



Protecting the Health of Patients and Professionals





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Introduction

"The health and safety of my medical and administrative team and the patients we serve is my top priority. As hospitals and clinics reopen, what steps can we take to protect our people and those for whom we provide care?"

Physicians, nurses, other medical professionals — and the staff who support them — have rightfully been called heroes of the COVID-19 pandemic. From the largest urban hospitals to the smallest rural clinics, millions of doctors, technicians, administrators, and support staff have stepped up to the task of identifying and treating victims of the novel coronavirus, all while continuing to provide care to patients suffering from cancer, heart disease, and other serious illnesses.

With each passing week, more is learned about COVID-19. In response, the US Centers for Disease Control (CDC) and other federal and state agencies are issuing regular updates on how hospitals, clinics, ambulatory surgery centers, and physician offices can more safely reopen their facilities. The following information includes guidance and checklists on specific COVID-19-related issues for the healthcare industry, including a review of regulatory requirements, employment matters, telehealth, and a summary of certain state and local laws and guidance.

For more information and updates, visit our COVID-19 Center.



Healthcare Regulatory Issues

"As my facility begins the reopening process, how can I ensure compliance with the latest federal, state, and local regulatory guidelines?"

From any perspective — business, economic, or public health — it is clear that the path through the COVID-19 pandemic will be neither straight nor smooth. The number of cases, transmission rates, and locations of potential "hot spots" will rise, fall, and shift. Infection-avoidance and treatment best practices will also be refined and improved.

With these realities in mind, it has been and will remain necessary for federal, state, and local authorities and regulatory agencies to maintain a certain level of flexibility in order to provide targeted support and solutions. In turn, healthcare providers must keep a close eye on emerging issues, maintain awareness of evolving guidance, and be prepared to respond accordingly. The following information includes a review of Centers for Medicare & Medicaid Services (CMS) guidance and specific considerations for medical practices, ambulatory surgery centers, hospitals, skilled nursing facilities, and other industry participants.

- Prioritize Prevention and Precautionary Measures
- Identify Medically Necessary Services and Telehealth Options
- Follow CMS and AMA Guidelines to Reopen Medical Practices
- Comply with ASC-to-Hospital Reversion Requirements
- Understand Federal Provider Relief Fund Requirements

Healthcare Regulatory Issues

Reopening of Healthcare Facilities

CMS RECOMMENDATIONS: PHASE I GUIDE

As areas of the United States continue to experience varying rates of COVID-19 cases, healthcare providers and facilities are preparing to reopen all healthcare services. The Centers for Medicare & Medicaid Services (CMS) published a "Phase I Guide" for reopening healthcare facilities to provide non-emergent, non-COVID-19 healthcare. CMS's Phase I Guide includes the following recommendations:

General Considerations

- ✓ Evaluate the necessity of the care based on clinical needs. Providers should prioritize surgical/ procedural care and high-complexity chronic disease management; however, select preventive services may also be highly necessary.
- ✓ Consider establishing non-COVID-19 care (NCC) zones that would screen all patients for symptoms of COVID-19, including temperature checks. Staff would be routinely screened, as would others who will work in the facility (physicians, nurses, housekeeping, delivery, etc.) and all people who would enter the area.
- ✓ Make sufficient resources available to the facility across all phases of care, including personal protective equipment (PPE), supplies, testing capacity, and post-acute care, without jeopardizing surge capacity.
- ✓ Ensure adequate supplies of equipment, medication, and other materials, but do not detract from the community's ability to respond to a potential surge.

Personal Protective Equipment

- ✓ Enforce the requirement that, consistent with Centers for Disease Control and Prevention (CDC) and CMS recommendations, all healthcare providers and staff wear surgical face masks at all times.
- ✓ Ensure that procedures on the mucous membranes, including the respiratory tract, and that involve a higher risk of aerosol transmission, are done with great caution. Staff should utilize appropriate respiratory protection such as N95 masks and face shields.
- Require patients to wear a cloth face covering that can be bought or made at home if they do not already possess surgical masks.
- ✓ Make every effort to conserve PPE.

Workforce Availability

✓ Screen staff routinely for symptoms of COVID-19; if symptomatic, they should be tested and quarantined. Staff who will be working in NCC zones should be limited to working in these areas and not rotate into

- "COVID-19 care zones" (e.g., they should not have rounds in the hospital and then come to an NCC facility).
- ✓ Maintain adequate staffing levels in the community in order to cover a potential surge in COVID-19 cases.

Facility Considerations

- ✓ Ensure NCC zones have in place steps to reduce risk of COVID-19 exposure and transmission. These areas should be separate from other facilities to the extent possible (i.e., in a separate building, or in designated rooms, or on a floor with a separate entrance and minimal crossover with COVID-19 areas).
- ✓ Establish administrative and engineering controls within the facility to facilitate social distancing, such as minimizing time in waiting areas, spacing chairs at least six feet apart, and maintaining low patient volumes.
- ✓ Prohibit most visitors; but if they are necessary for an aspect of patient care, they should be prescreened in the same way as patients.



Sanitation Protocols

- ✓ Establish a plan for thorough cleaning and disinfection prior to using spaces or facilities for patients with NCC needs.
- ✓ Ensure that equipment such as anesthesia machines used for COVID-19 patients are thoroughly decontaminated, following CDC guidelines.

