COVID-19: PRACTICAL AND LEGAL IMPLICATIONS OF CORONAVIRUS OUTBREAK FOR HEALTHCARE PROVIDERS

Date: 9 March 2020

U.S. Health Care Alert

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The respiratory disease caused by a novel coronavirus was first detected in China and has now been detected in almost 70 locations internationally, including in the United States. The virus has been named "SARS-CoV-2" and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19"). Patients with COVID-19 have experienced mild to severe respiratory illness, and symptoms can include fever, cough, and shortness of breath. Globally, the mortality rate has recently been estimated at 3.4%.[1] The virus seems to be spreading easily and sustainably in the community and is thought to spread from (i) person-to-person contact and (ii) contact with infected surfaces or objects.

To combat the virus, on March 4, 2020, the U.S. House voted 415-2 to approve an $8.3 billion emergency spending bill to combat the coronavirus, sending the legislation to the Senate, which could act expeditiously. The bill would allocate funding "to address nearly every aspect of the outbreak, from vaccine research and development, to support for state and local public health agencies, to medical supplies and preparation at home and abroad."[2]

Spearheading that fight will be U.S. healthcare providers. While healthcare providers and the U.S. public health system has been designed to support the care of highly infectious diseases, COVID-19 will likely offer unique challenges as hospitals, skilled nursing facilities, and other healthcare providers implement their standard infectious disease protocols on potentially an expanded scale while in the midst of also managing the disease's impact on their own work force, operations, and supply chain. While the ultimate path of the disease and impact remains unknown, this alert provides a snap shot of key guidance issued to date to U.S. healthcare providers related to managing COVID-19 and outlines key legal issues that are likely to arise for which healthcare providers should be planning.

In addition to the guidance specific to health care provided below, see other K&L Gates thought leadership content on COVID-19 at our website.

1. PRACTICAL IMPLICATIONS

In a series of guidance documents released over the past few weeks, the Centers for Disease Control ("CDC") has provided advice to providers on how to manage patient care and employee issues related to COVID-19.

Guidance for Patient Care Settings: On February 29, 2020, the CDC issued updated interim guidance for managing COVID-19 for outpatient departments and physician offices, inpatient facilities and long-term care facilities. The CDC urged healthcare facilities to begin planning and designating staff members who will be

responsible for caring for suspected COVID-19 patients.[3] When possible, the CDC first recommends that healthcare facilities manage mildly ill COVID-19 patients in the patient's home.[4] In regard to patient care settings, the CDC then advised as follows:

- **Outpatient departments and physician offices**[5]
  - Reschedule non-urgent outpatient visits as necessary.
  - Consider reaching out to patients who may be a higher risk of COVID-19-related complications to ensure adherence to current medications and therapeutic regimens, confirm they have sufficient medication refills, and provide instructions to notify their provider by phone if they become ill.
  - Consider accelerating the timing of high priority screening and intervention needs for the short-term, in anticipation of the possible need to manage an influx of COVID-19 patients in the weeks to come.
  - Symptomatic patients who need to be seen in a clinical setting should be asked to call before they leave home, so staff are ready to receive them using appropriate infection control practices and personal protective equipment.
  - Eliminate patient penalties for cancellations and missed appointments related to respiratory illness.
- **Inpatient facilities**[6]
  - Reschedule elective surgeries as necessary.
  - Shift elective urgent inpatient diagnostic and surgical procedures to outpatient settings, when feasible.
  - Limit visitors to COVID-19 patients.
  - Plan for a surge of critically ill patients and identify additional space to care for these patients.
- **Long-term care facilities**[7]
  - Limit visitors to the facility.
  - Post visual alerts (signs, posters) at entrances and in strategic places providing instruction on hand hygiene, respiratory hygiene, and cough etiquette.
  - Ensure supplies are available (tissues, waste receptacles, alcohol-based hand sanitizer).
  - Take steps to prevent known or suspected COVID-19 patients from exposing other patients.
  - Limit the movement of COVID-19 patients (e.g., have them remain in their room).
  - Identify dedicated staff to care for COVID-19 patients.
  - Observe newly arriving patients/residents for development of respiratory symptoms.

