EMTALA and Ebola

CMS Survey & Certification Memoranda 15-10 and 15-24 (Nov. 21, 2014 and Feb. 13, 2015)

Center for Clinical Standards and Quality/Survey and Certification Group

Ref: S&C: 15-10-Hospitals

DATE: November 21, 2014

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and

Implications Related to Ebola Virus Disease (Ebola)

Memorandum Summary

- **Ebola and EMTALA requirements:** This Memorandum conveys information useful in responding to inquiries from hospitals concerning implications of Ebola for their compliance with EMTALA.
- *EMTALA Screening Obligation:* Every hospital or critical access hospital (CAH) with a dedicated emergency department (ED) is required to conduct an appropriate medical screening examination (MSE) of all individuals who come to the ED, including individuals who are suspected of having been exposed to Ebola, and regardless of whether they arrive by ambulance or are walk-ins. Every ED is expected to have the capability to apply appropriate Ebola screening criteria when applicable, to immediately isolate individuals who meet the screening criteria to be a potential Ebola case, to contact their state or local public health officials to determine if Ebola testing is needed, and, when a decision to test is made, to provide treatment to the individual, using appropriate isolation precautions, until a determination is made whether the individual has Ebola.
- EMTALA Stabilization, Transfer & Recipient Hospital Obligations: In the case of individuals who have Ebola, hospitals and CAHs are expected to consider current guidance of public health officials in determining whether they have the capability to provide appropriate isolation required for stabilizing treatment and/or to accept appropriate transfers. In the event of any EMTALA complaints alleging inappropriate transfers or refusal to accept appropriate transfers, CMS will take into consideration the public health guidance in effect at the time.
- Centers for Disease Control and Prevention (CDC) Website: CMS strongly urges State Survey Agencies (SAs), hospitals and CAHs to monitor the CDC website at http://www.cdc.gov/vhf/ebola/ for the most current guidance and information concerning Ebola identification, treatment, and precautions to prevent the spread of the disease, as well as their State public health website.

Background

Due to increasing public concerns with Ebola, CMS is receiving inquiries from the hospital industry concerning implications for their compliance with EMTALA. Concerns center around

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the ability of hospitals and CAHs to fulfill their EMTALA screening obligations while minimizing the risk of exposure from Ebola infected individuals to others in the ED, including healthcare workers, and the isolation requirements for Ebola. In addition, we have also received questions about the applicability of EMTALA stabilization, transfer and recipient hospital obligations in the case of individuals who are found to have met the screening criteria for possible Ebola disease or who have been determined to have Ebola.

EMTALA requires Medicare-participating hospitals and CAHs that have a dedicated emergency department to, at a minimum:

- Provide an MSE to every individual who comes to the ED, for examination or treatment for a medical condition, to determine if they have an emergency medical condition (EMC); and
- Provide necessary stabilizing treatment for individuals with an EMC within the hospital's capability and capacity; and
- Provide for transfers of individuals with EMCs, when appropriate.

In addition, all Medicare-participating hospitals with specialized capabilities are required to accept appropriate transfers of individuals with EMCs if the hospital has the specialized capabilities an individual requires for stabilization as well as the capacity to treat these individuals. This recipient hospital obligation applies regardless of whether the hospital has a dedicated emergency department.

EMTALA Obligations when Screening Suggests Possible Ebola

It may be the case that hospitals, emergency medical services (EMS), and their State or local public health officials develop protocols for bringing individuals who meet criteria for a suspected case of Ebola only to hospitals that have been designated to handle potential or confirmed cases of Ebola. These pre-hospital arrangements do not present any conflict with EMTALA. This is the case even if the ambulance carrying the individual is owned and operated by a hospital other than the designated hospital, so long as the ambulance is operating in accordance with a community wide EMS protocol.

On the other hand, if an individual comes to an ED of a hospital or CAH, as the term "comes to the emergency department" is defined in the regulation at §489.24(b), either by ambulance or as a walk-in, the hospital must provide the individual with an appropriate MSE. We emphasize that it is a violation of EMTALA for hospitals and CAHs with EDs to use signage that presents barriers to individuals who may have been exposed to Ebola from coming to the ED, or to otherwise refuse to provide an appropriate MSE to anyone who has come to the ED for examination or treatment of a medical condition. However, use of signage designed to help direct individuals to various locations on the hospital property, as that term is defined in the regulation at §489.24(b), for their MSE would be acceptable.

