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Attorney Advertising
Epstein Becker Green Speakers

George B. Breen
Board of Directors / Member of the Firm
gbreen@ebglaw.com
Tel: 202-861-1823

Frank C. Morris, Jr.
Member of the Firm
fmorris@ebglaw.com
Tel: 202-861-1880

Amy F. Lerman
Associate
alerman@ebglaw.com
Tel: 202-861-1832
Guest Speaker

Bruno Petinaux, M.D.
Associate Professor, Co-Chief of the Emergency Management Section, Department of Emergency Medicine, George Washington University Medical Faculty Associates
Agenda

1. Ebola Virus Disease : Overview and Impact on Healthcare Delivery
2. Health Regulatory Considerations
3. Risk Management Considerations
4. Labor and Employment Considerations
5. Questions and Answers
EVD Overview

- Medical Overview
- Disease Overview
- The Effect on Healthcare Delivery
  - Ease of Transmission
  - Nonspecific Symptoms
  - Medical Waste
  - Media Impact
  - Public Health
  - Financial Implications
Ebola Virus Disease

- Medical Overview
  - Ebola is a Virus believed to exist in bats in Central and West Africa
  - Identified first in 1976
  - Carries a very high mortality rate in those lacking good access to healthcare (90%)
Ebola Virus Disease

- Medical Overview
  - Ebola is spread by
    - Direct contact with bodily fluids
      - Blood
      - Sputum
      - Vomitus/stool
      - Semen/vaginal fluids
      - Sweat
    - Requires contact and droplet precautions in addition to universal precautions
    - NOT believed to be airborne
Ebola Virus Disease

- Disease Overview
  - Time of exposure to disease to becoming ill (incubation period) is 2-21 days
    - During this incubation period, the patient is NOT infectious to other people
  - First symptoms tend to be very nonspecific
    - Fever
    - Malaise
    - Nausea/Vomiting/Diarrhea
    - Abdominal Pain
    - Muscle Aches
Ebola Virus Disease

- **Disease Overview**
  - Dehydration due to large diarrhea
    - Must hydrate appropriately
    - Replace electrolytes
  - Support organs/body
    - Kidneys – dialysis
    - Lungs – life support
    - Bleeding – transfusions
  - Novel, non FDA approved, treatments tried
    - Transfusion of serum of survivors
    - Novel medications
    - Vaccines
Ebola Virus Disease

- Disease Overview
  - To date in the United States
    - 10 patients – 2 deaths
      - Level of supportive care and early recognition and aggressive medical management
      - Use of novel medications in some cases?
Attributes That Affect Healthcare

- Ease of Transmission
- Nonspecific Symptoms
- Medical Waste
- Media Impact
- Public Health
- Financial Implications
Ease of Transmission

- Staff may be reluctant to care for such a patient, especially after the occupational infection of two nurses in the US
- High level of Personal Protective Equipment (PPE) necessary to care for these patients
  - necessitates some non traditional PPE normally stocked in hospitals
  - Need to educate healthcare staff in donning and doffing the PPE
  - Need to develop strict protocol to ensure staff safety
  - Need to exclude some staff who may not be suitable to wear PPE
Ease of Transmission

- Due to the use of complex PPE, staff may need to work in shorter shifts
- Minimize staff member contact with the patient
  - Type of contact
  - Number of staff members
Ease of Transmission

- Healthcare facilities put processes in place to protect the staff, what if these fail?
  - Staff members become ill with Ebola
    - Should hospitals limit the activities of staff who have cared for an Ebola patient prospectively?
    - Incubation period is up to 21 days
      - Where
      - Who
      - How
Ease of Transmission

- If a hospital does not feel adequately prepared to handle such patients
  - Can a hospital turn away an ambulance bringing a patient of concern?
- Can a hospital turn down a transfer of such a patient from another lower level care facility
Nonspecific Symptoms

- Identify symptomatic patients very early and quickly
- EVD presents with similar symptoms to a large number of other diseases
  - Influenza
  - Malaria
  - Infectious diarrhea
  - Viral illnesses
Nonspecific Symptoms

