COVID-19: EMTALA GUIDANCE ON COVID-19 WHILE HOSPITALS AWAIT POTENTIAL EMTALA WAIVERS

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U.S. Health Care Alert

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On March 9, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued guidance to State Survey Agency Directors regarding Emergency Medical Treatment and Labor Act ("EMTALA") requirements and implications related to the Coronavirus Disease-2019 ("COVID-19"). [1]

The CMS guidance letter addresses a number of urgent and important issues for hospitals (including critical access hospitals) that staff emergency departments ("EDs") and are subject to EMTALA requirements. Interested parties are encouraged to review the letter in its entirety, which is available here. As facilities put plans in place now to triage a potential surge of patients with influenza-like symptoms that may include COVID-19 patients, keeping EMTALA obligations in mind is a component of that planning, so the guidance is an important guidepost for hospital leaders.

With this said, hospitals should also be alert for further guidance related to potential waivers of some EMTALA requirements. When CMS issued this guidance, and as of the time of the writing of this Alert on March 13, 2020, the Department of Health & Human Services had not issued a waiver of EMTALA requirements. Such a waiver is not possible until, *inter alia*, the President declares an emergency or disaster under the Stafford Act or the National Emergencies Act, which, as of writing, has yet to occur. (*Author's Note: the President issued this declaration on March 13, 2020, shortly after publication of this Alert*).

However, upon a such a declaration, historically HHS will, in short order, provide an initial EMTALA waiver under its waiver authority through Section 1135 of the Social Security Act that allows hospitals to take actions not normally permitted by EMTALA: for example, directing individuals who come to an ED to alternative off-campus sites in accordance with state emergency pandemic prepared plans for a medical screening examination ("MSE"). [2] Therefore, some of the requirements specified in the CMS guidance letter and discussed in this Alert are subject to change in coming days and weeks upon the issuance of a Section 1135 waiver by Secretary Azar, including a standard EMTALA waiver or enhanced waivers.

Key takeaways from the CMS guidance letter include:

EMTALA Requirements Continue to Apply: Hospitals remain obligated under EMTALA to provide an MSE to every individual who comes to the ED for examination or treatment of a medical condition to determine if they have an emergency medical condition ("EMC"). Hospitals must provide necessary stabilizing treatment for individuals with an EMC within the hospital's capability and capacity, and hospitals must provide for transfers of individuals with EMCs, as appropriate.

Transfers of COVID-19 Patients to/from Hospitals: Hospitals with capacity and specialized capabilities needed to provide stabilizing treatment for COVID-19 are required to accept appropriate transfers from hospitals without

such necessary capabilities. CMS reminds providers that this obligation applies to all Medicare-participating hospitals regardless of whether the recipient hospital has a dedicated ED. CMS encourages hospitals to coordinate with state/local public health officials to help place—and treat—individuals who meet specified COVID-19 assessment criteria. When assessing whether a violation of EMTALA occurred, CMS states it will take into account the Centers for Disease Control and Prevention's ("CDC's") recommendations in effect at the time of the event in question to determine whether a hospital has requisite capabilities and capacity. Note again that transfer requirements may change upon the issuance of an EMTALA waiver.

Signage, Directing Patients, and Other Barriers to the ED: EDs cannot use signage or other barriers to prevent individuals suspected of having COVID-19 from coming to the ED. However, hospitals may use signage to direct individuals to certain locations within a hospital: e.g., if the hospital has set a dedicated location to triage potential COVID-19 patients.

CMS notes that after undergoing an MSE, a patient may meet the CDC criteria for potential COVID-19, but not have signs or symptoms that would require immediate medical attention. In such situations, it would not be an EMTALA violation for hospitals to stop providing care within the ED or to take steps like asking a patient to wait outside of the hospital or in their car. However, in such situations, CMS cautions that hospitals:

...should have a system in place to monitor those patients that opt to wait in their own vehicle to ensure that their condition has not deteriorated while awaiting further evaluation. Failure to do so could expose the hospital to a potential MSE violation because the MSE was not done timely. In that case, it could also be a violation of the Condition of Participation: Emergency Services.

COVID-19 Screening Locations (On-site): When patients come to the ED, a hospital may set up alternative MSE screening locations for COVID-19 <u>outside of the ED</u>. After a patient is logged-in at the ED, a patient can be re-directed to these separate locations. CMS also notes that this initial patient logging and re-direction can <u>also</u> take place outside of the ED. The person doing such re-direction to a screening location should be qualified to recognize individuals who are obviously in need of immediate treatment in the ED (e.g., a registered nurse). However, CMS notes that while these patient logging, re-direction, and MSE activities may all take place at locations outside of the ED, EMTALA requirements will continue to apply for such patients by virtue of the patient initially coming to the ED.

