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Complying with HIPAA, EMTALA and the Public Health Overlay During the COVID-19 Crisis

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On March 13, 2020, U.S. Department of Health and Human Services (HHS) Secretary Alex Azar waived certain regulatory requirements in response to the COVID-19 crisis. U.S. HEALTH & HUMAN SERVICES, *Waiver or Modification of Requirements Under Section 1135 of the Social Security Act,* PHE.GOV (Mar. 13, 2020). Prior to this authorization, the Centers for Medicare & Medicaid Services (CMS) and Office for Civil Rights (OCR) released guidance reiterating the role of existing privacy laws and emergency preparedness standards as an effective framework for navigating the COVID-19 crisis. Moving forward, providers must consider the effect of the waivers and the implications of the guidance in their response to COVID-19 because the public health overlay significantly affects their regulatory compliance obligations.

UNDERSTANDING THE IMPLICATIONS OF THE COVID-19 CRISIS AND THE HIPAA WAIVER

OCR issued a bulletin on February 3, 2020 confirming that the protections of the HIPAA privacy rule still apply in emergency situations such as the COVID-19 outbreak. OFF. FOR CIVIL RIGHTS, *Bulletin: HIPAA Privacy and Novel Coronavirus,* HHS.GOV (Feb. 3, 2020). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that regulates who can access and review patients' protected health information (PHI). During an emergency, providers must continue to apply administrative, technical, and physical safeguards to ensure the confidentiality, integrity, and availability of PHI.

The OCR bulletin restates HIPAA privacy requirements concerning the sharing of patient information with public health authorities and with families and friends to prevent further spreading of disease and places such disclosures in the context of the COVID-19 outbreak.

The OCR bulletin notes that while HIPAA protects patients' privacy, it does not preclude the use and disclosure of the minimum amount of PHI necessary to treat another patient, to protect the nation's public health, or to prevent a serious and imminent threat to the health and safety of a person or the public.

A COVID-19 patient's PHI can be disclosed to friends, family members, and other individuals involved in the care of that patient. Hospitals may also share patient information to identify, locate, and notify family members, guardians, and others responsible for the patient's care, location, general condition, or death. See 45 CFR § 164.510(b). Additionally, hospitals may share PHI with disaster relief organizations authorized by law or by their charters to assist in disaster relief efforts to help coordinate the notification of family members or other persons involved in the patient's care including the patient's location, general condition, or death.

Hospitals may also share PHI as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public, as long as the disclosure is consistent with applicable law, including state law, and the provider's ethical standards. See 45 CFR § 164.512(j). Under this exception, hospitals may disclose a COVID-19 patient's PHI to anyone who is in a position to prevent or lessen a serious and imminent threat, such as the threat of spreading COVID-19. For this purpose, hospitals may disclose PHI to family, friends, caregivers, and law enforcement without the patient's permission.

In situations where individuals have contracted COVID-19, there is a legitimate need to share information with public health authorities who may need PHI to protect the public from the spread of infectious disease and to ensure health and safety. To that end, the HIPAA privacy rule contains exceptions that permit hospitals to share information regarding employees or dependents who have contracted COVID-19 to state and federal public health authorities.

The guidance reminds providers that all disclosures regarding COVID-19 patients' PHI are subject to the minimum necessary rule. Shared information should be limited to the minimum amount necessary to accomplish the purpose for which the information is being disclosed. Hospitals may rely on representations from public health authorities that the PHI requested about patients exposed to or confirmed to have COVID-19 is the minimum necessary. *See* 45 CFR § 164.502(b) and 164.514(d).

Critically, the OCR bulletin does not articulate any new guidance, and is similar to other bulletins OCR has issued in the wake of other emergencies and natural disasters, such as hurricanes, earthquakes, and mass shootings.

Hospitals must now also consider the implications of the March 13, 2020 HIPAA waiver that waived sanctions and penalties with regard to the following requirements:

- Obtaining a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory. 45 CFR § 164.510.
- Distributing a notice of privacy practices. 45 CFR § 164.520.
- The patient's right to request privacy restrictions or confidential communications. 45 CFR § 164.522.

In each case, the waiver applies only with respect to hospitals in the designated geographic areas that have disaster protocols in operation during the time that the waiver is in effect. Unlike the other waivers issued by HHS that last for the duration of the emergency, the HIPAA waiver only applies for up to 72 hours from the time the hospital implements its disaster protocol. Once the emergency terminates, hospitals must comply with all HIPAA requirements for any patient still under their care, even if 72 hours have not elapsed since implementation of the disaster protocol.

UNDERSTANDING THE IMPLICATIONS OF THE COVID-19 CRISIS AND THE EMTALA WAIVER

Similar to OCR, CMS continues to issue frequent guidance to the healthcare industry, including guidance on fulfilling Emergency Medical Treatment and Labor Act (EMTALA) screening obligations by hospitals and critical access hospitals (CAH) while minimizing the risk of exposure from COVID-19 patients. Questions regarding the continued applicability of EMTALA stabilization, transfer, and receipt of COVID-19 patients are addressed in CMS's March 9, 2020 guidance, as hospitals prepare for the surge and possible transfer of patients. CTRS. FOR MEDICARE & MEDICAID, *Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19),* CMS.GOV (Mar. 9, 2020).

