

What Hospitals Need to Do to Prepare for a Coronavirus Outbreak: Overview and Checklist

Public Health System Affinity Group of the Hospitals and Health Systems Practice Group • February 21, 2020

Delphine O'Rourke (Duane Morris LLP)





American Health Lawyers Association

© 2020 American Health Lawyers Association

1620 Eye Street, NW
6th Floor
Washington, DC 20006-4010
www.healthlawyers.org
info@healthlawyers.org
All rights reserved.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means—electronic, mechanical, photocopying, recording, or otherwise—without the express written permission of the publisher.

Printed in the U.S.A.

This publication is designed to provide accurate and authoritative information with respect to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

—From a declaration of the American Bar Association.

Overview

Since the first reports of the novel Coronavirus, images of patients waiting in endless lines for treatment, reports of shortages of essential protective equipment and accounts of gross breakdowns in infection control protocols have focused international attention on the tragic failure of China's hospitals to prepare for a disease outbreak.¹ American hospitals are on alert to prepare immediately for a potential outbreak in their facilities.

On January 31, 2020, Department of Health and Human Services (HHS) Secretary Alex Azar declared a public health emergency (PHE) for the U.S. to aid the health care community in responding to the Coronavirus (2019-nCoV)² retroactive to January 27, 2020. As part of a coordinated U.S. public health response amid growing fears in the U.S., Secretary Azar assured Americans that "[W]hile this virus poses a serious public health threat, the risk to the American public remains low at this time, and we are working to keep this risk low."³ Secretary Azar's announcement came the day after the World Health Organization declared a world health emergency as the confirmed Coronavirus cases passed 10,000 and spread outside of China.⁴ To date, there are no vaccines to protect against Coronavirus infection and limited data on the disease still prevents a complete understanding of its impact.⁵

While the disease itself may not be entirely understood, what is understood based on the Chinese experience is that lack of hospital preparedness in the event of a full scale outbreak in the U.S. could be disastrous. It is therefore not surprising that the Centers for Disease Control and Prevention (CDC) declared that "[a]ll U.S. hospitals should be prepared for the possible arrival of patients with Coronavirus Disease 2019 (COVID-19)."⁶

¹ *Coronavirus Overwhelms Hospitals in Wuhan, Videos Show*, NY TIMES, Jan. 23, 2020, Muvi Xiao, Christoph Koettl, Caroline Kim,

<https://www.nytimes.com/video/world/asia/100000006936419/coronavirus-china-wuhan.html>;

"What if We All Get Sick?" Coronavirus Strains China's Health System, NY TIMES, Jan. 27, 2020, Sui-Lee Wee <https://www.nytimes.com/2020/01/27/world/asia/27china-coronavirus-health.html>;

China Pledged to Build a New Hospital in 10 Days. It's Close, NY TIMES, Feb. 3, 2020, Amy Quinn

<https://www.nytimes.com/2020/02/03/world/asia/coronavirus-wuhan-hospital.html>.

² Coronavirus (2019-nCoV) Situation Summary, CDC, Feb. 16, 2020,

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

³ Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus, HHS, Jan. 31, 2020, <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>.

⁴ *W.H.O. Declares Global Emergency as Wuhan Coronavirus Spreads*, NY TIMES, Jan. 30, 2020, Sui-Lee Wee, Donald G. McNeil Jr. and Javier C. Hernandez,

<https://www.nytimes.com/2020/01/30/health/coronavirus-world-health-organization.html>.

⁵ *WHO Official Calls on 'Whole World' To Be On Alert For Coronavirus; Limited Data Hindering True Understanding of Outbreak's Impact, Experts Say*, Kaiser Family Foundation, Jan. 30, 2020, <https://www.kff.org/news-summary/who-official-calls-on-whole-world-to-be-on-alert-for-coronavirus-limited-data-hindering-true-understanding-of-outbreaks-impact-experts-say/>.

⁶ Novel Coronavirus (2019-nCoV) and You, Hospital Preparedness Assessment Tool, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hospital-preparedness-checklist.pdf>

Even though the vast majority of the over 2,000 deaths and 75,000 confirmed cases to date are still outside of the U.S.,⁷ the domestic cases are increasing and no American hospital can guarantee that it will not be at the epicenter of a domestic Coronavirus outbreak. Unlike an emergency that affects a community and its health care providers without warning and prior knowledge, U.S. hospitals currently have the advantage of time—while not unlimited—and increasing knowledge of the specific attributes of this potential pandemic. Therefore, public expectations of our hospitals' preparedness for a Coronavirus outbreak is higher and delays in preparation will create unnecessary risks to patients, providers, and the public. As recent history of U.S. disasters has taught us, the public holds hospitals to very high standards and is unforgiving of a lack of preparedness.

