

EBOLA PREPAREDNESS: Mission Critical for Hospitals and Health Systems

October 28, 2014

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Heather L. Fields is a shareholder in the firm's Health Care Practice and chairs the firm's Hospitals and Health Care Systems group. She is also a member of the firm's Hospice and Palliative Care group and the Tax-Exempt Organizations group. She routinely serves as counsel to acute-care hospitals, multiprovider health care systems, multispecialty clinics, hospices and long term care providers, assisting them with a wide variety of regulatory, transactional, and compliance-related matters. She has extensive experience advising clients in connection with fraud and abuse issues that arise in the context of various health care provider relationships and transactions. She also advises clients on designing and implementing corporate compliance programs and assessing compliance program effectiveness, all aspects of HIPAA compliance, clinical research compliance, and 340B compliance. She is certified in Healthcare Compliance (CHC) and is a Certified Compliance and Ethics Professional (CCEP).

AGENDA

11:45am CT Attendees Sign On

12:00pm CT Webinar

Asking Questions

Throughout the webinar, type your questions using the "QUESTIONS" section in the webinar panel.

We will answer as many questions as possible at the end of the webinar.

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Information

This webinar provides general information about legal issues. It should not be construed as legal advice or a legal opinion. Attendees should seek legal counsel concerning specific factual situations confronting them.

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Overview

- Ebola-Preparedness and the Board
- EMTALA Implications of Managing Ebola
- Health Care Worker Protection – the Interplay Between CDC and OSHA
- Employment Considerations
- HIPAA Compliance
- Questions and Answers

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Ebola Preparedness and the Board

Heather L. Fields, Presenter

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Ebola Preparedness and the Board

- Medicare Conditions of Participation
 - 42 C.F.R. § 482.12: Hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution
 - 42 C.F.R. § 482.42: Hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases, including:
 - Maintaining an active program for the prevention, control and investigation of infections and communicable diseases
 - Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers

Ebola Preparedness and the Board (cont.)

- The Joint Commission Standards
 - LD.01.03.01: The governing body is ultimately accountable for the safety and quality of care, treatment and services
 - Element of Performance: The governing body provides the resources needed to maintain safe, quality care, treatment and services
 - IC.01.02.01: Hospital leaders allocate needed resources for the infection prevention and control program

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Ebola Preparedness and the Board (cont.)

- State Licensing Requirements
 - Wis. Admin. Code DHS 124.08: Hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases . . . the governing body or medical staff shall establish an infection control committee to carry out surveillance and investigation of infections in the hospital and to implement measures designed to reduce these infections to the extent possible
 - 77 Ill. Adm. Code 250.1100: When patients having a communicable disease, or presenting signs and symptoms suggestive of that diagnosis, are admitted, proper precautionary measures shall be taken to avoid cross-infection to personnel, other patients or the public . . . The hospital shall provide facilities and equipment for the isolation of known or suspected cases of infectious disease

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Board's Oversight Role in Ebola Response

- What are the key elements of the organization's overall response plan?
 - Management of patient's presenting to ED, urgent care, ambulatory care sites, affiliated physician practices?
 - Screening practices? Transfer protocols? Adequacy of facilities for isolation?
- What is the organization doing to protect employees?
 - CDC guidelines fully implemented and "stress tested"?
 - What is the organization's labor relations strategy?
 - How is this being communicated?
 - Hotlines for complaints? Town hall meetings?

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Ebola and EMTALA Compliance

Heather L. Fields, Presenter

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Ebola and EMTALA Compliance

- EMTALA Requirements
 - Screening: Any individual who comes to the emergency department and requests examination or treatment for a medical condition **MUST** be provided an appropriate medical screening examination within the capability of the hospital's emergency department to determine whether or not an emergency medical condition exists
 - Treatment: If it is determined that an Emergency Medical Condition exists, the hospital must provide treatment to stabilize the medical condition, or appropriately transfer the individual to another hospital

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Ebola and EMTALA Compliance (cont.)