Testing Capacity

- ✓ Screen all patients and all staff for potential symptoms of COVID-19 before they enter the NCC facility.
- ✓ Screen patients with the use of laboratory testing before care, when adequate testing capability is established, and screen staff working in these facilities regularly using laboratory tests, as well.

By following the above recommendations, in coordination with the recommendations of the facility's state and local public health officials, healthcare facilities can safely resume in-person non-emergent care of patients.

MEDICAL PRACTICES

Preopening planning is important to the success of a medical practice's reopening. The below checklist, which builds upon CMS's Phase I Guide and the recommendations of the American Medical Association (AMA), serves to assist in the reopening of medical practices:

- ✓ Make a plan: A period of "soft opening" is recommended to allow the practice to reopen incrementally, allowing initial issues to be identified and resolved quickly and providing flexibility to permit any necessary changes. Begin with a few in-person visits per day, working up incrementally to additional in-person visits. Communicate your reopening schedule clearly to the practice's patients, clinicians, and staff.
- ✓ Identify administrative staff who can continue to work remotely: Direct administrative staff who do not need to be physically present in the office to continue to work remotely. Additionally, consider having employees return in phases, or work on alternating days or different parts of the day, as this will reduce contact.
- ✓ Assess your PPE supply: Determine the practice's current and near-future PPE needs, as well as current supply levels, sources of additional supply, and alternatives in the event suppliers cannot meet the practice's needs in a timely manner. Place the necessary orders as soon as possible in advance of reopening and conserve the practice's supply of PPE.
- ✓ Identify which patient visits can be performed via telehealth: For safety reasons, determine whether certain patient visits and services can be rendered via telehealth or other modalities, and continue to perform those visits and services remotely. (See our telehealth discussion, below.)
- ✓ Institute safety measures for patients: Utilize a modified schedule to avoid a high volume or density of patients to ensure that patients minimize close contact with one another. Designate separate waiting areas for "sick" and "well" patients. Consider a flexible schedule, with perhaps a longer span of the day and more time in between visits to avoid backups. Limit patient companions to individuals necessary to the patient's situation (e.g., parents of children, spouse, or other companion of a vulnerable person). Per the CDC's guidance, practices should require all individuals visiting a practice to wear a cloth face

- covering or a mask. Any individuals arriving without a cloth face covering or a mask should be provided one by the practice if supplies are available.
- ✓ Ensure workplace safety for clinicians and staff: Communicate personal health requirements clearly to clinicians and staff. (See our firm's <u>Backto-Work Toolkit</u>: "Employment" section for further recommendations.)
- ✓ Implement a tele-triage program before scheduling in-person visits: Utilize a tele-triage program, in which the patient's condition and symptoms are discussed, to ensure that patients seeking in-person visits are put on the right path. Depending on the patient's condition and symptoms, the patient may need to be redirected to the practice's telehealth platform, a COVID-19 testing site, or a clinic or hospital. Before the COVID-19 public health emergency, some practices engaged a tele-triage service to handle after-hour calls, which service may be able to expand to handle daytime calls, as well.
- ✓ Screen patients before in-person visits:

Administrative staff of the practice should telephone patients within 24 hours of the patient's in-person appointment to (i) review the logistics of the reopening practice protocol, and (ii) screen the patient for COVID-19 symptoms. The AMA has developed a sample script for administrative staff conducting these screening calls to patients. Additionally, upon entering the practice, the patient, as well as any patient companions, should be screened. (See our firm's Back-to-Work Toolkit: "Business Reopening" section for further recommendations on in-person screening of individuals.)

- ✓ Coordinate testing with local hospitals and clinics: Situations may arise in which a patient requires COVID-19 testing. Contact your local public health authority for information on available testing sites. Contact the testing sites to ensure that tests are available and to understand the turnaround time on testing results. Provide clear and up-to-date information to patients regarding the location of, and the process for, the COVID-19 testing.
- ✓ Contact the practice's medical malpractice insurance carrier: Although Congress and several states have enacted legislation shielding clinicians treating COVID-19 patients from liability in certain instances, as the practice reopens there may be additional risks caused by the pandemic that do not fall under these legislative protections. Therefore, discuss with the practice's medical malpractice liability insurance carrier whether additional coverage may be warranted.

Establish confidentiality/privacy protections: Although certain HIPAA requirements related to telehelath are not being enforced during the COVID-19 public health emergency, HIPAA privacy, security, and breach notification requirements generally must continue to be followed. Institute or update confidentiality, privacy, and data security protocols. Results of any screenings of employees should be kept in employment records only (but separate from the personnel file). Remember that HIPAA authorizations are required for sharing information regarding a patient for employment purposes. Similarly, coworkers and patients can be informed that they came into contact with an employee who tested positive for COVID-19, but the identity of the employee and details about an employee's symptoms cannot be shared with patients or coworkers without consent. (See our firm's Backto-Work Toolkit: "Employment" section for further discussion.)