Potential unmitigated legal risks include, but are not limited to, violations of federal and state regulatory requirements, contract law claims, fraud and abuse exposure under the Stark Law and Anti-Kickback Statute, patient privacy and protected health information violations, criminal liability, professional malpractice liability, cyberattacks, and insurance disputes. Months and even years after an emergency is over and day-to-day operations have gone back to normal, hospital counsel will be handling the legal implications of the emergency.

U.S. hospitals are already subject to federal, state and local emergency prepared requirements. HHS has also established several preparedness initiatives. The Hospital Preparedness Program, for example, promotes sustained national focus on emergency preparedness to improve patient outcomes, minimize the need for supplemental federal and state resources during emergencies, and enable rapid recovery.⁸ The program is one of the only sources of funding for health care delivery system readiness.⁹

While participation in the Hospital Preparedness Program is voluntary, compliance with the Centers for Medicare & Medicaid Services' (CMS') Emergency Preparedness Rule (EP Rule) is mandatory.¹⁰ The EP Rule's requirements are Medicare Conditions of Participation, Conditions for Coverage, and Conditions for Certification that covered facilities—including most hospitals—must meet.¹¹

⁷ *Coronavirus death toll rises above 2,000 worldwide*, Ben Westcott, Adam Renton, Jack Guy and Ivana Kottasova, CNN, Feb. 19, 2020, <https://www.cnn.com/asia/live-news/coronavirus-outbreak-02-19-20-intl-hnk/index.html>.

⁸ <https://www.phe.gov/Preparedness/planning/hpp/pages/default.aspx>.

⁹ *Id.*

¹⁰ "Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers," Final Rule (81 Fed. Reg. 63860, Sept. 16, 2016). In a memorandum to State Survey Agency Directors dated February 1, 2019, CMS outlined several revisions and additions which were effective immediately to Appendix Z of the State Operations Manual as related to compliance with the Emergency Preparedness Rule.

¹¹ *Id.*

The EP Rule, in relevant part:

“[E]stablishes national emergency preparedness requirements for participating providers and certified suppliers to plan adequately for both natural and man-made disasters, and coordinate with Federal, state, tribal, regional and local emergency preparedness systems.”¹²

Since the EP Rule went into effect on November 16, 2016, hospitals have been required to review their emergency preparedness plan and update it at least annually. Hospitals are surveyed for compliance in conjunction with the existing survey process for health and safety compliance surveys or Life Safety Code (LSC) surveys.¹³ The Joint Commission certifies that the hospital’s plan follows an all hazards approach which is an “[i]ntegrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters.”¹⁴

A pandemic such as the Coronavirus falls squarely within the all hazards approach to emergency preparedness. And any integrated approach should include legal preparedness. While the CMS requirements touch on legal issues, they do not reflect the comprehensive review of potential risks necessary in advance of a widespread outbreak.

The checklist below is a starting point for hospitals to quickly prepare for a Coronavirus outbreak in close coordination with each facility’s legal team:¹⁵

¹² See <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule>; “The Final Rule (81 FR 63860, Sept. 16, 2016) assists providers and suppliers to adequately prepare to meet the needs of patients, clients, residents, and participants during disasters and emergency situations, striving to provide consistent requirements across provider and supplier-types, with some variations. Healthcare organizations that receive Medicare or Medicaid must follow Emergency Preparedness regulations in order to participate (aka Conditions of Participation (CoP)).” <https://www.jointcommission.org/resources/patient-safety-topics/emergency-management/>.

¹³42 C.F.R. Section 482.15: Condition of Participation: Emergency Preparedness, <https://www.law.cornell.edu/cfr/text/42/482.15>.

¹⁴ See <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/FAQ-Round-Four-Definitions.pdf>. The EM Standards require hospitals to regularly test their emergency preparedness plans and also monitors (1) adequate communication, supplies and security; (2) clear staff roles and responsibilities; (3) utility self-sufficiency; and (4) clinical activity that maintains care and supports vulnerable populations.

¹⁵ The checklist is not intended to serve as legal advice and should not be relied upon as legal counsel. Hospitals should consult with their legal teams.

Rapid Legal Preparation Checklist

- Pull out your Emergency Preparedness Plan, update it to include a Coronavirus outbreak
- Test it now!

