Coronavirus (COVID-19) Legal Issues for Healthcare Organizations

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This practice note provides an overview of significant legal issues facing healthcare organizations as a result of coronavirus disease 2019 (COVID-19) and provides practical guidance for effectively managing those issues.

This practice note addresses the following topics:

- Immigration
- Emergency Medical Treatment and Labor Act (EMTALA)
- Food and Drug Administration and COVID-19 Testing
- Federal Waivers for Healthcare Payment Programs
- Health Insurance Portability and Accountability Act (HIPAA)
- Telehealth and Prescribing
- Licensure of Healthcare Providers
- Legal Immunity from Claims of Loss
- Clinical Trials
- Governmental Actions regarding Ventilators

Immigration

Your clients in the healthcare industry that employ individuals pursuant to immigrant and nonimmigrant visas must monitor and comply with applicable coronavirus-related travel restrictions, U.S. Citizenship and Immigration Services (USCIS), and Department of State (DOS) closures and suspensions of specific services.

Travel Restrictions

Several travel suspensions since the beginning of the coronavirus pandemic have resulted in tremendous chaos for healthcare workers, businesses, and many individuals and families with nonimmigrant visas and those at various stages of immigrant visa processing—resulting in a race to reenter prior to being barred. Among the travel suspensions that you should consider when advising your clients in the healthcare industry are the following:

- On Jan. 31, 2020, President Trump signed a proclamation generally suspending entry to the United States by foreign nationals who had traveled to China during the previous 14 days. The China travel suspension excludes U.S. citizens returning to the United States though it may require them to undergo a 14-day quarantine upon arrival.
- On Feb. 29, 2020, President Trump expanded the restrictions to include all foreign nationals who had traveled to Iran during the 14-day period prior to applying for admission to the United States.

- On March 11, 2020, President Trump announced the suspension of travel from the European Schengen area to the United States (updated on March 14, 2020 to include the United Kingdom and Ireland). The European / United Kingdom / Ireland travel suspension excludes U.S. citizens and Lawful Permanent Residents (Green Card Holders) who may return to the U.S. and will undergo screening upon arrival.

USCIS and DOS Temporary Suspensions

Temporary suspensions by USCIS and DOS since the start of the coronavirus pandemic have wreaked havoc on healthcare organizations, with doctors and other healthcare professionals stuck abroad and unable to apply for and/or renew their immigrant and nonimmigrant visas, and those in the U.S. who cannot attend a basic InfoPass appointment or interview for their green card.

Effective March 18, 2020, USCIS suspended all in-person services at its field offices, asylum offices, and Application Support Centers until at least April 7, 2020. The USCIS suspension includes all interviews, naturalization ceremonies, and biometric collection. Applicants and petitioners with scheduled appointments are receiving cancellation notices subject to rescheduling when operations resume. You should periodically review the USCIS website for any updates to this suspension time line.

Likewise, the DOS has temporarily suspended visa services at all U.S. embassies and consulates around the world. The embassies and consulates cancelled all immigrant and nonimmigrant visa appointments as of March 20, 2020. You should review individual embassy or consulate websites for specifics about the temporary closure.

I-9 Compliance Changes

As of March 20, 2020, the Department of Homeland Security (DHS), Immigration and Customs Enforcement (ICE), announced temporary flexibility relating to Form I-9 rules requiring employers to review workers' identity and employment authorization in their physical presence. This DHS announcement provides huge relief to healthcare employers, including health systems and others, by allowing for flexibility in onboarding (or the reverification process) while recognizing the reality that many employers and employees are taking (sometimes required) physical proximity precautions due to COVID-19. You and your clients must understand the requirements for remote onboarding, which are generally summarized below.

For employers and employees operating remotely due to COVID-19, the employer may generally inspect the Section 2 documents remotely, via video, email, etc., and must obtain copies of these documents within three business days for purposes of timely completing Section 2.

Among other requirements, once normal operations resume, employees onboarded using remote verification procedures must report to the employer within three business days for the employer to conduct an in-person examination of the original documents. It is important to note the above provision only applies to businesses operating remotely. In other words, there are no exceptions to the Form I-9 in-person verification of identity and employment eligibility requirements if there are employees physically present at the workplace unless the newly hired employee is subject to COVID-19 quarantine or shelter-in-place orders.