Guidance Related to Healthcare Workforce: The CDC also issued guidance on February 16, 2020, with ways in which healthcare personnel can protect themselves in caring for patients with suspected or confirmed cases of COVID-19. In particular, the CDC recommended that healthcare personnel can protect themselves by:

- Assessing and triaging these patients with acute respiratory symptoms and risk factors for COVID-19,
- Using Standard Precautions, Contact Precautions, and Airborne Precautions and eye protection when caring for patients with possible COVID-19,
- Performing effective hand hygiene, and (iv) properly using personal protective equipment.[8] The CDC recommends that healthcare personnel caring for patients with confirmed or suspected COVID-19 should adhere to the CDC's recommendations for infection prevention and control.[9]

In In regard to training the workforce, the CDC recommends that facilities follow existing protocols to ensure that healthcare personnel:

- Are provided with specific training on preventing transmission of infectious agents,
- Medically cleared, trained, and fit tested for respiratory protection device use, and
- Educated, trained, and have an understanding of the appropriate use of personal protective equipment.[10]

The CDC also recommended that healthcare personnel should comply with the healthcare facility's policy on placing signage on patient's doors that indicate the presence of an infectious disease. To the extent feasible, the CDC recommends that healthcare facilities should also consider designing and installing engineering controls to reduce exposures by shielding healthcare personnel from infected individuals.[11]

Develop a Rapid Response Outbreak Management Team: From a practical perspective, consider activating a cross-disciplinary team to act as a command center that can manage tracking and responding to COVID-19 developments in the facility and the community. Most institutional providers should already have policies in place that will address the process and the composition of the team. While COVID-19 may have unique challenges, providers should consult existing policies as a threshold matter.

II. LEGAL IMPLICATIONS

HIPAA. The Office for Civil Rights of the U.S. Department of Health and Human Services published a bulletin reminding Health Insurance Portability and Accountability Act ("HIPAA") covered entities and business associates that the HIPAA Privacy and Security Rules continue to apply during an emergency, including an outbreak of an infectious disease. The bulletin describes some permitted uses and disclosures of protected health information ("PHI") under the HIPAA Privacy Rule:

- The HIPAA Privacy Rule generally permits covered entities to disclose needed PHI without individual authorization to (i) a public health authority, (ii) at the direction of a public health authority, to a foreign government agency that is acting in collaboration with the public health authority, and (iii) to a person at risk of contracting or spreading a disease or condition if other law authorizes the disclosure.
- In general, HIPAA allows (i) disclosures of PHI to family, friends, and others involved in an individual's care and (ii) disclosures of PHI to prevent a serious and imminent threat to the health and safety of a person or the public.

With this said, it is important to remember in this context that:

- Other than uses and disclosures for treatment purposes, the Privacy Rule generally requires a covered entity or business associate to make reasonable efforts to limit the use or disclosure of PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.
- **Reporting to the media or the public at large about an identifiable patient**, or the disclosure to the public or media of specific information about treatment of an identifiable patient, such as their COVID-19 status, **generally may not be done without the patient's written authorization**.[12]

This bulletin only addresses HIPAA. Healthcare providers should be aware that more stringent federal and state laws may further limit uses and disclosures of patient identifying information, particularly in the context of infectious disease.

CMS Response. In response to COVID-19, healthcare facilities should generally follow their established protocol for infectious diseases and consider adding any COVID-19 requirements as needed. In this regard, on March 4, 2020, CMS issued a "call to action to health care providers across the country to ensure they are implementing their infection control procedures," which CMS notes are required to maintain at all times.[13]

At the same time, CMS announced that until further notice it will suspend non-emergency inspections and will focus their facility inspections in an order of priority, focusing primarily on issues related to infection control and other serious health and safety threats, such as allegations of abuse.[14] CMS has provided guidance describing the circumstances under which it will authorize an on-site survey/investigation of a facility with persons who are known or suspected of being COVID-19 positive.[15] CMS has indicated it will be posting updated FAQs in real-time at the following website: https://www.cms.gov/medicare/quality-safety-oversight-generalinformation/coronavirus.

The emergency spending bill noted above, also includes a provision that would waive Medicare's geographical restrictions on telehealth during a public health emergency as a further means to combat COVID-19.[16]

Last month, CMS developed the first COVID-19-focused Healthcare Common Procedure Coding System ("HCPCS") code (U0001), which is used specifically for CDC testing laboratories to test patients for SARS-CoV-2.[17] On March 5, 2020, CMS developed the second HCPCS billing code (U0002) focused on COVID-19, which allows laboratories to bill for non-CDC laboratory tests for SARS-CoV-2 (COVID-19).[18] The Medicare claims processing systems will be able to accept these codes starting on April 1, 2020, for dates of service on or after February 4, 2020.[19]