If during the MSE the hospital or CAH concludes, consistent with accepted standards of practice for Ebola screening, that an individual who has come to its ED may be a possible Ebola case, the hospital or CAH is expected to isolate the patient immediately. Although levels of services

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provided by EDs vary greatly across the country, it is CMS' expectation that all hospitals and CAHs are able to, within their capability, provide MSEs and initiate stabilizing treatment, while maintaining the isolation requirements for Ebola and coordinating with their State or local public health officials, who will in turn arrange coordination, as necessary, with the CDC.

At the time of the drafting of this memo, CDC's screening guidance called for hospitals and CAHs to contact their State or local public health officials when they have a case of suspected Ebola. According to that guidance, the State or local public health officials, together with the hospital, will make a determination as to whether Ebola testing of the individual is required.

- If it is determined that Ebola testing is not required, the hospital or CAH is expected to complete its MSE in accordance with accepted standards of practice and to take appropriate actions, depending on whether or not the individual has an EMC.
- If it is determined that Ebola testing is required, the hospital or CAH is expected to maintain the individual in isolation, providing treatment within its capability for the individual's symptoms as needed, until it has the test results or if, prior to test results, there is a determination by the responsible public health authorities that the case presents a strong probability of Ebola.
- If the individual tests negative for Ebola, the hospital or CAH is expected to complete its MSE in accordance with accepted standards of practice and to take appropriate actions, depending on whether or not the individual has an EMC.
- If the individual tests positive for Ebola, or the hospital together with state or local public health officials otherwise conclude that the individual likely has Ebola, even prior to obtaining test results, the hospital or CAH is expected to comply with the most recent State or local public health guidance in determining whether it has the capability to provide stabilizing treatment on site, or whether to initiate an appropriate transfer, in accordance with §489.24(e), to a hospital which has the capability to provide the required stabilizing treatment.

We appreciate the work of public health authorities, the Centers for Disease Control and Prevention (CDC) and hospitals to develop specialized capabilities to treat patients with Ebola. However, the existence of hospitals with specialized capabilities does not relieve any other hospital or CAH of its obligation to provide an appropriate medical screening examination, or fulfill any other EMTALA requirement relevant to the situation.

Other Enforcement Considerations

Should CMS receive complaints alleging either inappropriate transfers by a sending hospital or refusal of a recipient hospital to accept an appropriate transfer, it will take into consideration the State or local public health direction and designations of hospitals as Ebola treatment centers at the time of the alleged noncompliance concerning where Ebola treatment should be provided. It will also take into consideration any clinical considerations specific to the individual case(s).

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Surveyors and managers responsible for EMTALA enforcement are expected to be aware of the flexibilities hospitals are afforded under EMTALA and to assess incoming EMTALA complaints accordingly in determining whether an on-site investigation is required. They are also expected to keep these flexibilities in mind when assessing hospital compliance with EMTALA during a survey.

Consistent with their obligations under the hospital and CAH Conditions of Participation (CoPs) §482.42 and §485.635(a)(3)(vi), hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of Ebola. Since the Ebola virus is transmitted via droplets, strict adherence to droplet and contact isolation precautions must be followed. The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance. CMS recognizes the difficulties securing the recommended personal protective equipment (PPE) required for training and patient care that may be present in some circumstances at the time of this Memorandum.

The U.S. Department of Labor Occupational Health and Safety Administration (OSHA) has also provided guidance on worker protection related to Ebola at https://www.osha.gov/SLTC/ebola/. Hospitals and CAHs are expected under their respective CoPs at §482.11(a) and §485.608(a) to comply with OSHA requirements, but CMS and state surveyors acting on its behalf do not assess compliance with requirements of other Federal agencies.

Latest CDC Guidance

The most up-to-date guidance regarding screening, testing, treatment, isolation, and other Ebola-related topics can be found on the CDC website at http://www.cdc.gov/vhf/ebola/index.html. Hospitals and CAHs are strongly urged to monitor this site as well as their State public health website and follow recommended guidelines and acceptable standards of practice. (See also S&C 15-02: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-02.pdf) SAs are also encouraged to monitor the CDC and their state public health websites for up-to-date information.