AMBULATORY SURGERY CENTERS

As discussed in our <u>prior client alert</u>, under CMS's Hospitals Without Walls initiative, ambulatory surgery centers (ASCs) have been able to enroll temporarily in Medicare as a hospital and be utilized to assist in expanding capacity for inpatient and outpatient hospital services during the pandemic. Any ASC that enrolled as a hospital for this purpose cannot be enrolled as an ASC at the same time. Therefore, as the pandemic begins to stabilize, ASCs will need to revert back to ASCs to resume their pre-pandemic operations as ASCs.

What is the process to revert back to an ASC?

Once the secretary of the Department of Health and Human Services (the HHS Secretary) determines there is no longer a need for ASCs to act as temporary hospitals, the applicable CMS Regional Office will terminate the ASC's temporary hospital CMS Certification Number (CCN), and the applicable Medicare Administrator Contractor (MAC) will deactivate the temporary hospital billing privileges and reinstate the ASC billing privileges effective on the date the ASC terminates its

temporary hospital status. Once the ASC's hospital CCN has been terminated, the ASC must come back into compliance with all applicable ASC federal participation requirements, including the Conditions for Coverage.

What if the ASC desires to revert back to an ASC prior to the end of the pandemic?

If the ASC desires to revert back to an ASC prior to the end of the public health emergency, the ASC must so notify its MAC in writing.

What if the ASC desires to continue as a hospital after the public health emergency has ended?

The ASC must submit CMS Form 855A to begin the process of enrollment and initial certification as a hospital under the regular processes.

Regulatory Response to COVID-19

SECTION 1135 WAIVERS

Background

Under the authority of Section 1135 of the Social Security Act, the HHS Secretary approved blanket waivers of many provisions related to, among other things, hospital and nursing facility standards, certain provider enrollment requirements, and Medicare telehealth services. Additionally, waivers of other federal provisions, including provisions related to the Emergency Medical Treatment & Labor Act, the Physician Self-Referral Law (the Stark Law), and certain Medicaid requirements, have been made available on a case-by-case basis. The Section 1135 waivers apply nationwide, and applicability is retroactive to March 1, 2020. A summary of the Section 1135 blanket waivers can be found here. Consult with your healthcare attorney if you have any questions about any of the Section 1135 waivers.

Note: Section 1135 waivers apply only to federal requirements and do not apply to state requirements for licensure or conditions of participation.

How long do the Section 1135 waivers last?

Section 1135 waivers typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The HHS Secretary can extend the waiver by notice for additional periods of 60 days, up to the end of the emergency period.

HIPAA WAIVERS

The HHS Secretary authorized a limited waiver of HIPAA sanctions and penalties during the current public health emergency, which applies to covered hospitals only. The hospital must have enacted its emergency plan in order for the waiver to apply, and the waiver is limited

to a 72-hour period beginning upon enactment of the emergency plan. In addition, HIPAA rules have been relaxed to allow for increased use of telehealth, meaning providers may, in good faith, use non-HIPAA platforms. These limited HIPAA waivers terminate at the end of the emergency declaration.

PROVIDER RELIEF FUND

As a result of recent congressional action providing significant funding for healthcare providers, HHS has distributed from the Public Health and Social Services Emergency Fund (the Provider Relief Fund) (i) approximately \$50 billion for "general distribution" to providers that bill Medicare on a fee-for-service basis and (ii) approximately \$50 billion for "targeted distribution" to providers in areas particularly impacted by the COVID-19 pandemic, rural providers, providers that predominantly serve the Medicaid population, and providers treating uninsured Americans. Since many payments were made automatically to providers prior to CMS's issuance of the terms and conditions applicable to such payments, some confusion has arisen as to how providers are to accept or reject such payments.

- ✓ Acceptance/Rejection: Providers that have received a payment are required to use the CARES Act Provider Relief Fund Payment Attestation Portal within 90 days of receiving the payment (i) to sign an attestation confirming receipt of the payment and to sign the terms and conditions of payment or (ii) to reject the payment. Not returning the payment within 90 days of receipt will be deemed acceptance of the payment and its terms and conditions.
- ✓ Submission of Documents/Applications for Additional Payments: Providers that automatically received funds prior to 5:00 p.m. on April 24, 2020, are required to submit to CMS certain tax forms and financial statements through the General Distribution Portal. Submissions of these documents serve as an application for additional funding. However, the deadline to request additional funding expired June 3, 2020. Therefore, only providers that submitted their documentation on or before June 3 and have not already received additional payment from the general distribution are eligible for a potential payment at this time.
- ✓ Rejection After Acceptance: Providers that affirmatively attested to a general distribution payment but now wish to reject the payment and retract the provider's prior attestation may call the provider support line at 866.569.3522 to do so.

The terms and conditions include a requirement that providers submit quarterly reports to HHS (and the Pandemic Response Accountability Committee) about how the providers are utilizing the relief payments. Providers were expected to file by July 10, 2020 their first report on the use of their payments for the quarter ending June 30, 2020. However, on June 13, 2020, HHS updated its guidance, reversing course and no longer requiring providers to submit that first report, stating that public data disclosures would fulfill the reporting requirement without further action by healthcare providers. However, HHS has indicated that in the coming weeks, it will release guidelines on the timing and contents of future reports.