State Responses: Given how easily COVID-19 is spread and the sensitivity associated with handling COVID-19, state departments of health will likely assume full control of the situation if a patient is suspected to be infected with COVID-19, and the state health department should begin interacting directly with the patient, the patient's family, and others that may have been in contact with the patient. According to CDC guidance, as COVID-19 spreads into a healthcare facility's community, the healthcare facility should prepare to work with local and state public health organizations, healthcare coalitions, and other local partners to understand the spread of the outbreak.[20]

Many states have begun posting COVID-19 resources on their state websites. Other states have begun responding to outbreaks of COVID-19 within their state with more forceful responses. For example, both Washington and California have declared states of emergency and both governors noted that the declaration of an emergency will allow their states to procure supplies and resources quicker.[21] California has also posted

links to helpful resources and information reminding certain employers that the California "Aerosol Transmissible Disease standard" contains requirements for protecting employees from disease and pathogens that are transmitted by aerosols, which includes COVID-19.[22]

Likewise, in North Carolina, the Department of Health and Human Services ("NCDHHS") recently published a memorandum on COVID-19, which provided the following relevant guidance: (i) clinicians in North Carolina are encouraged to screen for possible COVID-19 infection; (ii) physicians and laboratories in North Carolina are required to immediately report to NCDHHS when a patient is reasonably suspected to be infected with COVID-19; and (iii) any cluster of severe acute respiratory illness in healthcare workers should prompt immediate notification of local or state public health entities.[23] NCDHHS has also published "interim healthcare setting guidance" for patients with suspected COVID-19 infections and their healthcare workers that provides general advice and recommendations on how to manage infected patients.[24]

Finally, COVID-19 meets the definition for "severe acute respiratory syndromes" and, therefore, is a federally quarantinable communicable disease.[25] If a quarantinable disease is suspected or identified, the CDC may issue a federal isolation or quarantine order.[26]

Risk Management. Hospitals and other providers with an organized risk management function should be proactive and begin assessing the facility's or provider's risk exposure associated with COVID-19. Some questions to ask include the following:

- Can the provider handle a significant increase in patient load;
- Is the clinical staff informed on symptoms and notification procedures;
- Is the clinical staff and other workforce members trained on COVID-19 specific protocols and are education materials easily accessible;
- Does the provider have enough personal protective equipment, likely needed supplies and equipment and plan for managing/segregating affected patients;
- Is the provider prepared for any major disruption in the supply chain or distribution outlets;
- Is the workforce trained on what to do when they feel they have been exposed or experience symptoms;
- Does the provider have a policy for what to do if an employee has traveled through a high-risk area;
- Has the provider explored unintended consequences that may result from any major, local COVID-19 outbreak within the community as well as coordination strategies with other providers or resources; and
- Has the provider assessed the risk to business interruption and insurance coverage as related to a local outbreak of COVID-19?

Investigations and Outbreak Management. In particular, risk managers should be focused on preparing for the investigation (e.g., validating and verifying the accuracy of laboratory results) and the organization's response. Infectious disease specialists ("Infection Control") within or available to the provider should serve as lead investigators and notify leadership and risk managers of the investigation. A preliminary investigation to confirm the existence of an outbreak should be conducted. Notification to the state health department should simultaneously occur. Upon declaration of an outbreak, Infection Control should convene an outbreak

management team with leadership and risk management, who are responsible for communicating to team members, carrying out designated interventions, and providing requested information during the outbreak. The core members of the team should include members of the following: Infection Control, administration, department leadership, nursing leadership, physician leaders of affected services, risk management, public relations, occupational health, facilities services, and public health epidemiologist. Next, providers under the direction of state public health officials should characterize the outbreak to determine who may be at risk and who should be included in further investigation. The outbreak team should consider and make recommendations meant to minimize, to the extent possible, the outbreak so that normal operations can resume as reasonably possible.

Supply Chain. Provider should review important contracts to determine whether the force majeure clause could be triggered by COVID-19. When entering into new agreements, provider should consider how COVID-19 may impact the performance obligations of the parties and consider including a provision related to pandemics/epidemics. Planning as to how the facility's supply chain will be impacted is important, since part of a typical supply chain will rely on businesses in countries that are having major COVID-19 outbreaks. Providers should assess ways in which supply chain interruption may in particular lead to possible drug shortages, including ways to pivot to any short-term supply chain alternatives to satisfy key needs that may be at risk of disruption. Proactive discussions with key vendors regarding supply chain disruption may be appropriate.

NEXT STEPS

K&L Gates will continue to closely monitor COVID-19 updates and the guidance published by relevant authorities related to COVID-19. K&L Gates will be providing additional analysis and thought leadership content on COVID-19 and its potential impact as important developments occur.

