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<u>Frequently Asked Questions from Health Care Providers</u> <u>Re: COVID-19 and Legal Obligations</u> *As of March 19, 2020*

Health care providers will continue to receive instructions, guidance and recommendations on how to handle the COVID-19 pandemic from the Centers for Disease Control and Prevention ("CDC"), the U.S. Department of Health and Human Services ("HHS"), state and local health departments and other governmental agencies.¹ As our country navigates this new environment, our Dickinson Wright health care law attorneys are actively assisting health care providers with understanding their legal obligations on matters relating to the COVID-19 pandemic. This document sets forth frequently asked questions from health care providers regarding these legal obligations and our recommendations. We will update this article as laws, orders and other rules continue to change in response to the COVID-19 pandemic.

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¹ On March 11, 2020, the World Health Organization ("WHO") declared COVID-19, the disease caused by the coronavirus, a pandemic. As this situation continues developing, the guidelines in this article will be updated by our health care attorneys and re-posted. These guidelines should not be used in lieu of a comprehensive emergency preparedness plan as providers should consult the most up-to-date guidance issued by the Centers for Disease Control and Prevention ("CDC"), the U.S. Department of Health and Human Services ("HHS"), and state and local health departments.

See, CDC Guidance on the Steps Health care Facilities can take: https://www.cdc.gov/coronavirus/2019-ncov/health care-facilities/index.html

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1. What steps must my facility or practice take to reduce exposure to patients within the medical office or facility?

Providers have a legal obligation to comply with the standard of care and use all reasonable care in reducing/minimizing their patients' exposure to communicable diseases within their own health care office.² In furtherance of this standard, providers must closely review all risk assessment guidance published by state and federal public health authorities on public health management of persons with potential COVID-19 exposures. Providers should follow the guidelines to the extent reasonably possible under the circumstances and comply with at least industry standard precautions to minimize the risk of inadvertent transmission of COVID-19 within a provider's off, including for example:

- Place appropriate signage on the front doors of the office, at the front desk and at key locations throughout (such as, elevators) to provide patients with instructions as to appropriate hand hygiene and social distancing etiquette.
- Institute and train personnel on patient triage and screening protocols for every patient that enters the office.
- Ensure that a patient's travel history is received at check-in
- Install physical barriers between triage areas and potentially infectious patients. Identify a separate, well-ventilated space that allows waiting patients to be separated by six or more feet, with easy access to hygiene supplies. Providers should allow medically stable patients to wait in a personal vehicle or outside the health care provider's office where they can be contacted by mobile phone when it is their turn to be evaluated. Some practices may be able to establish areas within or outside of the office as screening areas, to evaluate potentially infectious patients separate from other patients and/or visitors.

² See also CDC guidelines, at https://www.cdc.gov/coronavirus/2019-ncov/health care-facilities/index.html

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- Health care providers should also determine whether it is possible to create an airborne isolation infection room for patients suspected to have been infected with COVID-19. At a minimum, providers should place such patients in a private room with a facemask on and door closed. The private room's air should not be recirculated without appropriate HEPA filtration.
- Develop a phone triage protocol when a patient calls with suspected symptoms.
- Promptly and properly disinfect all waiting and patient treatment rooms. Ensure that cleaning staff are following consistent and correct cleaning and disinfection procedures (such as using a EPA-registered, hospital-grade disinfectant with an emerging viral pathogens claim).
- Reschedule non-urgent visits when necessary and possible, including for patients in vulnerable populations (e.g., people 65 or older, those with compromised immune systems, pregnant women, etc.). Practices should also consider eliminating penalties for cancellation or missed appointments by patients, to encourage patients not in urgent need of care to stay home.

2. What steps is my practice legally required to take to reduce COVID-19 exposure to our workforce members?³

Under the Occupational Safety and Health Administration ("OSHA"), employers have a duty to provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm." OSHA has also set up a site to help employers prepare for a potential coronavirus outbreak: https://www.osha.gov/SLTC/covid-19/. Developing a plan now to address a potential coronavirus outbreak in the U.S. may help to keep employees healthy, alleviate public concern, and reduce corporate liability. Employees of health care providers are in a particularly precarious position with respect to the COVID-19 pandemic.