Questions about this document should be addressed to hospital SCG@cms.hhs.gov.

Effective Date: The information contained in this letter should be shared with all survey and certification staff, their managers, and the state/Regional Office training coordinators immediately.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-24-Hospitals

DATE: February 13, 2015

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) and Ebola Virus

Disease (EVD) – Questions and Answers (Q+A)

Memorandum Summary

EMTALA & Ebola Requirements:

- On November 21, 2014 the Centers for Medicare & Medicaid Services (CMS) Survey & Certification Group released SC 15-10-Hospitals concerning EMTALA Requirements and Implications Related to the EVD.
- The CMS has received follow-up questions regarding EMTALA and Ebola and has produced a Q+A document in response.

The CMS released S&C 15-10 on November 21, 2014 to provide guidance to hospitals and critical access hospitals (CAHs) regarding meeting EMTALA requirements in the case of individuals potentially exposed to Ebola. The memo is available via the following link:

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-10.pdf

Subsequently CMS has received questions seeking additional clarification or details. In response, we have developed the attached Q+A document.

Questions related to this memo and the attached Q+A document should be addressed to $\underline{\text{hospitalscg@cms.hhs.gov}}$

Effective Date: Immediately. This document should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

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/s/

Thomas E. Hamilton

Attachment- EMTALA Obligations & Ebola Virus Disease (EVD) Question and Answer Document

cc: Survey and Certification Regional Office Management

EMTALA Obligations & Ebola Virus Disease (EVD) Question and Answer Document

Note: For the purpose of this document, the term "hospital" includes all types of Medicare-participating hospitals and critical access hospitals (CAHs)

A. Patient Insurance/Payor Status:

A.1. Is a Medicare-participating hospital required to provide EMTALA-mandated screening and stabilizing treatment for non-Medicare beneficiaries with likely or confirmed EVD?

EMTALA applies to all individuals who come to the dedicated emergency department (ED) of a Medicare-participating hospital, regardless of type or presence of insurance coverage or ability to pay. Further, Medicare-participating hospitals with specialized capabilities are required within the limits of their capability and capacity to accept appropriate transfers of individuals protected under EMTALA from other hospitals, without regard to insurance or ability to pay.

B. Specialized Capabilities

B.1. EMTALA requires that hospitals with specialized capabilities to treat EVD accept appropriate transfers of individuals who require those services, if they have capacity to provide them. In the event of an EMTALA complaint related to an inappropriate transfer and/or a refusal of a recipient hospital to accept an appropriate transfer, how will CMS determine whether a hospital had the "specialized capabilities" with respect to EVD required by the individual?

If the responsible State or local public health officials have designated or otherwise formally identified the hospital as an EVD treatment facility, or if the hospital has held itself out to the public as qualified to treat EVD patients, then the hospital might be considered to have specialized capabilities to treat EVD. In an area where no hospitals have been designated or self-identified as EVD treatment centers, in the event of an EMTALA complaint alleging either an inappropriate transfer by a hospital that could have stabilized an individual with EVD, or refusal by a recipient hospital to accept an appropriate transfer, CMS would conduct a case-specific review to determine whether the hospitals in question had the capability and capacity to provide the treatment necessary to stabilize an individual with EVD.

B.2: Do the CDC's recommendations for State and local public health officials and hospitals to employ a tiered framework for designation of hospitals in relation to EVD conflict with hospital obligations under EMTALA?

No. The CDC's interim guidance recommending that State and local public health officials and hospitals employ a tiered framework for designating hospitals for the screening, assessment and treatment of potential EVD-infected patients does not conflict with EMTALA. The CDC released interim guidance recommendations on December 2, 2014 suggesting three categories of designation of hospitals with respect to EVD:

- 1. Frontline Healthcare Facilities
- 2. Ebola Assessment Hospitals
- 3. Ebola Treatment Hospitals

Specific details regarding this framework and the expectations for EBV assessment and treatment for hospitals in each category are available at the following link: http://www.cdc.gov/vhf/ebola/hcp/us-hospital-preparedness.html

This guidance presumes that hospitals at any of these levels would be expected to screen, isolate and begin stabilizing treatment, as necessary, of any individual who presents to the ED with possible EVD symptoms. The guidance also calls for hospitals to immediately contact their State and local health departments to coordinate ongoing care of individuals suspected to have EVD, including when transfers to higher levels of care are appropriate. This guidance is consistent with the EMTALA requirements for screening, stabilization and appropriate transfers.