COVID-19 Screening Locations (Off-site): Hospitals may also set up off-campus locations for influenza-like illness ("ILI") screening for COVID-19. CMS further notes that hospitals may encourage the public to go to these off-site locations rather than coming to the hospital to obtain screening for COVID-19. Such off-site locations cannot be held out as a location that provides emergency care (unless it is already a dedicated off-campus ED of the hospital). However, because the off-site location is not an ED (assuming there is not a dedicated ED onsite at the location otherwise), EMTALA requirements do not apply to such off-site ILI screening locations: i.e., hospitals are not obligated to provide an MSE at these sites.

However, note that this means that patients arriving at the ED cannot be directed to an off-site ILI screening location (unless, perhaps, an EMTALA waiver eventually applies). If a patient comes to an off site ILI screening location and needs emergent hospital medical attention, Medicare Conditions of Participation will require the

hospital to arrange for a referral or transfer to the hospital. Communities may also set up ILI screening clinics—there is likewise no EMTALA obligation at such sites.

EMTALA Waivers: As noted above, there is a potential for further guidance from HHS providing for certain EMTALA waivers. In this regard, three predicate steps are necessary for the issuance of an EMTALA waiver under Section 1135 of the Social Security Act:

i. The Secretary of HHS must declare a Public Health Emergency. Secretary Azar took this step on January 31, 2020; [3] ii. The President must declare an emergency or disaster under the Stafford Act or the National Emergencies Act. This has not yet occurred as of the writing of this Alert; and iii. Once both of the above are in place, Secretary Azar must invoke his waiver authority (which may be retroactive), including notifying Congress at least 48 hours in advance.

The issued waiver will specify what EMTALA requirements it waives, and which hospitals the waiver covers. Typically, Section 1135 waivers immediately provide flexibility in the following two areas:

i. permitting individuals that come to an ED to be re-directed to another non-ED location (e.g. an off-campus ILI screening site); ii. permitting normally prohibited transfers of patients with unstable EMCs when necessitated by the circumstances of the declared emergency.

For a public health emergency involving a pandemic infectious disease like COVID-19, the waiver will last until the termination of the declaration of the public health emergency.

In addition to the initial Section 1135 waiver issued by the Secretary, blanket waivers applicable to all providers may be issued by the Secretary and/or individual waivers may be requested by facilities through their CMS regional office. Given the potential surge in patients anticipated and the alternative and creative means hospitals may need to employ, such additional waivers may be needed as the COVID-19 crisis develops.

Importantly, hospitals should also be analyzing general Medicare Conditions of Participation [4] and state licensure laws related to handling of emergency patients to ensure any triage plans associated with COVID-19 surge planning also remain compliant with these other regulatory requirements.

The public health crisis caused by COVID-19 is evolving rapidly, as is the government's and public health sector's response. K&L Gates encourages hospitals and health systems subject to EMTALA to be prepared for further guidance and for potential waivers on this topic.

K&L Gates is committed to bringing its partners timely updates on the legal implications the COVID-19 outbreak is having on national and global business. Alerts and podcasts covering a range of topics and sectors impacted by COVID-19, including health care, employment, insurance, asset management, and others, are available at the K&L Gates Hub here

NOTES:

[1] Letter from Director Quality Safety and Oversight Group to State Survey Agency Directors, CMS, Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19) (Mar. 9, 2020), https://www.cms.gov/files/document/qso-20-15-emtala-requirements-and-coronavirus-0311-updated-003pdf.pdf-1.

[2] <u>See</u> Waiver of Modification of Requirements Under Section 1135 of the Social Security Act" for the Puerto Rico earthquake (January 8, 2020), https://www.phe.gov/emergency/news/healthactions/section1135/Pages/prearthquake-28dec19-aspx.aspx.

[3] Press Release, HHS, Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus (Jan. 31, 2020), https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html.

[4] As a reminder, Medicare Conditions of Participation include requirements related to emergency services provided to patients and emergency preparedness (e.g., § 482.55 and State Operations Manual ("SOM"), App. A and Z) and infection control (e.g., § 482.42). Additionally, hospitals that provide emergency services, but not at one or more off-campus departments of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus departments for appraisal of emergencies and referral when appropriate. See 42 C.F.R. § 482.12(f)(3) and SOM, App. A. Even if a hospital does not provide emergency services, the governing body must likewise assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate. See 42 C.F.R. § 482.12(f)(2) and SOM App. A.

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