME</strong> (Last)</td>
</tr>
<tr>
<td><strong>PARENT/LEGAL GUARDIAN’S NAME</strong> (Last)</td>
</tr>
<tr>
<td><strong>ADDRESS</strong></td>
</tr>
<tr>
<td><strong>CITY</strong></td>
</tr>
<tr>
<td><strong>SCHOOL NAME</strong></td>
</tr>
</tbody>
</table>

| **Section 2: Screening for Vaccine Eligibility** |
| If your child has already been vaccinated with 2009 H1N1 influenza vaccine, please tell us the number of doses and dates of vaccination. |
| ☐ Dose 1 | Date received: month ____ day ____ year ______ | Form (please circle): nasal spray shot |
| ☐ Dose 2 | Date received: month ____ day ____ year ______ | Form (please circle): nasal spray shot |

The following questions will help us to know if your child can get the 2009 H1N1 influenza vaccine. Please mark YES or NO for each question.
The Vaccination of a Child at Lisbon Central School Without Consent

- Madison Parker:
  - 5-year-old girl at Lisbon Central School in St. Lawrence County, New York

- Madison’s mother, Jennifer, contacted her doctor to ask if it would be safe for Madison to receive the vaccine because of a recent illness and a chronic medical condition
  - Ultimately, the doctor advised against it, and the mother decided not to have her daughter vaccinated

- Madison’s mother declined to return the form
  - However, there was another girl named Madison in her grade, whose parents had provided a consent form
On December 3, 2009, the vaccination clinic at Lisbon Central School began operations.

The school nurse went to each class and called for the names of the children whose parents had provided the consent forms.

Madison Parker was escorted by the school nurse to the health department’s clinic at the nurse’s office and was vaccinated by a health department nurse.
The Lawsuit Against the School and Health Department

Apology letter from the superintendent sent to Madison’s parents:

Mr. and Mrs. Parker,

Please accept my sincere apology for the mishap that happened during the vaccination clinic. I can't imagine how angry you must be with all involved in the process. Madison is a terrific, sweet child. I feel horrible that she received the injection without your consent. I'll take full responsibility in the breakdown in the process. I have a 4 and 5-year-old, and I would have...
The Lawsuit Against the School and Health Department

- As a result, the mother sued the school for negligence and the health department for battery
  - Claims against school were dismissed
  - Health department claimed that it was immune under the Public Readiness and Emergency Preparedness Act of 2005

STATE OF NEW YORK
SUPREME COURT

JENNIFER J. PARKER as GUARDIAN and
NATURAL PARENT of MADISON J. PARKER

Plaintiff,

VS.

ST. LAWRENCE COUNTY PUBLIC HEALTH
DEPARTMENT and LISBON CENTRAL
SCHOOL

Defendants.

COUNTY OF ST. LAWRENCE

VERIFIED COMPLAINT
Index No.: 
What is the PREP Act?


- **Purpose:** authorizes the Secretary of HHS to issue a declaration that provides immunity against claims relating to use of covered countermeasures to respond to a present or future public health emergency

- **Goal:** facilitates cooperation of federal, state, and local governments and private entities in a coordinated response to public health emergencies
How does the PREP Act provide immunity?

- The PREP Act provides that
  - A covered person shall be immune from suit and liability
  - Under federal and state law
  - With respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of recommended countermeasures
How does the PREP Act provide immunity?

- What losses are covered by the immunity?
  - Any claim for loss that has a causal relationship with the administration to, or use by, an individual of a covered countermeasure, including any physical, mental, or emotional
    - Injury,
    - Illness,
    - Disability,
    - Condition, or
    - Fear of physical, mental, or emotional injury, illness, disability, or condition
The PREP Act provides immunity for all parts of countermeasure distribution activities

- The liability protections are not limited to the administration of a countermeasure
  - “The Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.”

- Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines
Who is covered by the PREP Act?

When issuing a PREP Act declaration, the Secretary will articulate who are included in “covered persons”

- According to the law, “covered persons” can include
  - Manufacturers
  - Distributors
  - Program planners (state, local, and tribal governments and others who supervise or administer countermeasure programs, including the private sector)
  - United States government
  - Qualified persons (licensed health professionals and others identified by the Secretary to prescribe, administer, or dispense countermeasures, including volunteers)
  - Officials, agents, and employees of the above
The “Sole Exception” to PREP Act Immunity

- The PREP Act provides immunity for all claims with one exception: willful misconduct
  - Meaning, you cannot be liable for anything except an act or omission that is
    - Intentionally designed to achieve a wrongful purpose and
    - Taken knowingly without legal or factual justification and
    - In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit
  - This is more stringent than negligence, gross negligence, or recklessness

- Burden is on plaintiff to show by clear and convincing evidence that willful misconduct caused death or serious physical injury
  - Only a 3-judge panel of the US District Court for the District of Columbia can hear the case
The Secretary issued a number of PREP Act declarations and amendments during the H1N1 response.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Pandemic Influenza Vaccines—Amendment**

**Authority:** 42 U.S.C. 247d–6d.

**ACTION:** Notice of first amendment to the June 15, 2009 Republished Declaration under the Public Readiness and Emergency Preparedness Act.

**SUMMARY:** Amendment to declaration issued on June 15, 2009 (74 FR 30294) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to provide targeted liability protections.