See also the related CDC guidance recommendations for preparing hospitals in each tier:

http://www.cdc.gov/vhf/ebola/hcp/preparing-frontline-healthcare-facilities.html

http://www.cdc.gov/vhf/ebola/hcp/preparing-ebola-assessment-hospitals.html

http://www.cdc.gov/vhf/ebola/hcp/preparing-ebola-treatment-centers.html

B.3: If a hospital that does not have the specialized capabilities associated with a designated Ebola Assessment or Treatment Center has provided an appropriate medical screening examination to an individual who has come to its ED and concluded the individual meets the criteria to be considered a suspected case of EVD, how does it know where to make a transfer that would be appropriate under EMTALA?

A list of current designated Ebola Treatment Centers is updated weekly by the CDC and may be found at http://www.cdc.gov/vhf/ebola/hcp/current-treatment-centers.html. However, first and foremost, hospitals should be working with their State and local public health officials and be aware of the Ebola response plan within their region. They should work with these public health officials to assure the implementation of the regional plan, including facilitating appropriate transfers. The CDC is working with States and hospitals to assure that every "Frontline Healthcare Facility" would be able to make appropriate transfers of individuals with suspected or confirmed EBV in a timely fashion to a hospital with the requisite specialized capabilities for further assessment or treatment.

However, it is a State public health agency decision whether or not to adopt the CDC's recommended tiered hospital EVD response framework, and to make designations of specific hospitals accordingly. Further, if a State has not made any designations of Ebola Assessment or Treatment Centers within the State, this does not mean that every hospital in that State would automatically be considered a "Frontline Healthcare Facility" for EMTALA purposes. In the event of a complaint that a transfer of an individual suspected of having EVD was inappropriate, CMS would follow its standard EMTALA investigation procedures and consider the specific

facts of the case, informed by the available guidance from the CDC as well as any regional Ebola response plans and/or State designations of hospitals, when determining whether a violation of EMTALA had occurred.

B.4: Are hospitals required to accept transfers of patients with suspected or confirmed EVD from small or rural hospitals that don't have negative pressure rooms or other capabilities to care for patients with EVD?

Hospitals with capacity and the specialized capabilities needed for stabilizing treatment are required to accept appropriate transfers from hospitals without the necessary capabilities. Hospitals should coordinate with their State/local public health officials regarding appropriate placement of individuals who meet specified EVD assessment criteria, and the most current standards of practice for treating individuals with confirmed EVD infection status.

As in any case concerning a hospital's EMTALA obligations with respect to transfers of individuals, CMS would evaluate the capabilities and capacity of both the referring and recipient hospitals in order to determine whether a violation has occurred. Among other things, we would take into account the CDC's recommendations at the time of the event in question in assessing whether a hospital had the requisite capabilities and capacity. We note that the CDC's recommendations focus on factors such as the individual's recent travel history and presenting signs and symptoms in differentiating the types of capabilities hospitals should have to screen and treat that individual. The presence or absence of negative pressure rooms would not be the sole determining factor, and in some cases all that would be required would be a private room. See the CDC website for the most current infection prevention and control recommendations for hospital patients with suspected or known EVD: http://www.cdc.gov/vhf//hcp/infection-prevention-and-control-recommendations.html

B.5: If a State has, consistent with the CDC recommendations, designated hospitals according to their capabilities to handle differing levels of suspected or confirmed cases of EVD, does this affect a hospital's EMTALA obligations with respect to transfers from out of the State?

No. Hospitals with specialized capabilities and the capacity to provide the necessary stabilizing treatment required by an individual protected under EMTALA may not refuse an appropriate transfer from a referring hospital within the boundaries of the United States.

C. Screening Examinations and Stabilizing Treatment Requirements

C.1: What are the EMTALA requirements for hospitals in regard to screening and treating individuals with possible EVD?