Healthcare Delivery and Public Charge Considerations

Earlier this year, the Inadmissibility on Public Charge Grounds final rule (the Public Charge rule) became effective and applicable to certain filings received by USCIS on or after Feb. 24, 2020. The Public Charge rule directly affects Applications for Adjustment of Status (I-485) along with many filings by or on behalf of foreign nationals who are in the U.S. seeking an extension of stay or change of status.

Specifically, the Public Charge rule requires USCIS to assess a foreign national's receipt of certain public benefits in determining whether the individual will become a public charge and therefore be deemed inadmissible and ineligible for admission or adjustment of status.

As counsel to healthcare organizations, you should understand that these changes to the definitions of public charge and public benefits will affect your clients during the current pandemic because they will leave many foreign

nationals leery of seeking medical care for COVID-19 due to the potential impact on their immigration status. In response to mounting concerns within the immigrant community, and a hesitation by those impacted by COVID-19 to seek necessary medical care, USCIS formally clarified that it will not consider screening, testing, treatment, or preventative care related to COVID-19 as part of the public charge inadmissibility determination applicable to immigrants or in relation to the public benefit condition applicable to certain nonimmigrants, even where the medical care is provided or paid for by one or more public benefits such as Medicaid. This USCIS announcement should provide some relief to affected foreign nationals who may have otherwise hesitated in seeking proper healthcare in reaction to COVID-19. The government also reminds affected individuals that receipt of public benefits is only one consideration among many that the USCIS assesses when analyzing the totality of circumstances for an applicant over a period of time. No single factor is determinative, meaning medical treatment related to COVID-19 alone will not lead to a negative determination.

In order to assist foreign nationals within the purview of the Public Charge rule, your client may recommend that they maintain comprehensive documentation of any medical care sought or received related to COVID-19 for submission, as relevant, with their immigrant or nonimmigrant application.

Emergency Medical Treatment and Labor Act (EMTALA)

EMTALA is a federal law that requires Medicare-participating hospitals and critical access hospitals that have a dedicated emergency department to, at a minimum:

- Provide a medical screening exam and to every individual who comes to the emergency department for examination or treatment for a medical condition to determine if they have an emergency medical condition
- Provide necessary stabilizing treatment for individuals with an emergency medical condition within the hospital's capability and capacity –and–
- Provide for transfers of individuals with emergency medical conditions, when appropriate

An emergency medical condition is present when there are acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expecte to result in serious impairment or dysfunction.

On March 9, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a statement clarifying the EMTALA obligations in the context of the COVID-19 pandemic. Essentially, the statement reinforced the basic EMTALA obligations of medical screening, stabilization, and ability to transfer or discharge when patient is stabilized.

Medicare-participating hospitals and critical access hospitals with dedicated emergency departments may not use signage that presents barriers to individuals who are suspected of having COVID-19 from coming to the emergency department. They may not refuse to provide an appropriate medical screening examination to anyone who has come to the emergency department for examination or treatment of a medical condition. However, they may use signage designed to direct individuals to various locations on the hospital property, in accordance with the regulations for their medical screening examination.

Subsequently, on March 13, 2020, the U.S. Department of Health and Human Services (HHS) waived EMTALA sanctions for the inappropriate redirection, relocation, or transfer of an individual if the redirection, relocation, or transfer is necessitated by the circumstances of the declared federal public health emergency for the COVID-19 pandemic. This EMTALA waiver will terminate either upon the termination of the national emergency, or 60 days from the date of the waiver, which may be extended by HHS.

For information about CMS COVID-19 guidance activity, see Coronavirus (COVID-19) Key CMS Regulatory Guidance Tracker.

Food and Drug Administration and COVID-19 Testing

Under the federal Food, Drug, and Cosmetic Act (FDCA), drug treatments, vaccinations, and diagnostic equipment testing for the presence of the virus must, by default, undergo the traditional FDA approval process. However, in certain emergency circumstances, the FDA has the authority to issue an Emergency Use Authorization (EUA) in order to adequately respond to a public health crisis.

Specifically, under Section 564 of the FDCA, the FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear threat agents when there are no adequate, approved, and available alternatives. On February 4, 2020, in accordance with EUA requirements, the HHS Secretary determined that there is a public health emergency and that circumstances exist that justify the authorization of emergency for a COVID-19 testing kit, which is considered to be a medical device. On February 29, 2020, FDA issued a guidance that allowed certain laboratories to begin to use validated COVID-19 testing before concluding its review for its issuance of an EUA.

