COVID-19: HEALTH CARE IN TRANSITION: RE-OPENING FOR NON-COVID-19 RELATED CARE

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U.S. Health Care Alert

Recently, the dialogue surrounding the coronavirus pandemic has shifted focus to the reopening of communities that have been shut down over the past few months. The discussion around this reopening has extended to health care facilities that, during the initial response to the pandemic, state and federal agencies had directed to limit their services to essential care and to prepare for an influx of COVID-19 patients.[1] The economic impact of halting elective procedures has been significant, with the American Hospital Association estimating that there will be $206 billion dollars in attributable losses for hospital and health systems between1 March 2020 and 30 June 2020.[2] Reopening service lines and facilities requires consideration of numerous operational and legal issues. Additionally, facilities and providers must coordinate their approach with state and local health and governmental authorities, as well as engage in a comprehensive communication strategy so that that those individuals who have been delaying necessary care feel safe to seek services. Establishing clinically based protocols for the return of the broader, health care workforce for their protection and the protection of patients is also an additional challenge for the health care industry. This alert highlights these key operational and legal considerations and reviews the dynamic regulatory and liability landscape surrounding health care facilities' efforts to reopen.

GUIDANCE FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

On 19 April 2020, the Centers for Medicare and Medicaid Services (CMS) released guidance entitled “Recommendations [for] Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I.”[3] The document advises facilities on reopening service lines, such as chronic disease care, surgical procedures, and preventive care, that were previously deemed “non-essential” by CMS in guidance released on 18 March 2020.[4] The guidance is targeted to entities located in areas demonstrating “low, or relatively low and stable incidence of COVID-19” and is tied to the Gating Criteria released by the White House.[5]

CMS stressed that facilities should prioritize surgical care and high-complexity chronic disease management when deciding what service lines to reopen, while also recognizing that certain preventive care may be a high priority.

With regard to the physical environment, CMS suggests facilities may consider establishing “Non-COVID-19 Care (NCC) zones” that would provide this non-COVID-19 related care while still screening all patients for COVID-19 symptoms. If possible, CMS urges that these areas be in a “separate building or designated room or floor with a separate entrance and minimal crossover with COVID-19 areas” and that social distancing in common areas should be implemented. Facilities should also be mindful of the physical environment and capacity when scheduling appointments, aim to minimize waiting times, and continue to prohibit visitors unless necessary for an aspect of care. Notably, the resumption of regular visitors to hospitals is not contemplated until Phase 3 of the

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White House Gating Criteria. While the aim of the guidance is at the reopening of facilities so that necessary care can be provided in person, CMS emphasized that telehealth should continue to be used to the maximum extent possible for those services that can be provided via this modality. Lastly, facilities must have sanitation protocols to keep all areas clean and disinfected. At hospitals in particular, sterilization and cleaning protocols, including the use of newer technologies, such as pulsed UV disinfecting robots, as well as their specially trained, environmental service professionals are key elements of any reopening strategy.

In addition to evaluating the incidence of COVID-19 in the state or region, CMS also stressed that the adequacy of testing and supplies should be assessed when deciding to reopen. This assessment includes an adequate supply of personal protective equipment (PPE), including surgical facemasks; yet, the guidance also states that PPE should be conserved, when possible, in line with Centers for Disease Control and Prevention guidance.[6]

As a result, approaches will differ by region, type of health care facility, and the clinical judgments of local health care experts. It cannot be over-emphasized that testing capability is likely the most critical component of any reopening plan. For instance, non-emergency, surgery patients may undergo a COVID-19 screening and test (often 48 hours) prior to their procedure. While awaiting test results prior to the surgical procedure, patients will be asked to isolate, monitor their temperatures, and wear a provided mask in addition to following any other pre-procedure instructions. If the COVID-19 test comes back negative, the procedure will proceed. If the test comes back positive, the patient will be informed and their primary care physician will be contacted for further monitoring and care. The surgical procedure will be canceled.

Importantly, the ability to reopen these services is also dependent on the availability of the workforce across the spectrum of care. CMS recommends that staff be assigned to either a NCC zone or to COVID-19 care areas and should not cross between the two. Recommendations also include routinely screening the workforce for symptoms of COVID-19 as well as testing and requiring the quarantine of workers, if infected. It is important to note that the Americans with Disabilities Act (ADA) is implicated in any decision to medically track or test health care employees. The ADA permits employers to require employees to undergo medical examinations but only if they are job related and consistent with business necessity.[7] COVID-19 testing and even temperature tracking would be considered a medical examination. As a result, for an employer to require such tests and tracking, it must have a reasonable belief based on objective evidence that the medical condition (1) will affect the employee's ability to perform essential functions of his or her job or (2) poses a threat to the safety of themselves or others.[8] Consequently, the legal analysis and risk of testing or other medical examination requirements may differ among frontline health care professionals and other employee categories, and also may change as the COVID-19 crisis abates. Moreover, health care providers, which are thoroughly familiar with HIPAA privacy requirements, may be less cognizant of the additional restrictions surrounding the use of confidential employee medical record information under the ADA.[9] In this context, the lines between their role as employer and provider may be inappropriately blurred given the highly contagious nature of COVID-19 and their natural desire to want to protect patients and co-workers. Furthermore, the guidance issued by the Equal Employment Opportunity Commission, the agency charged with enforcing the ADA, has evolved since the pandemic began and employers must adapt to this dynamic regulatory landscape.[10]