The EMTALA requirements for hospitals are the same for individuals with possible EVD symptoms as all other possible emergency medical conditions (EMCs):

 Provide an appropriate Medical Screening Exam (MSE) to every individual who comes to the Emergency Department (ED) for examination or treatment of a medical condition, to determine if they have an emergency medical condition (EMC); and

- Provide necessary stabilizing treatment for individuals with an EMC within the hospital's capability and capacity; and
- Provide for appropriate transfers of individuals with EMCs if the hospital lacks the capability to stabilize them.

Specific to EVD, hospitals are encouraged to follow the CDC guidance for appropriate isolation procedures to minimize the risk of cross-contamination to other patients, visitors, and healthcare workers. For example, the CDC publishes and updates accepted national standards of infection control practice for EVD. Hospitals should consult the latest CDC guidance and coordinate with State/local public health authorities for guidance related to ongoing care and treatment of patients with EVD.

C.2: Are all hospitals expected to screen and treat individuals with possible EVD symptoms?

Yes, all hospitals are expected, at a minimum to screen, isolate, and begin stabilizing treatment, as appropriate, for any individual with possible EVD symptoms. Hospitals should coordinate with their State/local public health authorities regarding ongoing care and treatment, including when it is appropriate to transfer individuals to hospitals with specialized capabilities and capacity to provide further assessment and/or stabilizing treatment for suspected or confirmed EVD.

C.3: If a hospital does not have Intensive Care Unit (ICU) capabilities is it required to screen and, when appropriate, initiate stabilizing treatment for individuals with suspected or confirmed EVD?

Yes. The lack of ICU capabilities does not exempt a hospital from performing an MSE and initiating stabilizing treatment for individuals with known or suspected EVD who come to the hospital's ED seeking examination or treatment. Qualified medical personnel in hospitals that conduct the screening examination should be aware of the criteria for initial EVD screening and should apply such screening when appropriate. Note that the CDC guidance for preparing "frontline" hospitals, i.e., those hospitals in the lowest tier of the EVD framework, indicates that they should be able to do the following:

- "Rapidly identify and triage <u>patients with relevant exposure history AND signs or symptoms (http://www.cdc.gov/vhf/ebola/hcp/case-definition.html)</u> compatible with EVD as outlined in CDC's guidance for <u>Emergency Department Evaluation and Management for Patients Who Present with Possible Ebola Virus Disease(http://www.cdc.gov/vhf/ebola/hcp/ed-management-patients-possible-ebola.html).
 </u>
- Immediately isolate any patient with relevant exposure history and signs or symptoms compatible with EVD and take appropriate steps to adequately protect staff caring for the patient, including appropriate use of personal protective equipment (PPE) as outlined in CDC's guidance for Emergency Department Evaluation and Management of Patients with Possible Ebola Virus Disease(http://www.cdc.gov/vhf/ebola/hcp/ed-management-patients-possible-ebola.html).

- Immediately notify the hospital/facility infection control program, other appropriate facility staff, and the state and local public health agencies that a patient has been identified who has relevant exposure AND signs or symptoms compatible with EVD; discuss level of risk, clinical and epidemiologic factors, alternative diagnoses, plan for EVD testing, plan for possible patient transfer to another facility, and further care.
- Ensure there is no delay in the care for these patients by being prepared to test, manage, and treat alternative etiologies of febrile illness (e.g., malaria in travelers) as clinically indicated."

C.4: May hospitals refuse to allow individuals with suspected cases of EVD into their ED if other nearby hospitals have been designated as Ebola Assessment Hospitals or Ebola Treatment Centers?

No. For every individual who "comes to the emergency department," as that term is defined in §489.24(b) of the EMTALA regulations, for evaluation or treatment of a medical condition, whether by ambulance or by walking-in, hospitals are required to provide an appropriate medical screening examination. Qualified medical personnel in hospitals that conduct the screening examination should be aware of the criteria for initial EVD screening and should apply such screening when appropriate. Hospitals that refuse to screen an individual who comes to their emergency department would likely be found to have violated EMTALA, regardless of presenting signs, symptoms, and possible diagnoses.

C.5: Are all hospitals expected to have Personal Protective Equipment (PPE) and other equipment/facilities to screen and take care of suspected or confirmed EVD patients, even on a temporary basis until transferred?