The FDA further updated its policies to achieve more rapid testing capacity for the coronavirus in its Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency published March 16, 2020 (Policy).

The Policy specifically addresses options for laboratories and commercial manufacturers to help accelerate the use of tests developed in order to achieve more widespread testing capacity in the United States. In particular, the Policy provides the following:

- The FDA does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an EUA, under certain circumstances.
- A state or territory choosing to authorize laboratories within that state or territory to develop and perform a test for COVID-19 may do so under authority of its own state law, and under a process that it establishes, without any engagement with the FDA. The FDA does not intend to object to the use of such tests and does not require that test validation be submitted to the FDA, nor does it require that an EUA be submitted to the FDA.
- There are two options for commercial manufacturers developing COVID-19 testing for clinical laboratories or for point-of-care settings:
    - o First, if the test is a serological test (i.e., it measures the amount of antibodies or proteins present in the blood when the body is responding to a specific infection), the FDA has taken the position that it will not object to the distribution, so long as (1) the test has been validated, (2) notification has been provided to the FDA, and (3) disclaimer language is included on the test noting that the test has not been reviewed by the FDA.
    - o Second, if the test is anything other than a serological test (i.e., antigen detection, molecular, etc.), the distributor must provide assay validation with their notification to the FDA, then submit a complete EUA within 15 business days.

      If the FDA is not able to authorize an EUA, the FDA intends to notify the manufacturer and the manufacturer must suspend distribution and conduct a recall of the test.

You should review the FDA's website to track ongoing developments with respect to the FDA's EUA policy.

For detailed information about the EUA process, see FDA Emergency Use Authorizations.

Federal Waivers for Healthcare Payment Programs

When the president declares a disaster or emergency under the Stafford Act or National Emergencies Act and the HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act, the secretary is authorized to take certain actions in addition to his or her regular authorities.

In addition, under Section 1135 of the Social Security Act, HHS may grant waivers, commonly referred to as "1135 waivers," from certain regulatory requirements. These 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, unless the HHS Secretary extends the waiver by notice for additional periods of up to 60 days, until the end of the emergency period.

The 1135 waiver authority applies only to federal requirements and does not apply to state requirements for licensure or conditions of participation. There are blanket waivers that apply without need of a formal request and justification by the respective state governor. All other waivers must be requested by the respective state's governor with justification. For further information about these waivers, see this CMS At-a-Glance publication.

On March 13, 2020, CMS released information on the blanket waivers available to providers. These include, among other things, waivers of:

- The three-day prior hospitalization requirement for coverage of a skilled nursing facility stay –and–
- Face-to-face visits, new physician's order, or medical necessity requirements for replacement of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS) when the DMEPOS is lost, destroyed, or damaged

The March 13 waiver, effective on March 15, 2020, applies nationwide and its applicability is retroactive to March 1, 2020. It applies for a period of 60 days, subject to extension by the secretary for successive 60-day periods or for the duration of the COVID-19 national emergency (if earlier).

In addition, and importantly for healthcare organizations, states can request permission for the following:

- To waive prior authorization requirements in fee-for-service programs
- To permit providers located out of state/territory to provide care to another state's Medicaid enrollees impacted by the emergency
- To temporarily suspend certain provider enrollment and revalidation requirements to increase access to care
- To temporarily waive requirements that physicians and other healthcare professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state –and–
- To temporarily suspend requirements for certain preadmission and annual screenings for nursing home residents

For additional information about the March 13 waiver, see this CMS Fact Sheet.

Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that among other things, protects the confidentiality of protected health information (PHI) in the hands of healthcare providers, health insurance organizations, and medical information clearinghouses that conduct electronic transactions (together, Covered Entities).

On February 3, 2020, HHS released a bulletin entitled HIPAA Privacy and Novel Coronavirus, in which it outlined the various ways that PHI related to COVID-19 may be disclosed without patient authorization.

More notably, however, on March 17, 2020, the HHS Office for Civil Rights (OCR), the enforcement agency for HIPAA, published a Notice of Enforcement Discretion relating to the use of telehealth remote communications by healthcare providers.

Although HIPAA requires all Covered Entities to ensure the confidentiality and security of patient information, HIPAA does not specifically require encryption or explicitly prohibit use of certain technologies. Nevertheless, most HIPAA Covered Entities recognize that the lack of encryption and other security protections strongly discourage the use of unsecured audio/video communications apps. In other words, while it is not technically true that HIPAA

prohibits the use of Skype, FaceTime, and similar modalities, most providers have determined that their HIPAA safeguards and standards would not allow it.

Under its March 17th notice, OCR will "exercise enforcement discretion and not impose penalties for noncompliance with regulatory requirements under the HIPAA rules against covered healthcare providers in connection with the good-faith provision of telehealth during the COVID-19 nationwide public health emergency." In other words, while the OCR is exercising its enforcement discretion (i.e., during the time the COVID-19 national public health emergency is in effect), healthcare providers may use Skype, FaceTime, Zoom, Doxy.me, Updox, VSee, Google G Suite Hangouts Meet, and similar technologies for real-time audio/video communications with their patients, without fear that OCR might levy a penalty.

It is important for you and your clients to note that communication need not be about treatment of COVID-19; a provider can use Skype to "see" a patient with anxiety, a sprain, etc. The goal of OCR's exercise of enforcement discretion is to keep patients out of emergency rooms. Your client should also be aware of the following:

- Providers should get the consent of patients before using the technology. The consent should be obtained only after the provider advises the patient of the risks involved in using less-secure technologies.
- The decision to use the technology must be in good faith, which means after considering the availability of safer alternatives.
- The technology must be private and cannot be public-facing; Facebook Live, Twitch, TikTok, and the like are not covered by this enforcement discretion.
- Providers who use these apps should enable encryption and set privacy settings to the highest practical level.
- While the requirement to obtain a HIPAA-compliant business associate agreement (BAA) with the app provider is also waived, Covered Entities should obtain BAAs with those app providers if possible.

The general rule remains that HIPAA does not go away during a crisis or emergency. To seasoned HIPAA professionals, OCR's action highlights the flexibility that is inherent in HIPAA: what is a reasonable safeguard in normal times might be too tight a restriction during an emergency. While providers could have been using Skype in certain circumstances (i.e., telehealth communication was extremely urgent and no other safer technology could be reasonably implemented), OCR's action allows more providers to at least feel comfortable with using these technologies.

OCR's March 17th notice followed an announcement by HHS on March 16 that provided all relief from certain other HIPAA requirements in limited situations. Unlike the OCR's March 17th notice, however, HHS's announcement was specifically limited to HIPAA-covered hospitals that (1) are in the emergency area identified in the public health emergency declaration, (2) institute a disaster protocol, and (3) for up to 72 hours from the time the hospital implements its disaster protocol. Additionally, the HHS announcement only waives five specific HIPAA obligations:

- The requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care (45 C.F.R. § 164.510(b))
- The requirement to honor a request to opt out of the facility directory (45 C.F.R. § 164.510(a))
- The requirement to distribute a notice of privacy practices (45 C.F.R. § 164.520)
- The patient's right to request privacy restrictions (45 C.F.R. § 164.522(a))
- The patient's right to request confidential communications (45 C.F.R. § 164.522(b))

For additional information about HIPAA and COVID-19, see HHS Addresses HIPAA Privacy and Security Rule Issues in Combatting Coronavirus.

Telehealth and Prescribing

On March 17, 2020, CMS released a Fact Sheet in which it broadened access to Medicare telehealth services when it allowed Medicare patients to receive more services from their doctors without travel to a healthcare facility. This benefit is available on a temporary and emergency basis under the 1135 waiver authority and the Coronavirus Preparedness and Response Supplemental Appropriations Act to provide telemedicine services during the national emergency declared regarding COVID-19.

Before this CMS waiver, Medicare paid only for telehealth when the patient was in a designated rural area and left the home and went to a clinic, hospital, or certain other types of medical facilities for the service.

During the pendency of the declaration of the public health emergency (PHE) declared by the HHS Secretary, Medicare can pay for office, hospital, and other visits furnished via telehealth across the country including in patient's places of residence, retroactive to March 6, 2020. The PHE will last until the earlier of the following: (1) the secretary declares that the PHE no longer exists or (2) the expiration of the 90-day period beginning on the date the secretary declared a PHE exists or any subsequent renewal periods. You should periodically check to determine whether the PHE is still in effect.

As a result of the Medicare telemedicine payment policy, a range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, will be able to offer telehealth to their patients. Additionally, the HHS Office of Inspector General (OIG) is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.

Also, effective immediately, the OCR will exercise enforcement discretion and waive penalties for HIPAA violations against healthcare providers that serve patients in good faith through communications technologies, such as FaceTime or Skype, during the COVID-19 nationwide public health emergency.

One day earlier, on March 16, 2020, the requirements of the Ryan Haight Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 802 (Ryan Haight Act), that relate to telemedicine and opioid prescribing were suspended based upon the public emergency exception contained within the act. Accordingly, the determination that a public health emergency exists that allows this exception must be made by the HHS Secretary with the concurrence of the Administrator of the Drug Enforcement Agency (DEA). The DEA published a Q&A that included COVID-19 guidance on its website.

The Ryan Haight Act was intended to stop the selling of controlled substances through online pharmacies by generally requiring a provider to conduct an in-person examination of any person seeking a prescription for such substances.

The action by HHS suspends the requirements for all schedule II–V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the HHS Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II–V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.
- The telemedicine communication is conducted using an audiovisual, real-time, two-way interactive communication system. –and–
- The practitioner is acting in accordance with applicable federal and state laws.

Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for schedules II–V), by calling in an emergency schedule II prescription to the pharmacy, or by calling in a schedule III–V prescription to the pharmacy.

The term "practitioner" in this context includes a physician, dentist, veterinarian, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to prescribe controlled substances in the course of his/her professional practice (21 U.S.C. § 802(21)).

For additional information about telehealth transactions, see Telemedicine and Digital Health: Strategic Opportunities and Legal Considerations for Private Equity Investment.

Licensure of Healthcare Providers

Given limitations on a patient's ability to travel (sometimes out of state) for medical care and the projected need for additional healthcare providers during the COVID-19 pandemic, CMS determined in its March 17th Fact Sheet that it would "[t]emporarily waive requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. This applies to Medicare and Medicaid."

The Federation of State Medical Boards (FSMB), which through its Physician Data Center (PDC), states are able to instantly verify licensure information and disciplinary history for licensed physicians and physician assistants, released a statement on March 13, 2020, offering its assistance to verify licenses and credentials for physicians and other healthcare professionals wishing to practice across state lines to treat patients in areas heavily impacted by the COVID-19 virus:

> The PDC is continuously updated and is the most comprehensive repository of physician licensure information in the country. With an increase of physicians moving into impacted areas and practicing remotely through telehealth, the PDC is a resource to expedite care while ensuring patients are receiving high-quality care.

Some states have substantially loosened requirements to encourage healthcare providers to be available for that state's citizens. For example, the Florida Surgeon General of the Florida Department of Health issued Emergency Order 20-002 on March 16, 2020, that relaxes certain licensure and practice standards for 30 days (which may be extended). It allows healthcare professionals, advanced life support professionals, and basic life support professionals with valid unrestricted licenses in states outside Florida to provide care for patients in Florida without Florida licensure. It allows medical doctors, osteopathic physicians, physician assistants, and nurse practitioners with valid unrestricted licenses in other states to provide care to Florida residents via telehealth, although Florida's telehealth practice standards requirements in Florida Statues Section 456.47(4) must still be met.

The FSMB has published a list of States Waiving Licensure Requirements/Renewals in Response to COVID-19 on its website, and the list shows the status in the various states as to licensure of healthcare professionals.

Legal Immunity from Claims of Loss

Federal Immunity

On March 17, 2020 the HHS Secretary issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures) used to fight COVID-19, except for claims involving willful misconduct (the Declaration). Although issued on March 17, 2020, the Declaration was stated to be effective as of February 4, 2020, with protections in place until October 1, 2024.

This Declaration was issued to support innovation by healthcare, pharmaceutical, medical device, and public health professionals to combat COVID-19, as there is a concern that action taken now could be questioned later after the crisis has passed. Covered Persons under the PREP Act includes manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. To protect also healthcare workers, the Declaration expands the PREP Act's definition of "qualified person" to include:

- Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures, and their officials, agents, employees, contractors, and volunteers, following a Declaration of an emergency
- Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an EUA in accordance with Section 564 of the FDCA – and–
- Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FDCA

Covered Persons are covered with regards to use of Covered Countermeasures, which are any antiviral; any other drug or biologic; any diagnostic; any other device; or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19 or a virus mutating therefrom, including any device or component part or its constituent materials of any such product.

However, immunity only applies to activities conducted pursuant to either:

- Present or future federal contracts, cooperative agreements, grants, other transactions . . . or other federal agreements –or–
- Activities authorized in accordance with . . . the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures . . .

Scrutiny as to whether immunity exists will be determined on a case-by-case basis. There is a rebuttable presumption that the administration or use of a covered countermeasure was for the threat covered by the Declaration, and thus, to succeed, a plaintiff will have to produce evidence to overcome the presumption that the covered person is not entitled to immunity.

State Immunity

Keep in mind that it is possible for states to also give immunity against actions that may be brought under state law. For example, in New York, the New York Governor's Executive Order No. 202.10 issued on March 7, 2020, provided greater immunity through its waiver of certain sections of the New York State Education Law "to the extent necessary to provide that all physicians, physician assistants, specialist assistants, nurse practitioners, licensed registered professional nurse, and licensed practical nurses shall be immune from civil lability for any injury or death alleged to have been sustained directly as a restful of an act or omission by such medical professional in the course of providing medical services in support of the state's response to the COVID-19 outbreak, unless it is established that such injury or death was caused by the gross negligence of such medical professional." Practitioners should check their respective state executive orders or changes in law during the emergency to ascertain the existence and extent of any liability immunity provisions.

Clinical Trials

Many healthcare providers, particularly academic medical centers, are involved in clinical trials. Recognizing that quarantines, travel limitations, and interruptions to the supply chain, among other factors, may impact clinical trials, the FDA, on March 18, 2020, issued a Guidance entitled FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic.

The Guidance had a number of considerations for going trials, including the following:

- Any modifications of study conduct should be based upon the safety of the participants, whether continuing trial recruitment, continuing use of the investigational product for patients already participating in the trial, and the need to change patient monitoring during the trial.

- Sponsors should evaluate whether it is necessary for a trial participant to come in person to the trial site, or whether safety assessments may be conducted through other means such as phone contact, virtual visit, or alternative location for assessment.
- In some cases, trial participants who no longer have access to investigational product or the investigational site may need additional safety monitoring (e.g., withdrawal of an active investigational treatment).
- The IRB/IEC should be engaged as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. However, COVID-19 screening procedures that may be mandated by the healthcare system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol unless the sponsor is incorporating the data collected as part of a new research objective.
- Documentation of the basis for any missing information (e.g., due to missed visits) is key.

For all trials impacted by the COVID-19 pandemic, sponsors should describe the following in appropriate sections of the clinical study report (or in a separate study-specific document):

- Contingency measures to manage the study
- All participants affected –and–
- The impact of implemented contingency measures on the safety and efficacy results reported for the study

Governmental Actions regarding Ventilators

Given that one of the most serious symptoms of COVID-19 (in a small percentage of cases) is shortness of breath and ability to maintain normal oxygen levels, the federal government has taken action to ensure that a sufficient number of ventilators exist for patients that may need them.

The FDA on March 22, 2020, issued a policy titled Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency – Guidance for Industry and Food and Drug Administration Staff. The policy is in effect during the public health emergency related to COVID-19, as determined and renewed by HHS.

Wherever possible, healthcare facilities should use FDA-cleared conventional/standard full-featured ventilators when necessary to support patients with respiratory failure, or a device subject to an EUA, if any.

However, to help ensure the availability of the greatest possible number of devices for this purpose, the FDA does not intend to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency. This allows use of ventilators outside their cleared environment of use (e.g., use of a ventilator in a healthcare facility when it is only cleared for use at home or during transport, or use of devices indicated for sleep apnea (including noncontinuous ventilators delivering continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP)) to treat patients with respiratory insufficiency), provided that appropriate design mitigations are in place to minimize aerosolization. Other modifications notified as allowed are introduction of filtration to minimize aerosolization, or hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters (i.e., adjustment of parameters by trained healthcare providers from outside an isolation unit to avoid unnecessary exposures).

The FDA also stated that strategic stockpilers of authorized expired filtering facepiece respirators (FFRs) do not need to submit a request to the FDA to request authorization, and to allow use of decontaminated respirators that have been decontaminated in accordance with the terms and conditions of an authorized decontamination system.

With respect to the availability of ventilators, it should also be noted that although there have been no documented instances of a shortage of ventilators at the time of writing of this article, there is a concern that such could occur. The law as to end of life care differs from state to state, but an interesting reference point is a November 2015

report by the New York State Task Force on Life & the Law New York State Department of Health called Ventilator Allocation Guidelines.

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