We recommend that you consult with your healthcare attorney on any questions regarding relief payments, as HHS seems to be updating its guidance regarding the Provider Relief Fund almost daily.



Workplace Safety and Employment Issues

"As my facility begins the reopening process, how can I maintain staff morale and still comply with the latest requirements and guidelines?"

Healthcare workers at every level of skill and experience are concerned about workplace safety. Keeping workers healthy and on the job requires additional expenditures for testing, personal protective equipment, and perhaps even "combat pay" incentives. For their part, patients may be reluctant to seek treatment for non-life-threatening illnesses or conditions while the pandemic continues, meaning that providers may not see the patient volumes they planned and budgeted for. In the face of these concerns, hospitals, clinics, physician practices, and other healthcare organizations must maintain adequate revenues in order to continue to provide care.

In this section, we help healthcare organizations identify and balance the many issues that arise in the employer-employee relationship. We review federal and state guidance regarding OSHA, ADA, and other laws and regulations, offer insights and tips on workplace best practices, and suggest key questions that executives and leadership should ask themselves when planning their reopening strategy.

- Focus on Workplace Safety Issues
- Understand Your Responsibilities and Rights as an Employer
- Minimize Potential Litigation and Regulatory Enforcement
- Learn Correct Processes for Medical Testing, Return to Work, and Possible Accommodations

Workplace Safety and Employment Issues

WORKPLACE SAFETY ISSUES

The Occupational Safety and Health Administration (OSHA) requires employers to provide a workplace that is "free from recognized hazards that are causing or are likely to cause death or serious physical harm. ..." (29 C.F.R. § 654). OSHA and the CDC provide general, industry, and workplace-specific guidance on reopening the workplace and keeping employees safe. This guidance changes regularly, so it is important to monitor or work with counsel to stay up-to-date. Although helpful, the COVID-19 recommendations provided by OSHA and the CDC are all guidelines and not requirements. But following them could help protect employers from liability in the future.

OSHA has been receiving a large number of complaints relating to COVID-19, specifically regarding the lack of PPE, alleged exposures, and issues involving employees not wanting to return to work. OSHA's May 19, 2020, guidance on its response plan reinforces its prioritization of COVID-19 cases, including on-site inspections, and specifically targets hospitals and other high-risk workplaces.

OSHA also revised its guidance on recordability of COVID-19 cases on May 19. An employer must record COVID-19 exposure when:

- The case is a confirmed case of COVID-19.
- The case is work-related.
- The case meets general recording criteria set forth in the standard.

COVID-19 is a respiratory illness and should be coded as such on OSHA Form 300. Because this is an illness, if an employee voluntarily requests that his or her name not be entered on the log, the employer should not include such information.

Given the difficulty of determining work-relatedness of COVID-19 infection, OSHA is exercising enforcement discretion to assess employers' efforts in making work-related determinations. In determining whether an employer has complied with this obligation and made a reasonable determination of work-relatedness, OSHA will consider the reasonableness of the employer's investigation into work-relatedness and the evidence available to the employer.

Reopening directives and orders vary greatly, and each phase of reopening will bring different challenges. To ensure compliance with protective guidelines, healthcare providers should develop a COVID-19 response leadership team/committee/task force to:

- ✓ Monitor state/local guidelines.
- ✓ Manage communications to employees.
- ✓ Field questions and handle public relations.
- ✓ Keep track of safety measures taken by the employer.
- ✓ Consider daily/weekly checklists and photographs.

Healthcare providers must:

- ✓ Assess hazards to which employees may be exposed.
- ✓ Evaluate the risk of exposure.
- ✓ Select, implement, and ensure workers use controls to prevent exposure.
- ✓ Implement protective measures (see additional guidance regarding protective measures in the "Maintain Healthy Business Operations" and "Maintain a Healthy Work Environment" sections of our firm's Back-to-Work Toolkit).



Healthcare providers should ensure that their employees have proper PPE, including, as appropriate:

- NIOSH-certified, disposable N95 facepiece respirators or better
- Face coverings
- Eye protection (goggles or face shields)
- Gloves
- Gowns

Providers should also ensure that systems are in place to clean, disinfect, and maintain reusable equipment and PPE, and they must prioritize PPE where it is in short supply and make a good-faith effort to ensure proper use.

Healthcare providers must ensure there is no retaliation against employees who express safety concerns:

 There may be a potential OSHA whistleblower cause of action where an employee refuses to return to work or perform a task considered unsafe; see the April 8, 2020, guidance OSHA issued specifically reminding

- employers not to retaliate due to the number of complaints OSHA has received.
- Retaliation can include terminations, demotions, denials of overtime or promotion, or reduction in pay or hours.
- Remember that if employees express concerns as a group, or one employee speaks on behalf of a group, this may be considered protected activity under the National Labor Relations Act (NLRA). Keep in mind that the NLRA applies to union and nonunion employees.