There are no requirements established under EMTALA for hospitals to have specific PPE or equipment/facilities. Consistent with their obligations under the hospital and CAH Conditions of Participation (CoPs) at §482.42 and §485.635(a)(3)(vi), hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of EVD. Ebola is transmitted through direct contact with blood or body fluids of a person who is sick with Ebola; the virus is not transmitted through the air (like measles virus). However, large droplets (splashes or sprays) of respiratory or other secretions from a person who is sick with Ebola could be infectious, and therefore specific precautions are recommended for use in healthcare settings to prevent the transmission of Ebola from patients to healthcare personnel and other patients or family members. The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to follow this guidance.

CMS anticipates that many State and local public health authorities will employ the tiered hospital approach recommended by the CDC in their planning for potential EVD cases. That framework envisions that hospitals would have differing needs for PPE and specialized equipment or facilities, based on their designated status under the tiered hospital approach.

C.6: May hospitals decline to perform an MSE on an individual who comes to their ED with potential or suspected EVD due to a lack of PPE or specialized equipment/facilities?

No. For every individual who "comes to the emergency department," as that term is defined in §489.24(b) of the EMTALA regulations, for evaluation or treatment of a medical condition, whether by ambulance or by walking-in, hospitals are required to provide an appropriate medical screening examination. Qualified medical personnel in hospitals that conduct the screening examination must be aware of the criteria for initial EVD screening and apply such screening when appropriate. Hospitals that refuse to screen an individual who comes to their emergency department would likely be found to have violated EMTALA, regardless of presenting signs, symptoms, and possible diagnoses.

C.7: May a physician who is present in the hospital conduct the MSE through the use of telemedicine equipment in lieu of physically being in the same exam room as the patient?

The use of audio, video and other telehealth equipment by an on-site physician to perform medical screening examinations is not specifically prohibited under EMTALA. However, the hospital is still obligated to perform an appropriate medical screening examination to determine the presence or absence of an emergency medical condition. In investigating any complaints related to this, the appropriateness of an examination using this type of equipment would be determined based on the specific facts of each individual case, including the clinical signs and symptoms of the individual at the time of presentation. If an in-person or hands-on examination is necessary, use of equipment alone would not meet the EMTALA requirements for an appropriate screening examination.

Further, when the screening examination indicates an individual has an emergency medical condition, hospitals are required to provide stabilizing treatment within their capability/capacity prior to making an appropriate transfer. We recognize that not every hospital will have the same capabilities with regard to EVD, and that transfers of individuals who meet the criteria for suspected EVD to other hospitals, based on current State public health guidance, may be appropriate. But prior to the transfer, it is difficult to envision that the individual's care needs could be met via remote technology alone. Again, the individual facts of any case would be reviewed to determine what the individual's care needs were prior to transfer and what the hospital was capable of providing.

C.8: Will CMS issue EMTALA waivers for hospitals related to EVD?

The statute governing EMTALA waivers sets a high threshold for issuing such waivers and also limits the nature and duration of an EMTALA waiver. At this time the requirements for CMS to issue EMTALA waivers have not been met (i.e., issuance of a Presidential disaster declaration and a Secretary's declaration of a public health emergency). See Survey and Certification policy memorandum SC-10-05, issued November 6, 2009, for more information on EMTALA waivers: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter10 05.pdf

C.9: What about ambulances operating under emergency medical services (EMS) systems – are they subject to EMTALA?

Only ambulances that are owned and operated by a hospital are subject to EMTALA. Otherwise EMS services are considered pre-hospital care that is outside the scope of EMTALA. Public health officials, EMS systems and hospitals are free to develop protocols governing where EMS should transport individuals for emergency care. This includes developing protocols specific to individuals who meet criteria to be considered suspected cases of EVD.

Even in the case of ambulances that are owned and operated by a hospital, it is permissible to transport an individual to a different hospital for screening and treatment, so long as they are operating in accordance with a communitywide EMS protocol, or they are operating under the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance.

C.10: May hospitals turn away an EMS ambulance that comes to the "wrong" hospital ED and send it to another hospital that has been designated to assess or treat suspected or confirmed cases of EVD?

No. For every individual who "comes to the emergency department," as that term is defined in §489.24(b) of the EMTALA regulations, for evaluation or treatment of a medical conditions, whether by ambulance or by walking-in, hospitals are required to provide an appropriate medical screening examination for every individual who comes to the hospital's emergency department. Qualified medical personnel in hospitals that conduct the screening examination must be aware of the criteria for initial EVD screening and apply such screening when appropriate. Further, if an individual meets the initial screening criteria for possible EVD, hospitals are expected to isolate them and begin stabilizing treatment of symptoms.