- CDC guidance on Ebola patients
 - Isolate patients presenting with Ebola symptoms in a room with a private bathroom
 - Contact the local health department
- Adequacy of physical facilities to isolate?
- Proper training to ensure safe screening and stabilization?

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Ebola and EMTALA Compliance (cont.)

- "Appropriate" Transfers
 - Individual requests in writing after being informed of the hospital's obligations and the risks of transfer
 - A physician (or a qualified medical person under limited circumstances) signs a certification that, based on the patient's condition, the benefits of the transfer outweigh the risks of the transfer
 - Hospital has minimized the risks of transfer, the transfer is effected through qualified transportation equipment, the receiving hospital has agreed to the transfer, and medical records for the individual are sent to the receiving hospital

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Ebola and EMTALA Compliance (cont.)

- Receiving EMTALA Transfers
 - A participating hospital that has specialized capabilities or facilities may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual
 - Lateral transfers (*i.e.*, transfers between hospitals of comparable resources and capabilities) are not required to accept a transfer (except when the transferring hospital does not have the capacity)

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EBOLA: OSHA ISSUES

Jeffrey P. Clark, Presenter

With Contributions from Carolyn A. Sullivan and Scott D. Prill

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Ebola: OSHA Introduction

"Ebola hemorrhagic fever (EHF) is the disease caused by infection with an Ebola virus. **Workers performing tasks involving close contact with symptomatic individuals with EHF or in environments contaminated or reasonably anticipated to be contaminated with infectious body fluids are at risk of exposure. These workers may include workers in the healthcare . . . and other . . . industries.**"



OSHA, *Safety & Health Topics: Ebola – Introduction.*

Ebola – Medical Information of Concern to OSHA

"Though transmission through inhalation of airborne virus is not currently a primary concern during naturally occurring outbreaks, it may be possible for Ebola virus to be aerosolized under certain conditions. In all settings, avoid using compressed air or water when cleaning surfaces, as it might cause droplets containing infectious material to become airborne (i.e., create a bioaerosol)."

OSHA, *Safety & Health Topics: Ebola – Medical Information.*

OSHA's General Duty Clause

Section 5 of OSH Act of 1970, 29 U.S.C. § 654

(a) Each employer

(1) shall furnish to each of [its] employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this chapter.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this chapter which are applicable to his [or her] own actions and conduct.

OSHA's Standards Applicable to Ebola

"OSHA's Bloodborne Pathogens standard (29 C.F.R. 1910.1030) covers exposure to Ebola virus. Ebola is among the subset of contact transmissible diseases to which the Bloodborne Pathogens standard applies, as it is transmitted by blood or other potentially infectious materials as defined in the standard.

In situations where workers may be exposed to bioaerosols containing Ebola virus, employers must also follow **OSHA's Respiratory Protection standard (29 C.F.R. 1910.134)**.

Other elements of infection control for Ebola, including a number of precautions for contact transmissible diseases, are covered under **OSHA's Personal Protective Equipment (PPE) standard (29 C.F.R. 1910.132) and the General Duty Clause of the Occupational Safety and Health (OSH) Act of 1970**, which requires employers to keep their workplace free of recognized hazards that can cause death or serious harm to workers.

Employers may also be required to follow these and other standards to protect their workers from exposure to chemicals used for cleaning and disinfection. Depending on the specific chemicals used, different or additional PPE (e.g., elastomeric respirators with appropriate cartridges) may be required."

OSHA, *Safety & Health Topics: Ebola – Standards*.

OSHA's Personal Protective Equipment (PPE) Standard

29 C.F.R. Section 1910 Subpart I, Personal protective equipment

- Section 1910.132 General requirements
 - (a) *Application*. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.
- Section 1910.133 Eye and face protection
- Section 1910.134 Respiratory protection
 - Appendix A Fit testing procedures (Mandatory)
 - Appendix B-1 User seal check procedures (Mandatory)
 - Appendix B-2 Respiratory cleaning procedures (Mandatory)
 - Appendix C OSHA respirator medical evaluation questionnaire (Mandatory)
 - Appendix D Information for employees using respirators when not required under standard (Mandatory)
- Section 1910.135 Head protection
- Section 1910.136 Foot protection
- Section 1910.138 Hand Protection

OSHA's PPE Standard (cont.)

"Generally, healthcare workers must use proper personal protective equipment (PPE) and other infection control measures to avoid exposure to infected blood and body fluids, contaminated objects, or other contaminated environmental surfaces. WHO and CDC recommend that healthcare workers in close contact with EHF patients (< 1 meter) wear face protection (a face shield or a medical mask and goggles); a clean, non sterile long sleeved gown; and gloves (sterile gloves for some procedures)."

OSHA, *Safety & Health Topics: Ebola – Control and Prevention.*

OSHA's Bloodborne Pathogens Standard

29 C.F.R. § 1910.1030—Bloodborne Pathogens applies to all occupational exposure to blood or other potentially infectious materials.

- In general, the standard requires employers to:
 - Establish an exposure control plan
 - Update the plan annually
 - Implement the use of universal precautions
 - Identify and use engineering controls
 - Identify and use work practice controls
 - Provide personal protective equipment (PPE), such as gloves, gowns, eye protection, and masks
 - Make available hepatitis B vaccinations to all workers with occupational exposure
 - Make available post-exposure medical evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident
 - Use labels and signs to communicate hazards
 - Inform and train workers
 - Maintain worker medical and training records

OSHA's Chemical Hazard Communication Standard

29 C.F.R. § 1910.1200, Hazard Communication

- (a)(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

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OSHA's Proposed Infectious Diseases Standard

"The healthcare and social assistance sector is among the largest of the industrial sectors in the U.S. As of 2007, there were 16.5 million employees in this sector, 11 million of those are classified as healthcare workers (HCWs). HCWs work in a great variety of settings. A large proportion of these HCWs provide direct patient care (i.e., they provide healthcare services with face to face or hands on contact with patients) and have occupational exposure to infectious agents during the performance of their duties.

Employees in health care and other high risk environments face long standing infectious disease hazards such as TB, [and] influenza . . . that can cause significant disease. Although the Bloodborne Pathogens standard has been very effective in protecting workers, it does not address infectious diseases transmitted by other routes (e.g., contact, droplet and airborne). In addition, OSHA believes that a standard is needed because transmission based infection control guidelines, though readily available, are not consistently followed."

OSHA: *Infectious Diseases Rulemaking.*

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OSHA's Interim Guidance for Ebola-Exposed Workers

"The following are OSHA's requirements and recommendations for protecting workers whose work activities are conducted in an environment that is known or reasonably suspected to be contaminated with Ebola virus (e.g., due to contamination with blood or other potentially infectious material). These general guidelines are not intended to cover workers who have direct contact with individuals with EHF.

- Employers should follow recognized and generally accepted good infection control practices, and must meet applicable requirements in the **Personal Protective Equipment standard (29 C.F.R. 1910.132, general requirements) and the Respiratory Protection standard (29 C.F.R. 1910.134).**
- Use proper personal protective equipment (PPE) and good hand hygiene protocols to avoid exposure to infected blood and body fluids, contaminated objects, or other contaminated environmental surfaces.
- Wear gloves, wash hands with soap and water after removing gloves, and discard used gloves in properly labeled waste containers."

OSHA, *Safety & Health Topics: Ebola – Control and Prevention.*

OSHA's Interim Guidance for Ebola-Exposed Workers (cont.)

- "Workers who may be splashed, sprayed, or spattered with blood or body fluids from environmental surfaces where Ebola virus contamination is possible must wear face and eye protection, such as a full face shield or surgical masks with goggles. Aprons or other fluid resistant protective clothing must also be worn in these situations to prevent the worker's clothes from being soiled with infectious material.
- Workers tasked with cleaning surfaces that may be contaminated with Ebola virus must be protected from exposure.
- Employers must train workers about the sources of Ebola exposure and appropriate precautions. Employers must train workers required to use personal protective equipment on what equipment is necessary, when and how they must use it, and how to dispose of the equipment. In addition where workers are exposed to blood or other potentially infectious materials, employers must provide the training required by the **Bloodborne Pathogens standard.**"

OSHA, *Safety & Health Topics: Ebola – Control and Prevention.*



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Release Date: Monday, October 20, 2014

Tightened Guidance for U.S. Healthcare Workers on Personal Protective Equipment for Ebola

The enhanced CDC guidance has three principles:

- Rigorously train all healthcare workers so that they are practiced and competent with PPE, including correctly putting it on and taking it off
- No skin exposure when PPE is worn
- Trained monitor supervises all workers who wear PPE and watches each worker putting on and taking off PPE

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CDC Tightened Guidance (cont.)

Principle #1: Rigorous and repeated training

Focusing only on PPE can give a false sense of security of safe care and worker safety. Training is critical to ensuring infection control.

Principle #2: No skin exposure when PPE is worn

Given the intensive and invasive care that U.S. hospitals provide for Ebola patients, there should be no skin exposure when PPE is worn:

- Double gloves
- Boot covers that are waterproof and go to at least mid-calf or leg covers
- Single-use fluid resistant or impermeable gown that extends to at least mid-calf or coverall without integrated hood.
- Respirators, including either N95 respirators or powered air purifying respirator (PAPR)
- Single-use, full-face shield that is disposable
- Surgical hoods to ensure complete coverage of the head and neck
- Apron that is waterproof and covers the torso to the mid-calf (and covers the top of the boots or boot covers) should be used if Ebola patients vomit or have diarrhea

Principle #3: Trained monitor

- Trained monitor should actively observe and supervise each worker putting on and taking off PPE
- Ensure workers follow the step-by-step processes and disinfect visibly contaminated PPE

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Worker and Employer Rights

"Any worker who may reasonably be expected to come into contact with the Ebola virus, either from the work environment or from direct contact with individuals infected, has the right to know the hazards associated with this potential exposure and how to protect themselves during work activities. Any occupational exposure to blood or other potentially infectious materials fall under the requirements in the Bloodborne Pathogens Standard (29 C.F.R. 1910.1030). Other occupational exposures may require protection of workers under the PPE Standard (29 C.F.R. 1910.132), Respiratory Protection Standard (29 C.F.R. 1910.134), or the General Duty Clause of the OSH Act (29 USC 654(a)).

Information about communicating job hazards to workers is available on OSHA's Hazard Communication page. While OSHA's Hazard Communication Standard (29 C.F.R. 1910.1200) does not apply to the Ebola virus itself, employers may be required to comply with the standard when chemicals are used for cleaning and disinfection of the work environment."

OSHA, *Safety & Health Topics: Ebola – Control and Prevention.*

Worker Rights – Whistleblower Protection

"(1) No person shall discharge or in any manner discriminate against any employee because such employee has filed any complaint or instituted or caused to be instituted any proceeding under or related to this chapter or has testified or is about to testify in any such proceeding or because of the exercise by such employee on behalf of himself or others of any right afforded by this chapter.

(2) Any employee who believes that he has been discharged or otherwise discriminated against by any person in violation of this subsection may, within thirty days after such violation occurs, file a complaint with the Secretary alleging such discrimination."

29 U.S.C. § 660(c)

Worker and Employer Rights (cont.)

"As a general matter, there is no right afforded by the Act which would entitle employees to walk off the job because of potential unsafe conditions at the workplace. Hazardous conditions which may be violative of the Act will ordinarily be corrected by the employer, once brought to his attention. If corrections are not accomplished, or if there is dispute about the existence of a hazard, the employee will normally have opportunity to request inspection of the workplace pursuant to section 8(f) of the Act. Under such circumstances, therefore, an employer would not ordinarily be in violation of section 11(c) by taking action to discipline an employee for refusing to perform normal job activities because of alleged safety or health hazards.

(2) However, occasions might arise when an employee is confronted with a choice between not performing assigned tasks or subjecting himself to serious injury or death arising from a hazardous condition at the workplace. If the employee, with no reasonable alternative, refuses in good faith to expose himself to the dangerous condition, he would be protected against subsequent discrimination. The condition causing the employee's apprehension of death or injury must be of such a nature that a reasonable person, under the circumstances then confronting the employee, would conclude that there is a real danger of death or serious injury and that there is insufficient time, due to the urgency of the situation, to eliminate the danger through resort to regular statutory enforcement channels. In addition, in such circumstances, the employee, where possible, must also have sought from his employer, and been unable to obtain, a correction of the dangerous condition."

29 C.F.R. § 1977.12 (b)(emphasis added).

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Worker and Employer Rights (cont.)

"Employees who refuse to comply with occupational safety and health standards or valid safety rules implemented by the employer in furtherance of the Act are not exercising any rights afforded by the Act. **Disciplinary measures taken by employers solely in response to employee refusal to comply with appropriate safety rules and regulations, will not ordinarily be regarded as discriminatory action prohibited by section 11(c).** This situation should be distinguished from refusals to work, as discussed in §1977.12."

29 C.F.R. § 1977.22 (emphasis added).

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Ebola Preparedness and Employment Considerations

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Americans With Disabilities Act

- Background
 - What is a disability?
 - What are an employer's obligations?

Americans With Disabilities Act (cont.)

- Medical exams
 - When can we require medical exams of current employees?
 - Must be "job related and consistent with business necessity"
 - The EEOC has explained that medical exams are "job related and consistent with business necessity" when an employer has a reasonable belief, based on *objective* evidence, that:
 - An employee's ability to perform essential job functions will be impaired by a medical condition; or
 - An employee will pose a direct threat due to a medical condition

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Americans With Disabilities Act (cont.)

- Direct threat
 - "Significant risk of substantial harm to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation."
 - Consider:
 - » Duration of risk;
 - » Nature and severity of the potential harm;
 - » Likelihood that potential harm will occur; and
 - » Imminence of the potential harm
 - Rely on latest CDC and state or local public health assessments
- When can we ask medical questions?

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Americans With Disabilities Act (cont.)

- What are the ADA implications of Ebola?
 - Is Ebola a disability?
 - What are the possible accommodations?
 - What questions can we ask about Ebola?
 - When can we require employees to submit to a temperature check?
 - Can we send employees home if they display Ebola symptoms?
 - Can we require employees to report their travels to locations where there has been an Ebola outbreak, and/or contact they had with an Ebola- infected individual?

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Title VII

- Race discrimination
- National origin discrimination

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Family and Medical Leave Act

- Serious health condition
- FMLA obligations
- Can an employee qualify for FMLA leave for "suspected" Ebola?
- Wages

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National Labor Relations Act

- Employees have the right to engage in concerted activity for their mutual aid and protection

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Recommendations

- Be proactive – not overactive
- Review leave/time-off policies
 - What is the organization's position?
 - Ensure consistency
 - Exceptions due to CDC-identified outbreaks?
- Special "hotline" to report safety concerns?
- Establish self-reporting requirements of potential symptoms
- Educate and train employees
- Review EEOC guidance: "Pandemic Preparedness in the Workplace and the Americans With Disabilities Act"
- Ensure medical information is kept confidential and *not kept in personnel files*

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HIPAA Compliance

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HIPAA Compliance

- HIPAA permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease (45 C.F.R. § 164.512(b)(1)(i))
- HIPAA allows a covered entity to disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations (45 C.F.R. § 164.512(b)(1)(iv))

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HIPAA Compliance Steps

- Develop "VIP" Policy and Procedure:
 - E-mail blasts to remind all employees about the hospital's HIPAA policies and the consequences of inappropriately accessing medical records
 - Record locks on the medical records of Ebola patients
 - Access audits
 - Consider registering patients under an alias

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Additional Resources

- CDC Detailed Checklist for Ebola Preparedness:
<http://www.cdc.gov/vhf/ebola/pdf/hospital-checklist-ebola-preparedness.pdf>
- The U.S. Centers for Disease Control and Prevention (CDC):
<http://www.cdc.gov/vhf/ebola/>
- CDC Workplace Safety & Health Topics:
<http://www.cdc.gov/niosh/topics/ebola/>

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Questions?

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THANK YOU!

Thank you for attending our webinar.
If you have any questions, please contact
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