**Covered Persons:** As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms “manufacturer,” “distributor,” “program planner,” and “qualified person” are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

**Declaration of Emergency:** A
Back to the story of *Parker*…

- The trial court judge’s decision on July 5, 2009
  - Dismissed the claims against Lisbon Central School
  - Rejected St. Lawrence County Health Department’s claim of PREP Act immunity
- As a result, St. Lawrence County appealed and was joined by “friends” of the court:
  - The State of New York
  - The United States
The Outcome of *Parker v. St. Lawrence*

- The court ruled in favor of the St. Lawrence County Health Department and dismissed the case:
  - “[W]e must presume that Congress fully understood that errors in administering a vaccination program may have physical as well as emotional consequences, and determined that such potential tort liability must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency.”
  - “[T]he exclusive remedy under the statute is a federal cause of action to be brought in federal court, . . . the complaint must be dismissed for lack of subject matter jurisdiction.”
What has happened since the court ruling?

- Parker declined to appeal the case, and the statute of limitations for filing a willful misconduct claim in federal court has expired.
- The Secretary of HHS has issued many other PREP Act declarations including for countermeasures to the Ebola and Zika viruses.

- List of current PREP Act declarations can be found at [https://phe.gov/Preparedness/legal/prepact/Pages/default.aspx](https://phe.gov/Preparedness/legal/prepact/Pages/default.aspx)

**Current Declarations**

- Zika Virus Vaccines (effective February 10, 2017)
- Ebola Virus Disease Therapeutics (amended effective December 12, 2016)
- Ebola Virus Disease Vaccines (amended effective December 12, 2016)
- Pandemic Influenza Medical Countermeasures (amended effective January 1, 2016)
- Anthrax Medical Countermeasures (amended effective January 1, 2016)
- Acute Radiation Syndrome Medical Countermeasures (amended effective January 1, 2016)
- Botulinum Toxin Medical Countermeasures (amended effective January 1, 2016)
- Smallpox Medical Countermeasures (amended effective January 1, 2016)
Conclusions

- Based on past cases, preparing for emergencies is important for avoiding liability claims from patients, employees of a healthcare facility, and the public.

- Disease investigation is a fundamental public health action to detect and respond to emergencies, and a combination of federal and state law serve to ensure appropriate information sharing.

- PREP Act immunity can protect Points of Dispensing (PODs) from liability when distributing covered countermeasures to patients, employees, and the public.
For more information about PHLP, visit www.cdc.gov/phlp or email gsunshine@cdc.gov

Hospital Legal Preparedness: Relevant Resources

Hospitals are required by laws, regulations, and accreditation requirements to plan for disasters. Proposed regulations from the Centers for Medicare & Medicaid Services may have an effect on these requirements. Because law may impact all stages of emergency preparedness and response, it is a required consideration under the Joint Commission standard Leadership (LD) 04.01.01.04.01.07 [PDF 38.3KB]. Legal issues should be incorporated into hospital emergency planning. The following list, compiled by CDC's Public Health Law Program, can help hospitals incorporate law into emergency preparedness.

www.cdc.gov/phlp/publications/topic/hospital.html

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
A Corporate Community Approach to Disasters

Scott Cormier
Vice President

Emergency Management, Environment of Care and Safety
Resilience
Ascension Health Clinical Perspective

STATISTICS

Approximately 20% of Catholic Health Services in the U.S.

Number of Births <82k
ED Visits <2.6M
Outpatient Visits <21.8M
Surgical Visits – Outpatient <400k
Equivalent Discharges <1.5M

1,900 Sites of Care:
131 Hospitals
24 States and the District of Columbia

153k Associates
40k Affiliated Physicians

More than 21k Available Beds

Confidential. Do Not Distribute.
Corporate Community Approach

- All businesses and facilities are aligned and organized for a robust response to disasters

The function of professional care of causalities and sick people in catastrophic circumstances is the salvation and restoration of human resources to working capacity as rapidly and completely as possible.

-Excerpt from Main Osteopathic Hospital Emergency Management Plan, 1957.
Our Corporate Community

Corporate Office

Ministries

Data/Administrative Centers  Outpatient Centers  Physician Offices  Hospitals
Legal Implications

July 22, 2011 — A Louisiana judge Wednesday gave preliminary approval to a settlement of a class-action lawsuit in which Tenet agreed to pay $25 million to patients and visitors at Memorial Medical Center in New Orleans who died or sustained injuries during the aftermath of Hurricane Katrina in 2005.

Their lawsuit had accused the for-profit hospital company of failing to adequately prepare for such a catastrophe.
Management and Decision Making Process

- Goal: More hands on patients
- When hospital EOC activated, Ministry notified-POC
- Ministry sends notification to Corporate-POC
- Ministry coordinates response among local assets
  - Movement of patients, supplies, or staffing
- Ministry pushes requests to Corporate it cannot fulfill
  - Air assets, out of state movement of patients, disaster stockpile supplies
- Corporate assists in coordination of response and assists in decision making process
Business Continuity

• Business Impact Analysis performed
• Business Continuity Plans updated every 90 days
• Two exercises per year test restoration of services
• What is impact of electronic health records
  – From maps to GPS
## Estimated Savings Summary for Pre-Staging

### Hurricane Isaac 2012

<table>
<thead>
<tr>
<th>Location</th>
<th>Remediation</th>
<th>Savings from Pre-Staging</th>
<th>Construction</th>
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<td>Tulane - Lakeside</td>
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<td><strong>$3,021,000.00</strong></td>
<td><strong>$821,000.00</strong></td>
</tr>
</tbody>
</table>
2012 New England Compounding Center Recall

• Healthcare providers use compounding centers due to pharmaceutical shortages in main supply lines
  – Lasix
  – Atropine
  – Steroids

• A large provider in New England that supplied medications across the country had 3 infected lots of methylprednisolone
  – 75 facilities in 23 states
  – 720 ill
  – 48 deaths
Thank you for all you do in keeping our communities safe!

scott.cormier@medxcelfacilities.com