The CDC has developed interim guidance specifically for businesses and employers to reduce transmission and prepare for potential consequences related to the spread of the coronavirus.⁴ Recommended corporate actions include the following:

³ Response to this question is in coordination with Dickinson Wright's employment and labor law attorneys. In particular, see Coronavirus (COVID-19) Precautions for Employers, at http://healthlawblog.dickinson-wright.com/2020/03/coronavirus-covid-19-precautions-for-employers/

⁴ Employers are encouraged to study the CDC's guidance for businesses and employers available on the CDC's webpage: <u>https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/guidance-business-response.html</u>

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- Actively encourage sick employees or employees with sick family members to stay home. Encourage telecommuting for all positions possible;
- Test employees involved in patient care if symptoms warrant as provided herein;
- Send home employees who are sick or who become sick during the workday;
- Educate employees on coronavirus risk assessments and encourage sick employees to seek medical care;
- Ensure sick leave policies are flexible and consistent with federal, state, and local laws and guidance. Do not discipline employees who are absent due to illness or care for sick family members (note that legislation is proposed and/or pending across the U.S. to provide for additional paid sick leave for employees). Understand that you may have to make policy exceptions for unique situations;
- Provide awareness of modified, suspended, or active sick leave policies to employees immediately and often;
- Educate employees on respiratory etiquette (cough and sneeze cover) and hand hygiene (printable resources are available on the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/communication/factsheets.html);
- Perform additional and special routine environmental cleaning and provide disposable wipes for employee cleaning use during the day. Encourage cleaning stations at the beginning and end of each day and between all shift changes;
- Comply with travel bans. Cancel all non-essential business travel, including domestically. Discourage all employee personal travel. https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html.
- Cancel all non-essential large work-related meetings or events. Gatherings over 250 people are prohibited; more narrow restrictions are expected;
- Identify essential business functions, jobs or roles, and elements within your supply chains required to maintain business operations. Plan for how your business will operate if there is increasing absenteeism or supply chains are interrupted; and

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- Create (or refresh) an infectious disease outbreak response plan in writing now, recognizing that the plan's scope and procedures may vary depending on unique business operations and needs.
- Prepare to equip your workforce to handle increasingly high volumes of patient needs and plan for increased coverage accordingly.

Health care providers in particular should take action to determine whether they have sufficient personal protective equipment on hand for their staff and ensure that staff is properly trained on the use of the equipment (including how to don and doff the equipment). Such equipment includes respirators, fit-tested N95 mask or PAPR or better, gloves, gowns, goggles, and face shields. Instruct staff on the proper manner of donning and doffing such equipment.

When performing procedures that could produce or induce coughing or collecting specimens, health care providers must proceed with caution and should instruct employees to wear an N95 or higher respirator, eye protection, gloves, and gowns. The number of providers necessary to perform the procedure should be limited to minimum necessary and others, including family members, should not be present.

3. What controls over access to our office or facility are legally required or permissible?

Health care providers who submit claims to federal health care programs are required by law to develop access policies and procedures. It is recommended that all visitors be screened for symptoms of respiratory illness (e.g., coughing, fever, etc.) prior to being permitted to enter the office. Facilities, such as hospitals, should encourage alternatives to in-person visitations (e.g., telehealth, as set forth below) whenever possible and appropriate.

With respect to nursing homes, on March 13, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued guidance to all nursing homes on restricting visitation of all visitors and non-essential health care personnel, except for certain compassionate care situations, such as end-of life situations. It is likely that CMS will issue further guidance to other types of facilities and providers on access controls.

On March 18, 2020, the CDC published additional guidelines for preparing healthcare facilities for patients with possible COVID-19.⁵

⁵ <u>https://www.cdc.gov/coronavirus/2019-ncov/downloads/Clinic.pdf</u>



Many states have instituted specific rules surrounding controlling the access to medical offices and facilities. Check with your health care attorney to understand these state specific rules.