Communications

- Pre outbreak media strategy including preparedness for community and patients
- Pre and post content for traditional and social media outlets
- Prepared statements
- Protecting Patient Health Information in communications
- All communications should be reviewed by legal counsel before the emergency!

Privacy

- Ensure that PHI is only disclosed to lawful recipients in order to advance public health activities connected to Coronavirus outbreak
- Ensure that shared PHI is only sent securely (i.e., encryption)
- Determine whether disclosure of PHI is necessary for treatment of a sick patient or other patients (e.g., coordinating or managing services between providers, consultation between providers, and referral of patients for treatment)
- Check health care proxies for written direction from patient to identify individuals with whom PHI may be shared beyond family members, relatives, and friends
- Put protections in place to prevent access by employees tempted to access records for patients being treated for high profile diseases
- Consider monitoring who is accessing records
- Use of a “break the glass” feature if included in EHR system to prevent unauthorized access
- Remind employees of policies surrounding access to patient records

Key Supplies and Services

- Emergency response team to identify all key supplies and services that will be critical in the event of a Coronavirus outbreak
- Inventory that you have contracts in place for all key supplies and services
- Immediately address any contractual gaps identified
- Assemble/draft templates for services that you may need i.e. cots for families, transfer agreements, coalition agreements, limited services agreements with physicians, etc.
- Due diligence your contracts for terms that will be critical during a Coronavirus outbreak

Provider Issues: Physicians and Allied Professionals

- *Contracts*
 - Employed physicians – language regarding emergency services Independent contractors – emergency services
 - No contracts – template agreements
 - Standard call coverage agreement to cover emergency and short notice coverage
 - Fraud and abuse relief – Social Security Act §1135 Waiver
- *Insurance*
 - Scope of professional liability insurance
 - Policy provisions for emergencies
 - Process to add providers
 - Other, as applicable
- *Credentialing*
 - Medical Staff Bylaws regarding scope of credentialing for physicians who are already credentialed – emergency provisions
 - Emergency credentialing for physicians who were not pre-credentialed
- *Telemedicine providers*
 - Contracts
 - Licensure in state in where your facility is located
 - Licensure in state where patient is located if not the same as your facility
 - Provider-patient relationship – can it be established remotely?
 - Consent
 - Documentation
 - Reimbursement

Due Diligence Checklist for Critical Contract Terms

- Emergency specific language
- Flow through requirements
- *Force majeure*
- Standard (impractical, impossible, illegal)
- Business continuity or contingency plans (show facility)
- Exculpatory Clauses
- Non-exclusivity
- Surge requirements
- Length of emergency
- Indemnification
- Notice
- Name and contact information for vendors and legal counsel
- Other, as applicable

- Scope: is a Coronavirus outbreak covered by language regarding Acts of God, specifically listed events, catch all phrases, excluded events or anticipated events?
- Which party bears the risk of a Coronavirus outbreak?
- Consequences of the force majeure event?
- Flow through requirements?
- Liquidated damages?
- Continued payment?
- Other related documents/contracts?
- Termination for extended force majeure?

Negotiate the Gaps

- In force during emergency preparedness plan duration
- Negotiate new contracts – either for execution or for preparedness
- Templates for emergency supplies and services
- Amendments that can be broadly applied
- Call coverage agreements and short notice coverage
- Temporary agreements
- In force during emergency preparedness plan duration
- Negotiate new contracts – either for execution or for preparedness
- Templates for emergency supplies and services
- Amendments that can be broadly applied
- Call coverage agreements and short notice coverage
- Temporary agreements
- Draft notice to insurance carriers
- Draft notice to vendors
- Draft notice to suppliers
- Standing work orders
- Transfer agreements
- Emergency credentialing requests
- Telemedicine services agreements
- Other, as applicable

Establish Your Authority Matrix

- Authority
- Negotiation
- Signatory
- Other

Identify Your Emergency Legal Partners

- Legal lead during emergency 24/7
- Schedule and contact info for legal department based on travel, availability, health conditions etc.

- Emergency preparedness point of contact to partner with legal
- Partner with legal counsel for other facilities before the emergency occurs
- Outreach to regulatory agency legal counsel
- Outreach to law enforcement legal departments
- Identify outside counsel and engage prior to emergency
- The court of public opinion
- Social media
- Power of images
- Lack of preparedness

Although the wave of Coronavirus infection is approaching the U.S., there is still time to ensure that your hospital is prepared for the Coronavirus if you act now.