STATE GUIDANCE

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States have also been issuing guidance on reopening facilities with additional criteria beyond that suggested by CMS, including some that is mandatory and more stringent. While only binding on facilities within those states, such guidance may nevertheless provide insight and direction to all facilities on reopening procedures. Ohio, for example, requires facilities to have a plan to allow for the equitable provision of services, including recognizing "the social determinants of health and the disproportionate impact of COVID-19 on minority populations."[11] With regard to visitor policies, Pennsylvania's guidance encourages facilities to allow for visitors during labor and delivery and for pediatric patients and those with intellectual or developmental disabilities or cognitive impairments, such as dementia.[12]

Additionally, state medical societies and health care associations have issued guidance on reopening procedures. The North Carolina Healthcare Association and North Carolina Medical Society released a joint white paper on reopening that, in addition to reiterating CMS guidance, stresses that prior to any procedure, patients should be provided with a justification for why the procedure is necessary, including an evaluation of the risks versus the benefits and that this justification should be documented in the patient's chart.[13] The California Medical Association's guidance recognizes the need for reopening to be "inclusive of different practice sizes and settings" and suggests that physician practices may be inundated with patients who have delayed care over the previous months.[14] Therefore, community coordination across the spectrum of provider types will be necessary to successfully reopen care in a region or state. In deciding the types of care that should be reopened and their sequence, the California guidance not only suggests evaluating need, such as critical care, but the risk status of the patient, such as lower-risk pediatric patients.

Every facility must consult their own state guidance to ensure compliance with all rules and reporting requirements.

ADDITIONAL GUIDANCE

On 17 April 2020, the American College of Surgeons, American Society of Anesthesiologists, Association of periOperative Registered Nurses, and American Hospital Association released a document entitled a "Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic" (the "Joint Statement").[15] The Joint Statement provides a list of principles and considerations for reopening including timing, testing, and the adequacy of PPE. Additionally, the guidance recommends that facilities adopt a number of policies to address and standardize the process for numerous situations and scenarios. This includes establishing a Prioritization Policy Committee to develop a strategy for the selection of service lines to reopen and that such committee should account for previously cancelled cases, have an objective priority scoring tool, select specialties that are higher priority due to risk of postponement such as cancer and cardiac procedures, allot for and increase operating room/procedural time, and address workforce needs, among other topics. It also suggested that facilities adopt policies across the five phases of surgical care relating to the postponement of scheduling. Facilities should also adopt and reevaluate policies regarding data collection and management so that they may assess COVID-19 case numbers, bed capacity, ventilator and PPE availability, and quality of care metrics. With regard to testing, the guidance suggests adopting a policy that addresses responding to a "COVID-19 positive worker, [a] COVID-19 positive patient (identified preoperative, identified postoperative), [a] person under investigation (PUI) worker, and [a] PUI patient."

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The American College of Surgeons has independently released guidance for the triage, management, and resumption of non-emergent surgical procedures and suggests that facilities adopt the Elective Surgery Acuity Scale (ESAS) developed by St. Louis University to aid in decision making.[16] CMS also put forth a modified version of the ESAS in their initial guidance for limiting elective surgeries during the initial COVID-19 response period.[17]

The Children's Hospital Association (CHA) released a document on 1 May 2020 entitled “Guidance for Pediatric Patient Care Reengagement,” which incorporates the guidance released by CMS and the White House into a pediatric framework.[18] Importantly, CHA notes that pediatric care, including surgical and diagnostic procedures, are rarely elective and that delays in care for children may result in long-term health consequences. Moreover, the guidance stresses the need for pre-operative testing since most children with COVID-19 are asymptomatic or have a mild variation of the disease. Echoing the guidance released by Pennsylvania, the document stresses that visitor policies should be flexible to allow for parents and guardians of pediatric patients to accompany them.