EMTALA is a federal law that requires every hospital or CAH participating in federal healthcare programs with a dedicated emergency department (ED) to conduct an appropriate medical screening examination of all individuals who come to the ED, including individuals who are suspected of having COVID-19, regardless of whether they arrive by ambulance or are walk-ins. Under EMTALA, hospitals must provide necessary stabilizing treatment for individuals who are determined to have an emergency medical condition, like COVID-19, and/or arrange appropriate transfer of such individuals to a facility that has the capacity to treat and stabilize the patient.

The guidance contains frequently asked questions that provide additional detail with regard to transfers under EMTALA for specialized services and determinations relating to complaints that may be filed relating to inappropriate transfers.

Flexibility in managing EMTALA requirements and the current pandemic are also addressed by CMS.

While CMS reminds hospitals that they may not use signage as a barrier to entry for individuals who are seeking treatment for COVID-19, the use of signage designed to help direct individuals to various locations on hospital property can be appropriately implemented.

Addressing screening requirements for individuals who remain in their vehicles is also allowed, assuming the hospital performs the necessary screening to determine whether emergency intervention is needed and intervenes appropriately if a patient's condition deteriorates while awaiting further evaluation.

The guidance further highlights several key aspects of EMTALA compliance, including the following:

- Every hospital or CAH must conduct an appropriate medical screening examination (MSE) of any individual who comes to the ED, including those suspected to have COVID-19.
- Every ED is expected to have the capability to immediately identify and isolate individuals who meet the screening criteria of a positive case of COVID-19.
- In the case of individuals with suspected or confirmed COVID-19, hospitals and CAHs are expected to consider current Centers for Disease Control and Prevention (CDC) and public health guidance in determining whether they have the capability to provide the appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers.
- Hospitals may establish alternative screening sites on their campuses.
- Hospitals and community officials may encourage the public to go to off-campus, hospital-controlled sites for screening for influenza-like illness. However, *a hospital may not tell individuals who have already come to their ED to go to the offsite location.* Unless the offsite location is already a dedicated ED of the hospital, EMTALA requirements do not apply.
- Communities may set up screening clinics at sites not under the control of a hospital; *however, a hospital may not tell individuals who have already come to their ED to go the offsite location for the medical screening evaluation.*
- Hospitals may not refuse to allow individuals with suspected cases of COVID-19 into their ED.

- The lack of intensive care unit (ICU) capabilities does not exempt a hospital from performing a medical screening evaluation and initiating/stabilizing treatment for individuals with suspected COVID-19 who come to the hospital's ED.
- If a hospital lacks personal protective equipment (PPEs) or specialized equipment or facilities, the hospital may not decline to perform a medical screening evaluation on an individual who comes to its ED.
- The presence or absence of negative pressure rooms (airborne infection isolation rooms) is not the sole determining factor relating to transferring patients from one setting to another; in some cases, a private room may be all that is required.

With regard to PPE, the guidance recognizes that not all hospitals will have access to or have enough PPE. The guidance does not seem to give hospitals a "pass," however, in this regard, and reminds all hospitals that conditions of participation regarding infection control standards must be followed. CMS recognizes that hospitals may lose healthcare workers to the virus and may not have sufficient staff or ability to treat patients that may come to the ED. In these instances, if a hospital no longer has the "capacity to screen and treat individuals" it may go on diversion.

Another important issue addressed relates to approvals concerning certification and licensure of alternative screening locations by hospitals. For locations that are already part of a certified hospital, there is no additional requirement, but CMS does require the filing of an additional Form 855A for designation of a new practice location to advise CMS. Prior approval for this location from CMS is not required to bill for services provided in this location, however. There is also no survey requirement for compliance with conditions of participation, but CMS reminds hospitals to notify and consult with state licensing authorities.

Notably, CMS's guidance did not change any EMTALA requirements, but interpreted the requirements as they apply to the treatment of patients with COVID-19 and to the management of healthcare providers' responses to COVID-19.

The guidance also makes clear that EMTALA requirements may be waived. An EMTALA waiver allows hospitals to direct individuals who may come on campus to an alternative off-campus site, in accordance with a state emergency or pandemic preparedness plan, for their medical screening examination. Additionally, transfers normally prohibited under EMTALA may be allowed due to the necessity of the pandemic.

An EMTALA waiver may only be invoked if:

- The US president declares an emergency or disaster under the Stafford Act or National Emergencies Act; AND
- The Secretary of HHS has declared a public health emergency; AND
- The Secretary invokes his/her waiver authority (which may be retroactive), including notifying Congress at least 48 hours in advance; AND
- The waiver includes waiver of EMTALA requirements and the hospital is covered by EMTALA.

As of March 13, 2020, all four of the requisite steps have been taken to waive EMTALA:

- On January 23, 2020, HHS Secretary Alex Azar declared a public health emergency (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx),
- On March 13, 2020, President Donald Trump proclaimed a national emergency (https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/),
- On March 13, 2020, Secretary Azar invoked his waiver authority under Section 1135 of the Social Security Act (https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx), and
- On March 13, 2020, Secretary Azar specifically waived sanctions under EMTALA for "the direction and relocation of an individual to another location to receive medical screening pursuant to an appropriate state of emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic."

The EMTALA waiver became effective on March 18, 2020 at 6:00 PM EST and is retroactive to March 1, 2020. The waiver will last until the termination of the declaration of the public health emergency.

Now that these steps have been taken, Secretary Azar is empowered to grant additional waivers regarding the implementation and enforcement of EMTALA.

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