Medical Testing and Inquiries of Employees

- Even though the Americans with Disabilities Act (ADA)
 puts strict restrictions on medical testing and inquiries
 of its employees, employers currently may require
 employees to submit to medical testing and questions
 concerning COVID-19, but only after an offer of
 employment has been made.
- Employers cannot require COVID-19 testing of applicants.
- The Equal Employment Opportunity Commission currently allows employers to take employees' temperatures, to administer testing for COVID-19, and to ask about symptoms associated with COVID-19.
- OSHA has a requirement that if the temperature is recorded (written down) by a medical provider (e.g., doctor, nurse, or technician), the records are considered exposure records and must be maintained for 30 years.
- Employers may not require employees to undergo antibody testing.
- Employers cannot ask specifically about family members' health conditions.
- The Genetic Information Nondiscrimination Act prohibits employers from requesting "genetic information," which is defined broadly to include, for example, an individual's family medical history.
- Better practice is to ask whether the employee has had contact with anyone who has been diagnosed with COVID-19 or has symptoms of COVID-19.
- If a potential new employee is at high risk for COVID-19 according to the CDC, do not unilaterally postpone the employee's start date or withdraw the job offer.

Instead, discuss telework, voluntary postponement of the start date, or other possible accommodations.

What Employers Can Do When an Employee Tests Positive for COVID-19

- ✓ Delay the start date of a new employee, based on screening.
- Consider withdrawal of the job offer if a potential hire has COVID-19 or COVID-19 symptoms; this may be an option if the start date cannot be delayed or another accommodation cannot be provided.
- Focus on individuals who test positive, and gather information to determine the extent of potential exposure.
- ✓ Determine whether to report the infection or presence of symptoms on the OSHA log.
- ✓ Plan for cleaning.
- ✓ Evaluate, in advance, the best sanitation procedures appropriate for the particular workplace.
- ✓ Notify coworkers who were physically present and in close contact with the employee. Keep in mind the following:
 - The ADA requires the employer to maintain the confidentiality of infected employees. Infected employees should not be identified.
 - Supervisors should be provided with a script of what to say.
 - Determinations should be made as to whether coworkers who had direct contact with, or who were potentially exposed to, the infected individual should be instructed to self-isolate/quarantine.
 - Determinations should be made as to when the employee can return to work, using a symptom-based strategy or a test-based strategy (continue to monitor CDC's guidance, as these recommendations may change over time):
 - Under a symptom-based strategy, the employee may return to work after all three of the following occur:
 - The employee has had no fever for 72 hours, without the use of fever-reducing medicine.
 - Other symptoms (cough, shortness of breath, etc.) have improved.
 - At least 10 days have passed since the first symptoms appeared.
 - Under a test-based strategy, the employee may return to work after all three of the following occur:
 - The employee has had no fever for 72 hours, without the use of fever-reducing medicine.
 - Other symptoms (cough, shortness of breath, etc.) have improved.
 - The employee receives two negative test results in a row, 24 hours apart.
- ✓ Require the employee to wear a face mask at all times until all symptoms have resolved or are at baseline.
 - Note that a face mask does not replace the need for N95 or higher-level respirators when indicated.

Confidentiality of Employees' Health Information

- Employers that collect medical information from employees have an obligation to keep such information confidential.
- The ADA requires that all medical information about a particular employee be stored separately from the employee's personnel file.
- Medical information related to COVID-19 may be stored in existing medical files.
- Examples of ways in which practical confidentiality issues arise include the following scenarios:
 - Taking temperatures or asking questions about symptoms or potential exposures of employees
 - Logging results from daily temperature checks
 - Notifying coworkers that an employee tested positive for COVID-19

Employee Refusal to Return to Work

- ✓ Have a conversation with hesitant employees to evaluate their concerns.
- ✓ Note that an employer is permitted to insist that an employee report to work if concerns are determined to be unreasonable (and there is no disability for which a reasonable accommodation may need to be provided under the ADA):
 - The employer can enforce its attendance policy and take disciplinary action if the employee does not report to work.
 - Employers should be aware of potential disabilities requiring accommodation and follow the normal interactive process.

Employee Requests for Accommodation

- ✓ If an employee notifies the employer, either in conversation or in writing, that he/she needs a change for a reason related to a medical condition, start with the basics by determining whether this is a request for an accommodation or the expression of a preference. Note that the employee need not use the term "reasonable accommodation."
 - Reasonable accommodation is defined as a change in the work environment that allows an individual with a disability to have an equal opportunity to perform a job's essential functions or to enjoy equal benefits and privileges of employment.
- ✓ For higher-risk-category employees who must be in the workplace, consider reasonable accommodations that might allow them to perform the job; these include the following:
 - Physical modifications, such as barriers, to ensure minimum interaction with coworkers and customers and to reduce exposure
 - Policy modifications, such as a temporary job restructuring of marginal job duties, temporary transfer to another position, or modification of a work schedule or shift assignment

- Modified protective gear, such as modified face masks for employees who communicate with an employee who reads lips or alternative gloves (nonlatex), should be identified and made available.
- Even if an employer knows that an employee has
 a condition that places the employee at higher
 risk and is concerned that his or her health will
 be jeopardized upon returning to the workplace,
 according to the CDC, the employer cannot
 exclude the employee or take any other adverse
 employment action solely because the employee
 has a disability that may place him or her at higher
 risk of severe illness if COVID-19 is contracted.



Telehealth

"How do I know which healthcare services provided by my clinic are a good fit for telehealth, meet the requirements of federal and state regulations, and identify effective technology and vendors?"