For additional information, please contact Mary Beth Johnston or send an email directly to our COVID-19 Task Force.

IMPORTANT LINKS:

CMS, Guidance for Infection Control and Prevention Concerning Coronavirus Disease (COVID-19): FAQs and Considerations for Patient Triage, Placement and Hospital Discharge, available at https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf

CMS, Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes, available at https://www.cms.gov/files/document/qso-20-14-nhpdf.pdf

CMS, Suspension of Survey Activities, available at https://www.cms.gov/files/document/qso-20-12-allpdf.pdf-1

Office of Civil Rights, BULLETIN: HIPAA Privacy and Novel Coronavirus, available at https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf

CDC, Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

CDC, homepage for Coronavirus Disease 2019 (COVID-19) updates, available at https://www.cdc.gov/coronavirus/2019-ncov/index.html

CDC, Coronavirus Disease 2019 (COVID-19) Situation Summary, available at https://www.cdc.gov/coronavirus/2019-ncov/summary.html

CDC, What Healthcare Personnel Should Know, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-patients.html

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[1] World Health Organization, WHO Director-General's opening remarks at the media briefing on COVID-19 - 3 March 2020, available at https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---3-march-2020

[2] Washington Post, "House Passes $8.3 Billion Emergency Spending Package to Respond to Coronavirus Outbreak," available at https://www.washingtonpost.com/us-policy/2020/03/04/congress-coronavirus-emergency-spending/

[3] CDC, Interim Guidance for Healthcare Facilities, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

[4] CDC, Interim Guidance for Healthcare Facilities, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

[5] CDC, Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

[6] CDC, Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

[7] CDC, Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF), available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html

[8] CDC, What Healthcare Personnel Should Know, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-patients.html

[9] CDC, What Healthcare Personnel Should Know, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-patients.html

[10] CDC, Interim Infection Prevention and Control Recommendations, available at https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html

[11] CDC, Interim Infection Prevention and Control Recommendations, available at https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html

[12] Office of Civil Rights, BULLETIN: HIPAA Privacy and Novel Coronavirus, available at https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf

[13] CMS, CMS Announces Actions to Address Spread of Coronavirus, available at https://www.cms.gov/newsroom/press-releases/cms-announces-actions-address-spread-coronavirus

[14] CMS, Suspension of Survey Activities, available at https://www.cms.gov/files/document/qso-20-12-allpdf.pdf-1

[15] CMS, Memorandum re: Suspension of Survey Activities, available at https://www.cms.gov/files/document/qso-20-12-allpdf.pdf-1

[16] Washington Post, "House Passes $8.3 Billion Emergency Spending Package to Respond to Coronavirus Outbreak," available at https://www.washingtonpost.com/us-policy/2020/03/04/congress-coronavirus-emergency-spending/

[17] CMS, CMS Develops Additional Code for Coronavirus Lab Tests, available at https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests

[18] CMS, CMS Develops Additional Code for Coronavirus Lab Tests, available at https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests

[19] CMS, CMS Develops Additional Code for Coronavirus Lab Tests, available at https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests

[20] CDC, Interim Guidance for Healthcare Facilities, available at https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html

[21] Washington Governor's Office, Inslee issues COVID-19 emergency proclamation, available at https://www.governor.wa.gov/news-media/inslee-issues-covid-19-emergency-proclamation; KPBS, California Declares Emergency After 1st Coronavirus Death, available at https://www.kpbs.org/news/2020/mar/05/california-declares-statewide-emergency-coronaviru/

[22] State of California Department of Industrial Relations, Interim Guidance for Protecting Health Care Workers from Exposure to 2019 Novel Coronavirus (2019-nCoV), available at https://www.dir.ca.gov/dosh/Coronavirus-info.html

[23] NCDHHS, Memorandum re: Coronavirus 2019, available at https://epi.dph.ncdhhs.gov/cd/coronavirus/COVID-19_Provider%20Guidance_030220_FINAL.pdf

[24] NCDHHS, Interim Healthcare Setting Guidance for Patients with Suspected or Confirmed 2019 Novel Coronavirus (2019-nCoV) Infection and Their Healthcare Providers, available at https://epi.dph.ncdhhs.gov/cd/coronavirus/_Interim%20Guidance%20for%20Healthcare%20Settings.pdf?ver=1.4

[25] CDC, Coronavirus Disease 2019 (COVID-19) Risk Assessment and Management, available at https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html

[26] CDC, Legal Authorities for Isolation and Quarantine, available at https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html

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