C.11: May hospitals set up alternative screening sites within the hospital to screen possible EVD patients, even if they don't have an EMTALA waiver?

Yes, hospitals have flexibilities to set up alternative screening sites at other parts of the hospital, both on- and off-campus. See, for example, Survey and Certification policy memorandum SC-09-52, issued August 14, 2009, for guidance related to influenza that may also be informative for other types of situations: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter09_52.pdf

However, absent an EMTALA waiver issued by CMS pursuant to a declaration of a public health emergency, hospitals may not direct an individual who has already come to their on-site emergency department to any off-campus location for screening.

C 11(a): What constitutes an alternative hospital location? For instance, can this include a tarped-off area of another room, a room constructed in the ambulance bay, or the room previously used as the decontamination room?

Hospitals have flexibilities under EMTALA to determine alternative locations outside the ED but within the hospital for screening examinations of individuals potentially exposed to or infected

with EVD. Survey and Certification policy memorandum SC 09-52, issued August 14, 2009, provided guidance for handling a surge in demand for ED services related to the H1N1 influenza virus, and may be helpful in other situations: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter09_52.pdf

C11(b): Do the Life Safety Code (LSC) requirements under the hospital or critical access hospital Conditions of Participation apply to alternative care sites?

Since alternative care sites are expected to be within the hospital, they would be expected to meet LSC requirements.

However, there may be situations where temporary examination areas are set up. The following information on alternative care sites from the CMS emergency preparedness website may be helpful:

If compliance issues come up in such localized situations where no applicable section 1135 waiver [for declared public health emergencies] is available, CMS focuses on fundamentals, such as assuring medical and nursing staff have proper credentials and, in the case of medical staff, have privileges; assuring that care is safe, that patients' rights are protected and that medical records with sufficient information to promote safe care are maintained. Additionally, for facilities subject to the Life Safety Code (LSC), past experience has demonstrated that many facilities, even when functioning in a degraded status, or in the case of the establishment of alternative care sites, may continue to meet the LSC by implementing reasonable and prudent measures. For example, there were several hospitals that were damaged by Hurricane Katrina which continued to comply with the LSC by implementing reasonable and prudent measures, and therefore were able to continue operations in a degraded but safe environment for weeks or months until repairs could be completed.

The fact sheet on alternative care sites is available at this link: https://www.cms.gov/About-CMS/Agency-Information/H1N1/downloads/AlternativeCareSiteFactSheet.pdf

C.11(c): Can alternative sites include outbuildings on the campus or use of tents in the parking lot?

Alternative screening sites may be located in other buildings on the campus of a hospital or in tents in the parking lot, as long as they are determined to be an appropriate setting for medical screening activities and meet the clinical requirements of the individuals referred to that setting.

However, we note the following from the CDC's guidance for frontline healthcare facilities: "State and local public health departments are actively monitoring persons with a recognized EVD exposure risk within the last 21 days (CDC's Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure (http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html)). Therefore, these persons will be directed to designated facilities for evaluation if they become ill, making it unlikely that patients with unrecognized EVD disease will present

to a frontline healthcare facility without warning. However, it is also possible that patients with unrecognized EVD will present to a frontline healthcare facility unannounced, or rarely, patients may be temporarily referred to frontline healthcare facilities when it is not feasible to refer to an Ebola assessment hospital or treatment center (e.g. based on distance, bed availability, or other considerations)."

Given the unlikelihood that persons with a recognized EVD exposure will present to a hospital that has not been designated for EVD assessment or treatment, it may be misguided for hospitals to be contemplating measures more suitable to handling a surge in the volume of ED patients, such as setting up tents in the parking lot. This is particularly the case when such arrangements may expose individuals to inclement weather conditions.

C.11(d): What would be an acceptable alternative location <u>on campus</u>? Must the location currently exist as a part of the certified facility?

The location must be part of the certified hospital. If it is not currently part of the certified hospital, then the hospital must take steps to add the location as a new practice location of the hospital.

C.11(e): What type of approval process needs to be in place for a hospital to use an alternative location?