Telehealth can help minimize the spread of COVID-19 and other infections, improve quality of care, and increase patient access to essential healthcare services when hospital and clinic visits are limited to reduce the risk of exposure to the virus. The effective practice of telehealth, however, involves a great deal more than just setting up a video call between a patient and provider.

In this section, we pose a number of questions that can help healthcare providers identify relevant federal and state laws regarding licensure, prescribing, reimbursement, privacy, security, insurance, and other issues. We also provide insights on choosing a telehealth model that fits your needs, offer tips on current technology solutions and working with vendors, and underscore the importance of consulting with experienced telehealth attorneys.

- Seek Legal Advice on Telehealth Laws and Regulations
- Choose a Service Model that Fits Your Patients and Practice
- · Assess Technology and Tech Support Needs

Telehealth

At the start of the COVID-19 public health emergency, telehealth was quickly identified as a powerful weapon in the fight. Telehealth supports COVID-19 suppression by reducing the need for in-person or in-hospital visits, not only eliminating the risk of transmission between telehealth patients and providers but also slowing the spread of the coronavirus among actual or potential COVID-19 patients and medical staff by reducing the risk of contact with someone carrying the virus.

Telehealth also improves access to care in rural and underserved areas and reduces overall demand for medical supplies, equipment, and human resources in a health-care system already under stress. Sophisticated telehealth technologies can also support the dissemination of COVID-19-related data to epidemiologists, researchers, and government entities.

In the context of the current pandemic, and in recognition of the benefits of telehealth, in 2020 federal and state regulators have demonstrated a willingness to relax or change rules that previously slowed the expansion of telehealth services. Those changes, coupled with improvements in telehealth technology and broadband communications, have enabled telehealth to deliver significant, positive results in the management of COVID-19 and other illnesses and conditions. These results, in turn, will strengthen telehealth's position in the post-COVID-19 healthcare landscape.

It is no surprise, then, that health systems, hospitals, ambulatory surgery centers, clinics, and physician practices are seeking to implement telehealth solutions, not only in response to COVID-19 but also to support diagnosis and treatment in a broad range of settings and disciplines: radiology, emergency room care for stroke and heart events, psychiatry, family medicine, allergy, and immunology, just to name a few. However, as with any new technology, treatment, or methodology, it is important to test the depth and temperature of the waters before diving in.



In this context, this means taking three important steps:

- Seeking advice from experienced telehealth counsel on federal and state laws and regulations
- 2. Choosing a telehealth service model that works best for your patients and your treatment setting practice
- 3. Assessing technologies and tech support needs for successful telehealth consultations

Step 1: Understanding Federal and State Laws and Regulations

The federal and state laws and regulations that affect the practice of telehealth are complex, are changing rapidly, and may have unforeseen effects on a range of other financial and operational issues. Before introducing or expanding telehealth services, seek regulatory advice from a telehealth attorney regarding applicable legal requirements and restrictions.

The following list presents questions you should ask yourself — and your legal advisors:

- ✓ What are the relevant state medical licensure laws and regulations? If you intend to use telehealth to treat patients in another state, do you need a medical license in the state where those patients are located? Does the state have a special telehealth license for physicians located in another state? Has your state joined the Federation of State Medical Boards' Interstate Medical Licensure Compact?
- Are there any limitations on prescribing medication through telehealth? Does your state require a prior in-person visit, or is a videoconference visit before prescribing medication sufficient? Be aware that prescribing controlled substances is often subject to additional restrictions under federal law (although some of these restrictions have been temporarily loosened or modified in the face of COVID-19).
- ✓ Does your state require a prior in-person visit before conducting a patient examination via telehealth? What are the patient-physician relationship requirements for use of telehealth under state law? CMS has temporarily lifted the requirement that a patient could only receive telehealth services at a healthcare facility or clinic, subject to certain conditions, but these changes are limited in scope and have not been made permanent.
- Where will services be provided or made available to meet state law requirements (which may be more restrictive than what CMS currently requires)?
- ✓ What are the relevant federal and state patient consent requirements? How will consent be obtained and documented, and are there situations in which con-

- sent may be obtained from a caregiver (e.g., when a patient does not have the cognitive capacity to make her or his own care decisions)?
- How will you ensure that privacy and security requirements, including those under the HIPAA, are met?
- ✓ Are you appropriately credentialed and privileged to provide telehealth services? Remember to comply with documentation and record-retention requirements.
- Does your medical liability insurance carrier ensure coverage if you are practicing in other states or via telehealth? Remember to inform your carrier of your intent to add telehealth to your practice.
- ✓ Do the states in which you will offer telehealth services have a prohibition on the corporate practice of medicine? This can impact the legal structure of an entity that wishes to provide telehealth services.
- ✓ Is reimbursement for telehealth available? Do you understand the relevant telehealth requirements and reimbursement structures for patients? Different payers including private insurance companies, Medicare, and state Medicaid programs have different reimbursement coverage requirements and reimbursement rates.

Step 2: Choose a Telehealth Service Model That Works Best for Your Patients and Your Practice

There are a number of telehealth service models, all of which have certain strengths and weaknesses. An experienced telehealth attorney can assist you in choosing a model that is best for your practice.