4. What services should no longer be performed during the COVID-19 outbreak?

On March 18, 2020, CMS announced that all non-essential planned surgeries and procedures, including dental, should be postponed until further notice.⁶

As part of this notice, CMS implemented a tiered framework to inform health systems as they consider resources and how best to provide surgical services and procedures to those whose condition requires emergent or urgent attention to save a life, preserve organ function, and avoid further harms from underlying condition or disease. Decisions remain the responsibility of local healthcare delivery systems, including state and local health officials, and those surgeons who have direct responsibility to their patients. However, in analyzing the risk and benefit of any planned procedure, CMS states that not only must the clinical situation be evaluated, but resource conservation must also be considered. These recommendations are meant to be refined over the duration of the crisis based on feedback from subject matter experts. At all times, the supply of personal protective equipment (PPE), hospital and intensive care unit beds, and ventilators should be considered, even in areas that are not currently dealing with COVID-19 infections. Therefore, while case-by-case evaluations are made, CMS suggests that the following factors to be considered as to whether planned surgery should proceed:

- Current and projected COVID-19 cases in the facility and region. (consider the following tiered approach in the table below to curtail elective surgeries. The decisions should be made in consultation with the hospital, surgeon, patient, and other public health professionals.
- Supply of PPE to the facilities in the system
- Staffing availability
- Bed availability, especially intensive care unit (ICU) beds
- Ventilator availability

⁶ <u>https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf</u>

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- Health and age of the patient, especially given the risks of concurrent COVID-19 infection during recovery
- Urgency of the procedure.

Tiers	Action	Definition	Locations	Examples
Tier 1a	Postpone	Low acuity	HOPD*	-Carpal tunnel
	surgery/	surgery/healthy	ASC**	release
	procedure	patient-	Hospital with	-EGD
		outpatient surgery	low/no COVID-	-Colonoscopy
		Not life threatening illness	19 census	-Cataracts
Tier 1b	Postpone surgery/	Low acuity	HOPD	-Endoscopies
	procedure	surgery/unhealthy	ASC	
		patient	Hospital with	
			low/no COVID-	
			19 census	
Tier 2a	Consider	Intermediate acuity	HOPD	-Low risk cancer
	postponing	surgery/healthy	ASC	-Non urgent
	surgery/procedure	patient-	Hospital with	spine & Ortho:
		Not life threatening	low/no COVID-	Including hip,
		but potential for	19 census	knee
		future morbidity and mortality.		replacement and elective spine
		Requires in-hospital		surgery
		stay		-Stable ureteral
				colic
				-Elective
				angioplasty
Tier 2b	Postpone surgery/	Intermediate acuity	HOPD	
	procedure if	surgery/unhealthy	ASC	
	, possible	patient-	Hospital with	
			low/no COVID-	
			19 census	

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Tier 3a	Do not postpone	High acuity surgery/healthy patient	Hospital	-Most cancers -Neurosurgery -Highly symptomatic patients
Tier 3b	Do not postpone	High acuity surgery/unhealthy patient	Hospital	-Transplants -Trauma -Cardiac w/ symptoms -limb threatening vascular surgery

5. What steps can my practice take to better protect my patients and workforce members in a shared office building that we do not own?

If a health care provider is located in a shared office building having space in common with other tenants, it is important to discuss with the landlord the full extent of what can be done within the building to further protect its patients and workforce. It is important to note the Lease may be silent in this respect. For example, the health care provider should discuss with the property owner the following:

- Whether the property owner or landlord will agree to limit access entry points into the building and direct all visitors into a specific entrance;
- Temperature checks of all visitors entering the building (not just the health care provider's patients);
- Enhanced cleaning efforts such as frequent sanitization of common areas, bathrooms and elevators, which are not otherwise under the health care provider's control.

In these situations, we believe the best approach would be a shared obligation between the health care provider, the property owner/landlord and other businesses located within the same building.