- Travel history is critical to identify a patient population at risk
  - Where the disease is known to be geographically active
  - Includes our own staff members
- Contact history is critical to identify a patient population at risk
  - Known or likely contacts with EVD patients
  - Includes healthcare workers caring for EVD patients
- Travel AND contact history do not apply to New York City case
Medical Waste

- The care of an EVD patient generates large amounts of medical waste
- The medical waste is infectious for a certain period of time before the virus dies in the environment
- Regulated as Category A Medical Waste by US DOT
- Requires complex packaging and permitting process
Public Health Implications

- Public Health Departments need to provide for contact tracing for any EVD infection in the US
  - Where was the patient while symptomatic?
  - Identify at risk persons and institute monitoring and surveillance for those who may become symptomatic over the next 21 days of last contact
Focus by the Media

- Prior EVD patients in the United States have attracted a lot of media coverage for the patients as well as healthcare facility caring for that patient
- Privacy must be maintained
Financial Implications

- The preparedness efforts for an EVD patient generates a lot of costs to a healthcare facility (planning, training, equipping, exercising)
- The presence of an EVD patient may impact ED volume and elective procedures at the healthcare facility
Available Resources

http://www.cdc.gov/vhf/ebola
Health Regulatory Considerations
Ebola – Health Regulatory Considerations

- **The Tension**: Coping with patients infected with Ebola, while at the same time keeping up with existing demand for health care services

- **The Reality**: Legal and regulatory standards that govern the provision of health care services, and in particular, health care providers, may need to be more flexible or completely reworked in the wake of a pandemic such as Ebola.

- **The Solution**: Recalibrating traditional legal and regulatory standards for provision of health care services and the practices of health care providers in the context of a pandemic such as Ebola, for:
  - Protecting patients
  - Regulating and protecting health care workers
  - Apportioning risk
Consideration #1: Scope of Practice & Licensure

- Every state has laws regulating the “practice of medicine”
  - Some states define “practice of medicine” as including—directly or indirectly—activities related to providing health care at a distance

- States monitor the practices of health care providers within their boundaries
  - State medical boards are responsible for regulating the practices of physicians and other health care professionals within their states
  - Licensure is the process through which states validate providers’ credentials

- State scope of practice and licensure laws may present challenges when health care providers are forced to mobilize a workforce to manage the treatment of Ebola patients
  - Processes for obtaining licensure in multiple states
  - Potential avenues for increasing license portability
    - Federation of State Medical Boards Interstate Medical Licensure Compact
    - National Council of State Boards of Nursing Nurse Licensure Compact
Consideration #2: Credentialing & Privileging

- Credentialing – evaluating qualifications and practice history of providers
  - Education, Licensure, and Certifications
  - National Practitioner Data Bank
  - References

- Privileging – determining scope and content of patient care services authorized for a provider to perform within a health care organization
  - Evaluation of a provider’s credentials and performance
  - Peer review

- Traditional credentialing and privileging policies and processes may present challenges when health care providers are forced to mobilize a workforce to manage the treatment of Ebola patients
  - Provider movement from one health care facility to another
  - Identification and training of potential health care volunteers
Consideration #3: Patient Data Privacy

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA")
  - Privacy Rule (45 C.F.R. Part 160 and Part 164, Subparts A and E)
  - Security Rule (45 C.F.R. Part 160 and Part 164, Subparts A and C)

- All patients are protected under HIPAA and any applicable state privacy laws
  - Certain disclosures are permitted and are reasonable
  - Otherwise, patients have a right to privacy, which **must** be respected

- Health care providers, as Covered Entities, must comply with HIPAA and applicable state laws regarding the privacy of patient information
  - May disclose PHI to comply with public health laws, for purposes of reporting communicable diseases, for public health surveillance, and for public health investigations
  - May disclose PHI to prevent or lessen a serious threat to the health or safety of a person or the public, if the disclosure is to a person or entity that is reasonably able to prevent or lessen the threat

- HHS Office for Civil Rights Bulletin: HIPAA Privacy in Emergency Situations (Nov. 2014)
Consideration #3: Patient Data Privacy

Nebraska Medical Center

In October 2014, NMC fired two employees who allegedly “inappropriately accessed” the medical records of Dr. Rick Sacra, a patient who contracted Ebola while working in West Africa.