SECOND WAVE OF COVID-19 INFECTIONS

Each of the above-referenced guidance also discusses the need to plan for another surge—or a “second wave”—of COVID-19 infections, whether attributable to relaxed social distancing guidelines or a resurgence of cases in the fall and winter of 2020. With regard to the workforce, CMS stated that “staffing levels in the community must remain adequate to cover a potential surge in COVID-19 cases.”[19] Ohio's guidance also emphasized that facilities must evaluate their supply chains for both reopening and “to respond to an unexpected surge of COVID-19 patients.”[20] More bluntly, the California Medical Association's guidance stated that “[a] key consideration when assessing health system capacity is *the very likely resurgence of the disease*.”[21] The Joint Statement also addresses this concern for resurgence with a section entitled “COVID-related Safety and Risk Mitigation surrounding Second Wave,” which encourages the adoption of social distancing policies for staff, patients, and visitors that are responsive to the “then-current local and national recommendations.”

Facilities must also recognize that their surge capacity may be directly tied to the ability of the larger to community to relax social distancing and stay-at-home orders. For example, for rural areas in Texas, occupancy limits at businesses will decrease from 50 percent to 25 percent of their listed capacity if “less than 15% of the surge capacity in hospitals for the catchment area is available.”[22]

Therefore, it is incumbent on facilities to simultaneously plan for both a reopening of their facility and a future need to re-implement restrictions and, thus, facilities should evaluate any recent processes used to restrict service lines and update or adapt accordingly.

LIABILITY CONCERNS

As the threat of infection continues to loom during the reopening of communities and health care facilities, entities must remain cognizant and plan for potential risks and liabilities including if a patient becomes infected while receiving care at a facility (i.e. it is a hospital acquired infection).[23] Other areas of assessment should include employment related claims, workers compensation matters, and wrongful death claims.[24]

Notably, some states have enacted laws extending immunity to health care providers and facilities during the public health emergency. On 4 May 2020, North Carolina enacted a law limiting civil liability to health care

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providers and facilities from not only care provided to patients infected with COVID-19, but also to nearly any care provided during the public health emergency, as long as the provision of that care or other decisions made were impacted, directly or indirectly, by the COVID-19 pandemic.[25] Additionally, some states, including New York, have utilized Executive Orders to provide limited immunity to health care facilities and providers.[26]

The U.S. Department of Health and Human Services ("HHS") has also made limited federal immunity available under the Public Readiness and Emergency Preparedness Act (PREP Act) through a 4 February 2020 Declaration.[27] The HHS Immunity Declaration contains a number of technical requirements, but in general grants liability immunity for claims of loss brought against "Covered Persons"[28] engaging in "Recommended Activities" (i.e., the manufacture, testing, development, distribution, administration, prescription and use of "Covered Countermeasures against COVID-19.)"[29] These parameters include situations such as hospitals providing COVID-19 testing or vaccine administration, as well as the administration of other drugs and devices used to treat, cure, prevent, or mitigate the disease, such as ventilators. However, it does not reach situations such as a patient contracting COVID-19 while receiving unrelated care at a facility.

Overall, health care facilities must create a comprehensive and dynamic approach to reopening that simultaneously creates a structured plan for doing so while remains flexible to account for the realities of the pandemic in their communities.

K&L Gates LLP has created a HUB webpage to address the legal implications of the COVID-19 outbreak on businesses generally and health care providers, in particular. K&L Gates' health care and FDA practice can provide guidance to providers and suppliers on these and other matters related to the COVID-19 pandemic. Contact the authors of this article or your K&L Gates attorney for assistance or to receive updates during the COVID-19 emergency.

FOOTNOTES

[1] Long-term care facilities are facing extreme and special challenges responding to and containing the spread of COVID-19. Due to the unique circumstances, the issues of long-term care facilities are beyond the scope of this alert.

[2] Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19, AMERICAN HOSPITAL ASSOCIATION.

[3] Ctrs. for Medicare & Medicaid Servs., Opening Up American Again, Centers for Medicaid Services (CMS) Recommendations Re-opening Facilities to Provide Non-emergency Non-COVID-19 Healthcare: Phase 1 [hereinafter CMS Recommendations: Phase 1].

[4] Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Releases Recommendations on Adult Elective Surgeries, Non-Essential Medical, Surgical, and Dental Procedures During COVID-19 Response, (Mar. 18, 2020).

[5] Guidelines Opening Up America Again, [hereinafter, Gating Criteria].

[6] Ctrs. for Disease Control & Prevention, Strategies to Optimize the Supply of PPE and Equipment.

[7] 42 U.S.C. §§ 12112(d)(4), 12113(a). *See also* US Equal Emp't Opportunity Comm'n, Pandemic Preparedness in the Workplace and the Americans with Disabilities Act.

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[8] Equal Employment Opportunity Comm'n, Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees under the Americans with Disabilities Act, § A.5 of "Job-Related and Consistent with Business Necessity" (2000); *See also* Equal Employment Opportunity Comm'n Technical Assistance Questions & Answers: "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws."

[9] 42 U.S.C. §§12112(d)(3)(B), (4)(C); 29 C.F.R. §1630.14(b)(1).

[10] *See, e.g.,* EEOC Reboots Virus Guidance for Employers With At-Risk Workers, BLOOMBERG LAW.

[11] Ohio Dep't of Health, Director's Stay Safe Ohio Order, at 4, [hereinafter Ohio Order].

[12] Pa. Dep't of Health, Guidance on Hospitals' Responses to COVID-19.

[13] N.C. Healthcare Ass'n, North Carolina's Responsible Return to Elective Surgeries and Procedures.

[14] Cal. Med. Ass'n, Guidelines and Recommendations for Reopening the Health Care System, [hereinafter California Guidance].

[15] Am. Coll. Surgeons et al., Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic.

[16] Am. Coll. Surgeons, COVID-19: Guidance for Triage of Non-Emergent Surgical Procedures, American College of Surgeons, (Mar. 17, 2020); *see also* Am. Coll. Surgeons, Local Resumption of Elective Surgery Guidance, (Apr. 17, 2020); Am. Coll. Surgeons, COVID-19 Elective Case Triage Guidelines for Surgical Care, (Mar. 24, 2020).

[17] Ctrs. for Medicare & Medicaid Servs., Non-Emergent, Elective Medical Services, Treatment Recommendations, (Apr. 7, 2020).

[18] Children's Hosp. Ass'n, Guidelines for Pediatric Patient Care Reengagement, Children's Hospital Association, (May 1, 2020).

[19] CMS Recommendations: Phase 1, at 2.

[20] Ohio Order, at 2.

[21] California Guidance, at 4 (emphasis added).

[22] OFF. OF THE GOVENROR, THE GOVERNOR'S REPORT TO OPEN TEXAS, (Apr. 27 2020), at 45.

[23] *See, e.g.,* Evan Bush, *Patient at Harborview Medical Center likely got coronavirus at the hospital, infection expert says*, SEATTLE TIMES (Apr. 16, 2020.)

[24] *See, e.g.,* Complaint For Damages: Fraud And Wrongful Death, *Deborah De Los Angeles, Individually And As Daughter And Personal Representative Of The Estate Of Twilla June Morin v. Life Care Centers Of America, Inc. D/B/A Life Care Center Of Kirkland, A Foreign Corporation; Lake Vue Operations, Llc, A Foreign Limited Liability Company; Ellie Basham, Individually; Todd Fletcher, Individually; And Unknown John And Jane Does*, Case #: 20-2-07689-9 SEA, King County Superior Court.

[25] S.B. 704, General Assembly of N.C., 2019 Session. The bill added the following section:

"§ 90-21.133. Immunity.

- (a) Notwithstanding any law to the contrary, except as provided in subsection (b) of this section, any

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health care facility, health care provider, or entity that has legal responsibility for the acts or omissions of a health care provider shall have immunity from any civil liability for any harm or damages alleged to have been sustained as a result of an act or omission in the course of arranging for or providing health care services only if all of the following apply:

- (1) The health care facility, health care provider, or entity is arranging for or providing health care services during the period of the COVID-19 emergency declaration, including, but not limited to, the arrangement or provision of those services pursuant to a COVID-19 emergency rule.
- (2) The arrangement or provision of health care services is impacted, directly or indirectly:
  - a. By a health care facility, health care provider, or entity's decisions or activities in response to or as a result of the COVID-19 pandemic; or
  - b. By the decisions or activities, in response to or as a result of the COVID-19 pandemic, of a health care facility or entity where a health care provider provides health care services.
- (3) The health care facility, health care provider, or entity is arranging for or providing health care services in good faith.

- (b) The immunity from any civil liability provided in subsection (a) of this section shall not apply if the harm or damages were caused by an act or omission constituting gross negligence, reckless misconduct, or intentional infliction of harm by the health care facility or health care provider providing health care services; provided that the acts, omissions, or decisions resulting from a resource or staffing shortage shall not be considered to be gross negligence, reckless misconduct, or intentional infliction of harm.
- (c) Notwithstanding any law to the contrary, a volunteer organization shall have immunity from any civil liability for any harm or damages occurring in or at its facility or facilities arising from the State's response and activities under the COVID-19 emergency declaration and in accordance with any applicable COVID-19 emergency rule, unless it is established that such harm or damages were caused by the gross negligence, reckless misconduct, or intentional infliction of harm by the volunteer organization.

[26] Exec. Order. No. 202.10.

[27] 85 Fed. Reg. 15198.

[28] Covered Persons are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. See 85 Fed. Reg. 15201.

[29] *See* 85 Fed. Reg. 150202 (“Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product. Covered Countermeasures must be 'qualified pandemic or epidemic products,' or 'security countermeasures,' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.”).

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