CMS does not require any approval process to use an alternative screening location that is already part of the certified hospital. If the hospital is adding a practice location, it must file a Form 855A with its Medicare Administrative Contractor to advise it of this action. The hospital is not required to obtain prior approval from CMS in order to bill Medicare for services at the added location. There is also no requirement for all added locations to be surveyed for compliance with the Medicare Hospital Conditions of Participation, but CMS retains the discretion to require a survey in individual cases.

States may have licensure requirements for prior approval of any additional practice locations, so hospitals are encouraged to consult with their State licensure authority on any applicable State requirements.

C.11(f): In the past when there have been disasters that resulted in ED surges alternative locations needed to be submitted and approved by State licensure authorities and also by CMS. Does this hold true for alternative locations for screening of potential EVD patients?

See answer to the prior question. As stated, CMS does not require prior approval for hospitals that are adding a practice location. Hospitals should consult with their State licensure authority on any applicable State requirements.

D. Patient Rights

D.1: What action should the hospital take if an individual who meets the screening criteria for suspected EVD wants to leave the hospital against medical advice?

Hospitals do not have authority to prevent the individual from leaving against medical advice. However, State or local public health authorities may have such authority under State or local law, and hospitals should coordinate with their local authorities on the appropriate way to handle an individual suspected of having EVD who wants to leave the hospital environment.

Note that there is an EMTALA requirement at §489.24(d)(3) for a hospital to take all reasonable steps to secure the individual's written informed refusal (or that of the individual's representative) of further medical examination or treatment that the hospital has offered.

D.2: What should the hospital do if a patient who has been deemed likely to have Ebola refuses to be transferred to a designated EVD treatment facility or other facility with the capabilities to treat this condition?

Hospitals do not have authority to compel the patient to accept a transfer. However, State or local public health authorities may have authority under State or local law to address such situations, and hospitals should coordinate with their local authorities on the appropriate way to handle an individual deemed likely to have EVD who refuses to be transferred to another hospital that has the specialized EVD capabilities the individual needs and which the referring hospital lacks.

Note that there is an EMTALA requirement at §489.24(d)(5) for a hospital to take all reasonable steps to secure the individual's written informed refusal (or that of the individual's representative) of an appropriate transfer. The written document must indicate that the individual has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal.

E. Enforcement

E.1: What will CMS do when a survey reveals that a hospital is not following nationally recognized guidelines regarding EVD infection control processes?

EMTALA does not establish requirements for infection control practices. However, consistent with their obligations under the hospital and CAH Medicare CoPs at §482.42 and §485.635(a)(3)(vi), hospitals and CAHs are expected to adhere to accepted standards of infection control practice to prevent the spread of EVD. Ebola is transmitted through direct contact with blood or body fluids of a person who is sick with Ebola; the virus is not transmitted through the air (like measles virus). However, large droplets (splashes or sprays) of respiratory or other secretions from a person who is sick with Ebola could be infectious, and therefore specific precautions are recommended for use in healthcare settings to prevent the transmission of Ebola from patients to healthcare personnel and other patients or family members. The CDC has issued extensive guidance on applicable isolation precautions and CMS strongly urges hospitals to

follow this guidance. Hospitals may be cited for deficiencies under the CoPs related to failure to follow accepted infection prevention and control standards of practice.

E.2: How will CMS handle complaints about violations of EMTALA related to transfers/attempts to transfer individuals suspected or confirmed as having EVD?

If CMS receives complaints alleging either inappropriate transfers by a referring hospital or refusal of a recipient hospital to accept an appropriate transfer, the agency will consider the following (along with other factors) when making a determination of whether violations of EMTALA have occurred:

- The individual's clinical condition at the time of presentation to the referring hospital and at the time of the transfer request;
- The capabilities of the referring hospital, including whether State or local public health authorities have designated it as having specialized capabilities related to EVD, and the hospital's capacity at the time of the transfer request;
- The screening and treatment activities performed by the referring hospital for the individual;
- Whether the request for transfer was consistent with any nationally recognized guidelines in effect at the time of the transfer request for EVD screening, assessment, or treatment, including guidance about transfer for further assessment or treatment of suspected or confirmed EVD; and
- The capabilities of the recipient hospital, including whether State or local public health authorities have designated it as having specialized capabilities related to EVD and the recipient hospital's capacity at the time of the transfer request.