You might offer telehealth using one or more of the following service models:

- ✓ Providing direct care for your new and existing patients using videoconferencing. This may be done with or without peripheral devices (which often include cameras, thermometers, otoscope adaptors, and stethoscopes, etc.) that connect via the patient's home internet connection. This model and these tools can be effective for handling routine issues for example, for evaluating acute flu-like symptoms and deciding whether an in-person visit is needed.
- ✓ Serving as an originating site to connect patients to other physicians. In this model, for example, videoconferencing may be used to connect the patient, the primary care physician, and a specialist (e.g., working with a specialist to establish a course of treatment for a patient with a newly diagnosed medical condition).
- ✓ Serving as an originating site to connect to other physicians and offer services through store-and-forward consultation applications. In this model, medical data or images are captured and the data file is forwarded to a specialist at another location, who reviews the information at a later time and provides feedback; radiology is a prime example.

- ✓ Serving as a distant-site, where you provide consultation to physicians or other practitioners without working directly with patients.
- ✓ Serving as a distant-site consulting physician to offer services and follow-up visits to patients through offices or at the hospital, either through videoconferencing or through store-and-forward technologies.
- Contracting with a telehealth services company to offer consultations to the company's patients, separate and apart from your "regular" practice. Here, you must be aware of all applicable state and federal laws regulations regarding the establishment of a valid patient-physician relationship, including those related to prescribing and the need for an in-person physical examination or a face-to-face (videoconference) exam (see Step 1, above).
- ✓ Utilizing remote patient monitoring tools to manage chronic illnesses to supplement in-person care and possibly prevent hospital readmissions for patients in your practice. For example, devices such as electronic scales, glucometers, and sphygmomanometers can help remotely manage patients with congestive heart failure.



Step 3: Assess Your Technology and Tech Support Needs for Successful Telehealth Consultations

Not all technology is equal, nor is there a one-size-fitsall telehealth solution. It is important that you conduct appropriate due diligence, select the technology that best addresses your needs and objectives, and adhere to state and federal privacy and record retention laws.

At the top of the "things to consider" list is patient privacy. The importance of selecting HIPAA-compliant videoconferencing, store-and-forward technologies, and electronic medical record systems cannot be overstated.

Keep in mind that many apps (especially popular videoconferencing technologies such as Zoom, Skype, Face-Time, and Google Meet) that are temporarily approved for use by the Office for Civil Rights at the U.S. Department of Health and Human Services are not HIPAA-compliant, nor have they been cleared or approved by the Food and Drug Administration (FDA). Even taking temporarily relaxed federal restrictions into consideration, you should be forward-looking and proactive: select and use encrypted, password-protected systems and enter into business associate agreements with technology partners to conform to all HIPAA regulations. Also, be mindful of state privacy laws and regulations, which may be more restrictive than HIPAA and broader in coverage.

Additionally, you should:

- ✓ Understand relevant technical requirements for the service that will be provided (e.g., requirements for peripheral devices such as electronic stethoscopes, otoscopes, and ophthalmoscopes that may be required at the originating site).
- ✓ Wherever possible, conform to practice guidelines developed by specialty societies that may contain guidance on selecting appropriate technologies.
- ✓ Ensure adherence to appropriate informed consent and documentation requirements. Encrypt data to help protect it from a privacy breach.
- Seek out devices and technologies that are interoperable.
- Ensure FDA clearance or approval of devices and mobile health apps and technologies when required.
- ✓ Find internet connectivity that has enough bandwidth and quality of service to support the type of telehealth care you will be providing. Consult with your internet service provider if additional bandwidth is required for your telehealth service model.
- Develop an emergency plan in case escalation of care is required or technology fails.

Although the analysis and recommendations above speak in the context of physician practices, institutional providers, such as hospitals, and independent telehealth management companies must be aware of them as well. Because physicians and non-physician practitioners are at the heart of any telehealth strategy, any organization implementing such a strategy needs to be aware of the issues discussed above.

One way or another, the current COVID-19 pandemic will be a part of our history. (Ideally, this will be the result of effective public health strategies combined with more powerful, targeted treatment modalities and the development of an effective, widely available vaccine.)

However, telehealth is here to stay — and for good reason. Providers who take this opportunity to identify and implement telehealth solutions that work for their patients and their practices will likely see immediate and long-term rewards.



State and Local Laws and Guidance

"My state and city are permitting businesses to reopen — but where can I find specific information on the requirements that apply to healthcare providers like me?"

COVID-19 is affecting cities, counties, and states at differing rates and in unique ways. In response, local and state officials are developing and issuing their own requirements and asserting enforcement rights that also vary from jurisdiction to jurisdiction.

In this section, we highlight key legislation and recent executive orders from state and local agencies and officials in states across the southeast, identifying important similarities and differences.

- Identify Reliable Sources for Information
- Understand Potential Liabilities and Immunities
- Be Flexible

State and Local Laws and Guidance

State and Other Guidance

States have also been issuing guidance on reopening healthcare facilities. In fact, some states have issued more expansive guidance than that provided by CMS, including some that is mandatory and more stringent.