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6. When does HIPAA allow health care providers to share information about patients suspected or confirmed to have COVID-19?⁷

The Privacy Rule of the Health Insurance Portability and Accountability Act of 2006 (the "HIPAA Privacy Rule"), to the extent applicable to your practice⁸, sets forth strict rules surrounding when health care providers may share identifiable information relating to their patients (such as name, address, medical record number, and any other information that may reasonably lead to identification of the patient). However, there are several situations where the HIPAA Privacy Rule will permit disclosures relating to cases of COVID-19 when necessary, including:

- To public health authorities, such as the CDC or a state or local health department, that are authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability. This allows health care providers to disclose to the CDC and their local health authorities information needed to report all cases of patients exposed to or suspected or confirmed to have COVID-19.
- To disaster relief organizations that, like the American Red Cross, are authorized by law or by their charters to assist in disaster relief efforts, for the purpose of coordinating the notification of family members or other persons involved in the patient's care, of the patient's location, general condition, or death.
- As necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public consistent with applicable law (such as state statutes, regulations, or case law) and the provider's standards of ethical conduct. Under this, providers may disclose a patient's health information to anyone who is in a position to prevent or lesson the serious and imminent threat, including family, friends, caregivers, and law enforcement without a patient's permission. The HIPAA Privacy Rule expressly defers to the professional judgment of health professionals in making determinations about the nature and severity of the threat to health and safety. It is advised that such a determination be made in coordination with legal counsel.

⁷ If you are not a health care provider but become aware of a case or suspected case of COVID-19, you should contact the local health department regarding the recommended steps as to when and how it is recommended you notify others and/or identify the person at issue.

⁸ The determination of whether HIPAA applies to a health care provider requires an analysis of the definition of "Covered Entity" under HIPAA. Many, but not all, providers of health care services are Covered Entities under HIPAA.

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- To family, friends and others involved in the patient's care who have been identified by the patient as involved in his or her care. Ideally, health care providers have secured from the patient a written list of those individuals on the patient's intake form. Health care providers may also rely on verbal list of those individuals (and in such situation it would be best for the provider to incorporate that verbal list into the patient's medical record). Otherwise, if necessary the health care provider may make a disclosure if the health care provider is able to reasonably infer that the patient would not object to disclosure to family, friends or others whom the health care provider is aware has been involved in the patient's care.
- Regarding patients who are unconscious or incapacitated, health care providers may share certain minimum and relevant information with the patient's family, friends, or others involved in the patient's care or payment for care, if the health care provider determines, based on professional judgment, that doing so is in the best interests of the patient.
- Also as a reminder, disclosures to other health care providers are permitted when necessary to treat the patient or a different patient. This includes, by way of example, coordinating or managing health care and related services by one or more health care providers, consulting between providers and referring patients for treatment for COVID-19.

7. When are we legally required to report a case or suspected case of COVID-19?

The legal obligation to report, and parameters around that reporting, is specific to each state. Generally, providers (such as physicians and clinical laboratories) are required to report known or suspected cases of COVID-19 to the appropriate local health department. Providers must ensure they have plans in place to work with and report to public health authorities. Reach out to your health care attorney if you have any questions on whether, when or how to make such a report.

8. How can we promote the use of a telehealth program to curb the spread of COVID-19?

The use of telehealth technology for providing health care services implicates various laws, regulations, licensing, and payor billing and reimbursement rules. However, the recent passage of new laws and orders surrounding telehealth for the purpose of curbing the COVID-19 outbreak will start to make it easier to use telehealth at this time. For example:

• On March 6, 2020, Congress signed the Coronavirus Preparedness and Response Supplemental Appropriations Act which grants the Secretary of HHS power to dismiss

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telehealth restrictions for Medicare beneficiaries. Policymakers intended for the law to create a new pathway for seniors to receive care during COVID-19.