The HIPAA violation was discovered by NMC officials conducting an audit of their electronic health records system. Hospital officials conducted an investigation that resulted in the ultimate corrective action. NMC informed Dr. Sacra of the breach prior to his release from the facility.

“This is a violation of HIPAA regulations and an issue we take very seriously. Based on the results of the investigation conducted, two employees no longer work for the organization and other corrective action has been taken. While this is extremely uncommon, we have a zero tolerance for unauthorized access to patient information.”
Consideration #4: FDA’s Role in Ebola

- Sharing Information
- Collaborating with Other Agencies / International Partners / Private Industry
- Working with Medical Product Sponsors
- Utilizing Agency-Specific Powers and Processes
  - Emergency Use Authorization (EUA)
  - Expanded Access (e.g., via emergency Investigational New Drug applications)
- Monitoring for Fraudulent Products and False Product Claims
- Encouraging Development of Treatments for Ebola
  - Orphan designation and other drug developmental programs
  - Collaboration with the European Medicines Agency
Consideration #4: FDA

- FDA may provide access to unapproved drugs under limited conditions:
  - Life-threatening disease with no generally accepted treatment
  - No time for submission of an Investigational New Drug application
  - Manufacturer must agree to the use
  - May use without Institutional Review Board approval

- FDA considerations for user facilities include:
  - Proper informed consent for use of experimental / investigational therapies
  - FDA authorization / IRB approval for use of investigational therapies
  - Adverse event reporting obligations

- FDA considerations for manufacturers include:
  - Adverse event reporting obligations
  - Obligations (cGMPs) to prevent contamination of products
  - Content of communications with the public
Consideration #5: Cost, Coverage & Reimbursement

- **Private Payer Considerations**
  - Who is a “participating provider”?  
  - How will plans cover Ebola-specific treatments, products used in treatment, etc.?

- **Public Payer Considerations**
  - Medicare Conditions of Participation (e.g., 42 C.F.R. Part 482 for hospitals)
    - CoPs address issues including infection control (§ 482.42), emergency services (§ 482.55), compliance with federal, state, and local laws (§ 482.11)
    - CoP violations could result in termination of a hospital’s provider agreements
  - Federal Employees Health Benefits Plan (FEHBP)
    - OPM guidance to FEHBP carriers on their responsibilities for handling members who have been exposed to the Ebola virus
    - Guidance covers issues including coverage of various therapies, compensation for work-related exposures, and medical evacuation / patient transport
Risk Management Considerations
Consideration #1: Policies and Training

- Monitor developments reported by international, national and local health authorities.
- Demonstrate compliance by utilizing most current protocols and best practices in developing policies.
- Train and re-train staff as polices and protocols change.
- Document training and re-training.
- Audit to ensure training was effective – intervene if there are lapses.
Consideration #2: Communication

- Consider establishment of crisis management and response teams.
- Manage communications – both internal and external.
- Speak through one voice.
  - Identify speaker.
  - Be consistent.
- Control press inquiries and responses.
  - Legal review of public statements.
Consideration #3: EMTALA

- EMTALA (Emergency Medical Treatment and Labor Act).
  - Hospitals participating in the Medicare program that offer emergency services must provide medical screening for the presence or absence of emergency medical conditions.
    - Hospital must provide stabilizing treatment for patients within the hospital’s capability and capacity of conditions forward.
    - Transfer may be necessary.
    - Appendix V of the Medicare State Operations Manual: “The enforcement of EMTALA is a complaint driven process. The investigation of a hospital’s policies / procedures and processes and any subsequent sanctions are initiated by a complaint.” If an investigation determines that the hospital violated the provisions of EMTALA “a hospital may be subject to termination of its provider agreement [with the Medicare program] and/or the imposition of civil monetary penalties (CMPs). CMPs may be imposed against hospitals or individual physicians for EMTALA violations.”
    - EMTALA also provides a private cause of action as a result of a hospital’s violation of EMTALA’s requirements.
Consideration #4: Informed Consent

- If Ebola patients present at U.S. hospitals and certain medications have not yet approved by the FDA, hospitals will have to decide whether to administer such unproven drugs to these patients. To do so, hospitals must obtain informed consent from the patient.

- To provide informed consent, provider required to advise patient of all of the potential benefits, risks and alternatives involved in a course of treatment and must obtain patient’s written consent to proceed.

- Failure to provide informed consent can result in negligence claims, as well as FDA sanctions.

- Need to ensure informed consent policies are updated and involved staff are trained.
Consideration #5: Evaluate Insurance Coverage

- Review and assess applicability of available coverage:
  - Workers Compensation
  - Business Interruption
  - Directors and Officers Liability
  - Environmental Coverage / PLL Policy
  - General Liability
Consideration #6: Other Issues

- Know your facility and its capacity.
- Internal monitoring and assessment.
- Documentation and Privilege concerns.
- Monitor staff caring for patients and establish care protocols.
- Protect hospital staff and employees.
Employment Law Considerations
Ebola in the Workplace

Managing Employee Concerns

- Likelihood of Ebola in your organization is generally low
  - There is no outbreak in the United States
  - A person who does not have symptoms cannot transmit the disease
  - A person who does have symptoms is likely too sick to come to work

- Healthcare organizations obviously at a higher risk, but risk is still very low for most
Ebola in the Workplace

Managing Employee Concerns

- Educate your workforce
  - Healthcare providers or healthcare support providers must comply with the most up to date guidelines from the CDC and WHO
    - Let employees know about your preparations as to both equipment and training
  - If non-healthcare employer and believe employees are concerned about the disease, educate them on symptoms, transmission, and the unlikelihood of an American outbreak of Ebola

- Appoint a point of contact, perhaps a clinician and a Human Resources director, to field all questions and concerns
EVD and Pandemic Planning

- Infectious disease plan including EVD
- Anticipate employee questions about safety, leave, compensation and benefits
- Explore possible changes to flexible work, pay, PTO and unpaid leave policies
- Anticipate needs for personal protective equipment and decontamination protocols and facilities and training
- Communicate with employees regarding:
  - Staying home if sick
  - Confidentially communicating about any symptom
Legal Concerns

- Disability discrimination – The Americans with Disabilities Act (ADA)

- Discrimination on the basis of other protected categories
  - Federal – Title VII of the Civil Rights Act
  - State
  - Local
  - Leave
    - Family and Medical Leave Act (FMLA)
    - State and local laws

- Retaliation – ADA, Title VII, FMLA etc.

- Health and safety laws – The Occupational Safety and Health Act (OSHA)

- Wage and Hour – The Fair Labor Standards Act (FLSA), paid sick leave laws

- Union activity – The National Labor Relations Act (NLRA)

- Protected Concerted Activity - NLRA
The Americans with Disabilities Act

- Employers may not discriminate against a **qualified** employee or applicant with a **disability** who can perform **essential functions of the job** in question.

- A person is covered by ADA if:
  - **they have a physical or mental impairment** which substantially limits a major life activity; or
  - have a record of such impairment; or
  - is **regarded as** having such impairment.

- Employees may also base a claim of discrimination on being “associated with” a person with a disability

- Ebola could be considered a disability
The ADA & Medical Inquiries

- Employer cannot make medical inquiries of employees unless the inquiry is voluntary or job-related and consistent with business necessity.

- Guidelines to making medical inquiries:
  - Confidential maintenance of medical information, which must be kept separate and apart from an employee’s personnel file, and
  - Limit distribution of such information to individuals with a legitimate need to know

- Exception: The Direct Threat – Significant risk of substantial harm to health or safety of employee or others that cannot be eliminated or reduced by a reasonable accommodation

- Factors:
  - (i) the duration of the risk,
  - (ii) the nature and severity of the potential harm,
  - (iii) the likelihood that the potential harm will occur, and
  - (iv) the imminence of the potential harm.
Discrimination and Retaliation

Title VII, FMLA, State and Local Laws

- National origin discrimination
  - Example: Employee says he is traveling to his home country of Sierra Leone for his father’s funeral.

- FMLA
  - Example: Employee wants to travel to Liberia to care for her sick mother

- Lawful off-duty conduct laws
  - Various states have laws prohibiting discrimination based on lawful off-duty conduct, including travel

- Whistleblowing: reporting unsafe working conditions
The Occupational Safety and Health Act (OSHA)

- Employers must provide a safe workplace, free from serious recognized hazards under “General Duty Clause”
  - No OSHA Ebola standard just “Fact Sheet”
  - Workplaces where employees may be exposed to Ebola should:
    - Conduct a risk assessment, document findings and actions taken to address any identified issues
    - Provide additional training necessary to protect employees from any risks identified
    - Inform employees if any of their job activities may put them at reasonable risk for exposure to Ebola
    - Ensure employees provided with all personal protective equipment (PPE) needed to safely do their jobs per CDC
    - Ensure that employees fully understand how to use the PPE by providing training on its use and conducting practice sessions using the equipment per CDC
The Occupational Safety and Health Act (OSHA)

- Establish a policy requiring supervisors to provide updated Ebola-related information to employees as it develops
- Establish a point of contact for employees to address any questions they may have related to Ebola
- When cleaning surfaces potentially contaminated with Ebola, be aware of certain additional requirements imposed by OSHA
The Fair Labor Standards Act

- Non-exempt employees
  - Must be paid for any hours actually worked, even if from home as a result of possible exposure to or infection with Ebola

- Exempt employees
  - Must be paid for any workweek in which the employee performed any work

- Also consider state and local laws
The National Labor Relations Act (NLRA)

- Protects union activity
  - Collective action by union represented employees
  - Unless strike violates contractual no strike clause, etc., no discipline may be imposed
    - Employer can use replacement workers to meet patient care or other business needs
- NLRA also protects “protected concerted” activities by employees
  - Even non-union employees who refuse to work because of fear of Ebola – protected
  - No discipline permissible but employer can use replacement workers to meet patient care or other business needs
What can employers do or not do?

- Employers must navigate the employment laws, while keeping their workplace safe
- Limited ability to ask certain questions, require medical testing, or share information with other employees
Disclosure: Employee’s Own Exposure

What Can You Do?

- Can employers require employees to disclose confidentially whether they have Ebola, have symptoms of Ebola, or have been exposed to Ebola?
  - Yes
  - Job related and consistent with business necessity
  - Direct threat
Disclosure: Positive Test

What Can You Do?

- Can employers require that employees who test positive for Ebola disclose confidentially the test results to them?
  - Yes

- The ADA permits an employer to require that an employee disclose health information with respect to whether the employee poses a *direct threat* to the health or safety of himself or others and because it’s job related and a business necessity.

- Practical consideration: if an employee currently has symptoms, may be too sick to actually be at the workplace
Disclosure: Exposure to Others

What Can You Do?

- Can employers require that an employee disclose confidentially whether he or she has been exposed to others who have tested positive for Ebola?
  - Yes

- May raise “regarded as” ADA claims
  - Compare to regarded as claims that were brought when the transmission of HIV was less understood

- May raise “disability association” ADA claims
  - No reasonable accommodation required for an association with a disabled person
Can employers require that employees with symptoms of Ebola be tested?

- Yes

Individualized assessment
- Under the ADA, an employer who reasonably believes based on an individualized assessment that an employee has symptoms of Ebola can require that the employee undergo medical testing to determine whether the employee, in fact, is infected.
  - Direct threat theory
  - Business necessity
Informing Colleagues: Consent

What Can You Do?

- May employers ask an employee to make a truly voluntary disclosure so that the employer may inform co-workers, managers and supervisors that the employee has been exposed or is infected?
  - Yes

- Disclosure to state Department of Health or CDC may be mandatory
  - In this instance, the Department of Health or CDC will make contact with any individuals who may have been exposed
  - Facilitate the governmental agencies ability to do so

- If employee refuses, must maintain confidentiality to colleagues to extent possible
Informing Colleagues: No Consent

What Can You Do?

- May employers inform co-workers, managers and supervisors that an employee has been exposed or is infected without the employee’s consent?
  - No (unless compelled to do so by department of health)

- An employer’s obligation is to take reasonable steps to protect the confidentiality of the positive test result by:
  - not identifying the employee by name and
  - avoiding, to the extent reasonably feasible, making other references that would permit a manager or co-workers to guess that an employee has been infected.

- The employer cannot prevent speculation in the workplace but must take reasonable steps not to contribute to it.
May employer ask an employee to leave the premises if there is a reasonable belief that the employee has been exposed to, or has contracted, Ebola?

- Yes

Need to have actual reasonable belief

- Discrimination claims can arise if an employee is singled out based on some protected characteristic

Confidentiality
Travel Restrictions

What Can You Do?

- May employers restrict travel to afflicted countries?
  - Yes, if travel is for business

- If FMLA eligible
  - No, if travel is to care for a family member or adoption of a child

- Off-duty conduct laws
  - Cannot prohibit employees from performing legal activities outside the workplace

- Discrimination claims
  - National origin – restricting travel to certain countries
Employees Who Do Not Want To Come To Work

Retaliation

- You may encounter employees who refuse to come to work because they are aware that a colleague has Ebola or has been near an infected person
  - If an employee *reasonably believes he is in imminent danger*, an employer may not terminate that individual for refusing to come to work under OSHA’s anti-retaliation guidelines
    - However, an employer need not pay the employee while he is home
    - If your organization has a flexible work-from-home policy, you may wish to provide this as an option for the 21 day incubation period for those individuals who are reasonably concerned about Ebola transmission
Employees Who Do Not Want To Come To Work

Union Activity

- If a group of employees refuses to come to work for fear of transmission, this could constitute “concerted activity” under the National Labor Relations Act, regardless of whether the employees have a reasonable concern of immediate danger
  - Nurses at the Dallas hospital where Thomas Duncan was treated brought concerns to the hospital’s management
  - LaGuardia airport employees boycotted work after learning that a Dallas nurse flew on a commercial flight after being exposed to Ebola
  - 18,000 California nurses struck on Nov. 11 and 12 for alleged lack of adequate equipment and training for treating Ebola patients and other bargaining issues
  - Providence Hospital nurses in Washington staged 24 hour strike Nov. 11 over similar issues and also during bargaining
Employees Who Do Not Want To Come To Work

Paid or Unpaid Leave?

- For an employee’s own exposure
  - FMLA unpaid leave – serious health condition
    - but employee can elect to use available paid leave
  - State/City/Local paid sick leave laws
  - State or private Short Term Disability laws – if monitoring/exposure lasts more than 7 days and employee is considered “disabled”

- For exposure of a family member
  - FMLA unpaid leave – serious health condition of spouse, child, parent
    - but employee can elect to use available paid leave
  - State/City/Local paid sick leave laws – if the law covers care of another

- For fear of coming into work
  - Unpaid leave
  - Option to take accrued sick, vacation, paid time off
  - If not protected concerted activity and not OSHA protected, potential discipline
Questions & Answers
Epstein Becker Green Resources

- **Act Now Advisory** - Protecting Your Workforce: What You Need to Know About Ebola

- **Health Law Advisor Blog** - Ebola Preparedness Portal Launched by The Joint Commission


- **Health Law Advisor Blog** - OPM Issues Ebola Guidance to FEHBP Carriers
  (http://www.healthlawadvisor.com/2014/11/14/opm-issues-ebola-guidance-to-fehbp-carriers/)

- **OSHSA Law Update Blog** - Practical Strategies for Addressing Employee Concerns About Ebola in the Workplace


Resources To Watch For

- An article on Ebola from *Wolters Kluwer* featuring Patricia Wagner and Frank Morris.
- An article in *Healthcare Risk Management* on the risks and potential liabilities confronting hospitals as a result of Ebola, and programs, practices and policies providers should be considering, featuring George Breen and Kathleen Williams.
Questions?

George B. Breen
Board of Directors / Member of the Firm
Epstein Becker Green
gbreen@ebglaw.com
Tel: 202-861-1823

Frank C. Morris, Jr.
Member of the Firm
Epstein Becker Green
fmorris@ebglaw.com
Tel: 202-861-1880

Amy F. Lerman
Associate
Epstein Becker Green
alerman@ebglaw.com
Tel: 202-861-1832

Bruno Petinaux, M.D.
Associate Professor, Co-Chief of the Emergency Management Section, Department of Emergency Medicine, George Washington University Medical Faculty Associates
Thank you.