In addition, many national and state health associations and medical societies have also issued guidance regarding reopening procedures. For example, the American College of Surgeons, the American Society of Anesthesiologists, the Association of periOperative Registered Nurses, and the American Hospital Association released a document titled "Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic." This joint statement includes recommendations for reopening, including timing, testing, and adequacy of PPE. The American College of Surgeons has independently released additional guidance regarding the resumption of elective surgical procedures. Healthcare providers should evaluate state and other guidance, in addition to federal guidance, when planning for the reopening of healthcare facilities and the resumption of services.



Compliance with State and Local Laws and Regulations

Healthcare providers should also be careful to ensure compliance with all state and local laws and regulations. Although there has been recent congressional action to assist providers on a federal level in response to the pandemic, not all states have adopted corresponding response measures. For example, the Section 1135 waivers apply only to federal law requirements, so providers must continue to comply with applicable state law requirements, such as licensing and conditions of participation.

Liability Concerns

The COVID-19 public health emergency has created a healthcare environment that is unprecedented and

ripe for litigation. As healthcare facilities begin to reopen, liability concerns have arisen among healthcare providers and facilities that resume healthcare services.

- Is a provider or facility liable if a patient becomes infected with COVID-19 while receiving care at a facility?
- Is a provider or facility liable if an employee becomes infected with COVID-19 in the course of performing employment duties?
- Can a wrongful death claim be filed against a provider?
- Can a facility be liable to its healthcare professionals for requiring them to treat patients without supplying adequate PPE?

In response to these concerns, some states have enacted laws or issued executive orders extending immunity to healthcare providers and facilities during the public health emergency. Although most states have some form of "Good Samaritan Law" that immunizes providers from medical liability when providing volunteer services at the scene of an emergency, these laws generally do not provide immunity for services performed for compensation or services performed at a healthcare facility rather than at the scene of an accident or other emergency. Therefore, additional state action has been necessary in many states to provide immunity to healthcare providers and facilities during the pandemic.

- In Alabama, Governor Kay Ivey issued an executive order on May 8, 2020, providing liability protection or immunity to healthcare providers "that operate reasonably consistent with public health guidance."
- Similarly, in Mississippi, Governor Tate Reeves issued an <u>executive order</u> on April 10, 2020, providing civil liability protection to healthcare providers and facilities providing care in response to COVID-19, absent a showing of malice, reckless disregard, or willful misconduct.
- In Louisiana, existing state law (La. R.S. § 29:771) grants civil immunity to healthcare providers during a state of public health emergency, except in the event of gross negligence or willful misconduct. Louisiana's immunity is triggered solely by the declaration of a public health emergency. This differs from many other states, which may have existing legislation in place but need to take an additional step, such as an executive order, before the protections apply.
- Additionally, on June 13, 2020, Louisiana Governor John Bel Edwards signed into law House Bill 826, which grants liability protections for businesses from claims brought by both customers and employees related to COVID-19 exposure. The bill, which is

retroactive to March 11, 2020, when Louisiana declared its state of emergency related to COVID-19, provides as follows:

- o Businesses are not liable for damages for injury or death related to actual or alleged exposure to COVID-19 in the course of business operations unless the business "failed to substantially comply with the applicable COVID-19 procedures established by the federal, state or local agency which governs the business" and the injury or death was caused by the business's "gross negligence or wanton or reckless misconduct." If more than one set of procedures or guidelines applies to the business, the business must only "substantially comply" with one of them.
- Planners of any kind of events (e.g., conventions, trade shows, sporting events) cannot be held liable for injury or death related to actual or alleged COVID-19 exposure "unless such damages were caused by gross negligence or willful or wanton misconduct."
- o An employee who contracts COVID-19 in the workplace has no tort remedy against the employer unless the exposure resulted from an "intentional act." In Louisiana, as in many states, this is a very difficult threshold for an injured employee to meet.

While this law will come as welcome relief to businesses that are already facing other challenges, it is important to note that the protections it affords do not create blanket immunity for businesses from these types of claims. Businesses should still anticipate the possibility of such claims and make sure to document the actions being taken to keep both employees and customers safe. Likewise, businesses should document the source of the recommendations they are following in implementing these procedures (i.e., OSHA, CDC, etc.).

Other potential areas for liability fall under the Americans with Disabilities Act (ADA), Family and Medical Leave Act (FMLA) and Fair Labor Standards Act (FLSA). To minimize liability, employers should:

- ✓ Ensure that FMLA process is being followed when applicable for time off for an employee with COVID-19
- Ensure there are policies and training prohibiting working off the clock and providing reporting options if employees have worked off the clock
- ✓ Ensure that shift differentials or extra "hazard pay" are properly included in the regular rate of pay to calculate overtime pay
- ✓ Ensure following the appropriate interactive process under the ADA for accommodation, leave from work, or potential reassignment.



We are here to help.

While COVID-19 will be with us for the foreseeable future, we expect the situation to remain fluid as new information, policy, and guidance is released by government agencies and industry groups. For ongoing updates, we encourage you to visit our COVID-19 Center on our Disaster Prep and Recovery Blog.

For answers to your specific questions and solutions that address your unique needs and circumstances, please reach out to one of the designated Jones Walker attorneys below. You may also contact the firm at info@joneswalker.com.

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