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- On March 10, 2020, CMS issued a Memorandum to permit Medicare Advantage Organizations to waive or reduce enrollee certain cost-sharing for beneficiaries impacted by the outbreak. CMS also authorized Medicare Advantage Organizations to provide access to telehealth services in any geographic area and a variety of places, including beneficiaries' homes. CMS also advised Part D Sponsors that they may relax "refill-toosoon" edits if circumstances are reasonably expected to result in disruption in access to medications and relax policies restricting mail or home delivery. CMS also authorized Part D sponsors to reimburse enrollees for prescriptions obtained from out-of-network pharmacies. For Medicare Advantage Organizations and Part D sponsors, plans may authorizations choose to waive prior for medications or services. https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf. These actions are considered permissive on the part of Medicare Advantage Organizations and Part D sponsors, not required at this time.
- On March 13, 2020, President Donald Trump in response to the COVID-19 Pandemic declared a national emergency to open access to up to \$50 billion in funding for states, territories and localities. President Trump requested every hospital to activate emergency preparedness plans to meet the needs of patients. Additionally, President Trump issued broad new authority to the Secretary of HHS to immediately waive provisions of applicable laws and regulations to give doctors, all hospitals and health care providers maximum flexibility to respond to the virus and care for patients. This broad new authority and funding will likely impact the use of and laws surrounding telehealth services.
- Many states have issued specific rules and orders in an effort to expand the use of Telehealth at this time.
- On March 17, 2020, effective immediately, the OCR announced its Notification of Enforcement Discretion on telehealth remote communications during the COVID-19 nationwide public health emergency.⁹ The OCR will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith

(Notification of Enforcement Discretion)

⁹ <u>https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html</u> (Press Release); <u>https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html</u>

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provision of telehealth during the COVID-19 nationwide public health emergency. Note that "[t]his exercise of discretion applies to telehealth provided for any reason, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19." This includes telehealth services for a sprained ankle, dental consultation or psychological evaluation, for example.

- The following applications may be used for video communication with patients *without risk that OCR might seek to impose a penalty for noncompliance* if used in good faith:
 - Apple FaceTime
 - Facebook Messenger video chat
 - Google Hangouts video
 - Skype
- Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications."
 - Under the Notice, the following, however, **<u>should not</u>** be used for telehealth services:
 - Facebook Live
 - Twitch
 - TikTok
 - Similar video communication applications that are public facing
 - The following list includes some vendors that represent they provide HIPAA-compliant video communication products and that they will enter into a HIPAA BAA (these BAA's have not been reviewed by OCR and the OCR does not endorse them):
 - Skype for Business
 - Updox
 - VSee



- Zoom for Healthcare
- Doxy.me
- Google G Suite Hangouts Meet

Telehealth is particularly well suited for initial screening of patients and providing quicker and safer access to providers. Telehealth includes for example, the use of real-time video interaction, "store and forward" technology, remote patient monitoring or online chat groups and internet sites, provided that HIPAA privacy and security rules still apply. When using these technologies a health care provider must ensure HIPAA compliant security levels (for example, the use of Skype is not likely to be considered HIPAA compliant) to avoid inadvertently triggering a breach under the HIPAA rules.¹⁰

The CDC has issued the following guidelines on promoting the increased use of telehealth:

- Health care facilities can increase the use of telephone management and other remote methods of triaging, assessing and caring for all patients to decrease the volume of persons seeking care in facilities.
- If a formal "telehealth" system is not available, health care providers can still communicate with patients by telephone (instead of visits), reducing the number of those who seek face-to-face care.
- Health plans, health care systems and insurers/payors should message beneficiaries to promote the availability of covered telehealth, telemedicine, or nurse advice line services

9. What should be done with regard to developing or revising my emergency preparedness plan?

It is necessary for every health care provider to develop, review and follow an emergency preparedness plan with respect to the COVID-19 pandemic. In fact, CMS now requires all

¹⁰ To date, no law or order has been issued that would specifically change a health care provider's HIPAA privacy and security obligations surrounding the use of technology to share protected health information with respect to COVID-19.

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Medicare participating providers and suppliers to implement emergency preparedness regulations.¹¹ Such plans should be developed in coordination with legal counsel.

Dickinson Wright Health Care Law attorneys are able to assist with developing, reviewing and/or revising your emergency preparedness plan in the wake of the COVID-19 pandemic.

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¹¹ See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule