Beyond Ebola: Environmental, OSHA, and Other Regulatory Issues Creating Business Risks to Health Care Providers in the Future

William J. Walsh and Gregory S. Narsh | Webinar | March 25, 2015

Moderated by Mark A. Kadzielski
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• Experience encompasses all major federal environmental statutes, such as the Clean Air Act, the Clean Water Act, Superfund, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, and many state and local environmental laws

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What You Will Learn

• Introductions
• Background
• The role of pesticide law in protecting healthcare workers
  – Distinction between Food and Drug regulation and the Federal Pesticide statute regulation
  – Requirements for disinfectants
  – The Treated article exemption
  – Business risks
What You Will Learn

• Infectious waste disposal requirements
• OSHA requirements
• American with disabilities act requirements
• National labor relations board requirements
• What you can do
Background
Lessons Learned from Ebola, Enterovirus, Legionellosis

• Infectious disease regulation differs the regulation of chemicals
  – Infectious microorganisms grow and may spread through indirect contact
  – Unlike most chemical exposure injury claims, infectious disease is caused within a short period of time and is often traceable

• The number of new strains of infectious diseases are predicted to rise over the next few decades
Lessons Learned from Ebola, Enterovirus, Legionellosis

- Regulators are diverse and jurisdictional lines sometimes unclear
  - Centers for Disease Control and Prevention/State Health (tracking of infected people and guidance on treatment of people)
  - Food and Drug Administration (regulation of substances used to treat people/animals/medical equipment), e.g., recent outbreak of fatal infections from medical equipment
  - Environmental Protection Agency/State environmental agencies (regulation of substances used to treat things and disposal of infectious waste)
  - OSHA/state safety agencies (workers)
  - Other worker regulatory agencies
• When injuries can occur, plaintiffs often file personal injury suits
  - The nurse at Dallas Presbyterian hospital who contracted Ebola from the hospital’s patient has sued the hospital alleging, among other things, negligence and a failure to warn
  - The case should be watched to see if vendors of medical protective gear will be added to the suit
  - Particularly when public and political concerns are high, following government guidance may not always provide legal protection

• Regulators may file enforcement actions
Business and Legal Risks Facing Healthcare Companies

• Business risk reach beyond scientific uncertainties in protocols for prevention of infectious diseases or lack of clarity by regulators

• Opportunistic individuals seek to exploit new risk and claim to be “first to the market” with miracle solutions which solve the problem, e.g.:
  - During Legionnella and AIDS epidemics, a flood of products on the market without prior review and approval
  - Healthcare organizations/end users (doctors, nurses, dentists, and other healthcare professionals) could not readily distinguish between products that complied and those which did not
  - EPA aggressively exercised its statutory enforcement authority, resulting in stop sale orders, injunctions, substantial fines and bad press
The Role of Pesticide Laws in Protecting Against Infectious Agents
• FIFRA has long regulated the sale or use of disinfectants on inanimate objects and surfaces

• Requires registration of such products for their intended uses by EPA (and approval of specific marketing claims by the agency) prior to sale or distribution for sale in the U.S.
For disinfectants, companies must submit data demonstrating:

- The exposure over a lifetime given the intended use will not present an unreasonable risk to human health or the environment; and

- The efficacy of the treatment claim on the label for the specific microorganism (e.g., that the use of the chemical as directed on the label kills 99.99% or higher of microorganism X within a given period of time)
• EPA approval is for a “specific” use of a “specific” substance on a “specific” inanimate object at “specific” concentrations over “specific” durations to support a “specific” claim that the substance is effective.

• Even physical devices (such as filters that remove microorganisms from water) are “pesticide devices,” albeit they are subject to less stringent regulation under certain provisions of the pesticide statute.
EPA’S Treated Article Exemption

• Allows use of a regulated disinfectant to protect the object itself (for example, paint treated with a pesticide to inhibit the growth of mold, or wood products treated to protect against insect or fungus infestation, but only if the pesticide is registered for such use.” (40 CFR § 152.25(a))

• EPA excludes from this exemption any product for which the manufacturer or distributor makes a public health claim, e.g., EPA rejected the use of the treated article exemption for a product which treats air conditioning systems to prevent the spread of Legionella
Application of the Pesticide Law to Infectious Agents
Application to Ebola and EV-D68

- No pesticide is registered to treat the Ebola virus
- EPA had to issue guidance on disinfectants for use against the Ebola (last updated December 8, 2014)) based on data other similar or more difficult to kill viruses
  - The users of these disinfectants must “follow the specific use instructions on the label for each disinfectant in order for the disinfectant to be effective.”
  - The product labels “will not specifically mention effectiveness against the Ebola virus”
Enforcement Penalties

- Stop sales of the pesticide or restrict uses
- Bar imports at the port of entry
- Maximum civil penalty is $7,500 for each offense, which EPA interprets as each sale (of late, EPA pesticide enforcement and penalties have increased)
- Indirect effects --- Damage lawsuits for personal injury, disruption of the healthcare supply chain and/or damage to long-term commercial relationships
Compliance
• Manufacturers cannot sell products unless the disinfectant is registered for the “specific” microorganism and use

• Hospitals and healthcare facilities should know that generally, it is unlawful to use any registered disinfectant in a manner inconsistent with its EPA approved labeling
  – E.g., EPA advised a manufacturer of burlap fabric packaging treated for “rot resistance” does not qualify for the treated article exemption unless the EPA registered label for the chemical has specifically been approved for this use
− Considering EPA’s history of narrowly interpreting pesticide and its aggressive and typically successful enforcement of this law, a careful analysis should be performed prior to either making claims in marketing materials using a disinfectant in a manner that may not be identified on the face of the EPA approved label, or relying upon the treated article exemption
Infectious Waste Disposal Requirements
The regulation of the disposal of infectious waste is primarily at the state level:

- The federal Medical Waste Tracking Act of 1988 creates a cradle-to-grave tracking system for medical wastes (which includes infectious wastes) and requirements for segregation, packaging, labeling, marking, and storage of medical wastes.

- Treatment technology, such as medical waste incineration, is regulated by EPA Clean Air Act regulations.
• EPA and CDC have guidances on measures to control infection (at least for specific infectious microorganisms) in health care settings
  − These guidances, although not legally binding, are likely to be considered a floor on reasonable industry practice in negligence actions
  − They generally include a hierarchy of measures to eliminate exposure, to implement engineering controls, to use administrative controls (work practices), and to use personal protective equipment
  − They allow for flexibility and all require consultation with state regulators concerning disposal of infectious waste
Requirements

- State requirements are state dependent:
  - Registration of health care facilities (e.g., MI, SC);
  - Segregation of infectious waste;
  - Regulation of the movement of medical wastes within a health care facility
  - Packaging/consider labeling; and
  - Storage

- Local sewage treatment agencies have the authority to require pretreatment of liquid infectious waste discharged to the sewer system
Requirements

• Failure to comply with a State regulation may be considered negligence in a personal injury suit

• Use of an off-site facility to treat or otherwise dispose of infectious waste that has a “poor” compliance record is likely to increase the likelihood of being considered negligent

• Prudence dictates using the same type of due diligence for infectious waste
Regulators May Not Practice What They Preach

- During the height of the Ebola crisis, the Missouri and Louisiana Attorney Generals sue to prevent disposal of the ash from the incineration of Ebola waste from being accepted by disposal facilities in their States.
  - Scientifically, the residuals from the treatment of Ebola wastes present no risk of infection since incineration destroys the virus.
  - Historically, EPA and States often have taken regulatory action beyond their regulatory authority for wastes where there is high public concern.
  - It is predictable that the public will have a “not in-my backyard” reaction.
What Can You Do Concerning Disposal?

• If your health care facility has a environmental, health and safety program, it is prudent to review the program (and any associated environmental audits performed pursuant to the program) to ensure in incorporates the lessons learned from the Ebola and other recent outbreaks.

• If your facility does not have such a program, you may want to consider adopting one. One size does not fit all.
• Health care industry trade associations should track developments and may want to advocate that federal and state regulators to update their guidances and regulations to ensure that the requirements are clear and the principles can be adapted for new future infectious agent outbreaks.
OSHA Requirements
A Brief History of … OSHA

- 1970 to present
- Enforcement
- Penalties
- Inspections
- Emphasis areas
Protecting America’s Workers Act

- “PAWA”
- History
- Implications
State vs. Federal OSHA

- Environmental: Federal and State
- OSHA: Federal or State
- 25 States, Puerto Rico, Virgin Islands
- 5 state plans cover only state & local gov’t workers (private sector under Federal OSHA)
- State requirements must be “identical to or at least as effective” as federal requirements
- State penalties and appeal procedures
Reporting & Recordkeeping

Former Rule

- Fatality
- 3 or more hospitalized from single incident
Reporting & Recordkeeping

Effective January 1, 2015*

• Fatality (8 hours)
• One (1) or more hospitalized (24 hrs)
• Amputation (24 hrs)
• Loss of eye (24 hrs)
• Partially exempt industries – *not exempt*
Reporting & Recordkeeping

Implications & Considerations

• Employee direct contact to OSHA
• Unions / employee representatives
• Media coverage
• Plaintiff’s attorneys
• Family of injured worker
• Worker’s Compensation Bar
Employers have three options for reporting the event:

1. Call the nearest OSHA Area Office during normal business hours.

2. Call the 24-hour OSHA hotline (1.800.321.OSHA or 1.800.321.6742).

3. OSHA is developing a new means of reporting events electronically, which will be released soon and accessible on OSHA's website.
Who is Regulated by OSHA?

- Employers who have employees
- Employer: “Person engaged in a business…who has employees”
- Employee: “An employee of an employer…. ”
Certain Exemptions For...

- Employers with 10 or fewer employees…but
- Never > 10 employees at any time
- Includes all employees at all locations
- Includes full time, part time, temporary, seasonal
- Low-risk Industries
Recordkeeping Exemptions

Exempt Regardless of Size

• Offices of physicians (NAICS 6211)
• Offices of dentists (NAICS 6212)
• Offices of other health practitioners (NAICS 6213)
• Outpatient care centers (NAICS 6214)
• Medical and diagnostic laboratories (NAICS 6215)
OSHA and Ebola

- OSHA regulations do not expressly address Ebola, as they do some issues.
- OSHA regulations are, in the agency’s view, broad enough to cover Ebola and other diseases of that type.
- However, there are many OSHA requirements applicable to the healthcare and related industries.
OSHA Standards for the Healthcare Industry

- Bloodborne Pathogen Standard
- Hazard Communication Standard
- Ionizing Radiation Standard
- Personal Protective Equipment Standard
- Medical and First Aid Standard
- Others
Bloodborne Pathogen Standard

• Protects employees from occupational exposure to bloodborne pathogens (“BBP”)
• BBP means pathogenic microorganisms present in human blood that can cause disease in humans
• BBP standard covers occupational exposure to blood and “other potentially infectious material” (“OPIM”)
• OPIM includes all bodily fluids, secretions, etc.
• Occupational exposure means: “reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials (OPIM) that may result from the performance of the employee's duties”
Bloodborne Pathogen Standard

- Training of all affected employees
- Perform exposure determinations
- Develop written Exposure Control Plan
- Use of universal precautions: treat all blood and OPIM as if positive for HIV, HBV and other BBPs
- Provide and maintain PPE
- HBV vaccination and post-exposure evaluation and follow-up
- Recordkeeping requirements
Needlestick Safety and Prevention Act

- Congress required modification of OSHA's Bloodborne Pathogens standard to set forth in greater detail (and make more specific) OSHA's requirement for employers to identify, evaluate and implement safer medical devices such as needleless systems and sharps with engineered sharps protections. The Act also mandated additional requirements for maintaining a sharps injury log and for the involvement of non-managerial healthcare workers in identifying, evaluating and choosing effective engineering and work practice controls.
Hazard Communication Standard

- 29 CFR 1910.1200
- Employees must be informed of and trained regarding the presence of hazardous chemicals in the workplace
- Employers must maintain Safety Data Sheets (“SDSs”) (f/k/a MSDSs) in the workplace for all hazardous chemicals
Ionizing Radiation Standard

- 29 CFR 1910.1096
- Facilities with X-ray machines
- Must perform a survey of the workplace to determine the types of radiation present
- Must designate restricted areas to limit exposure
- Employees working in designated areas must wear personal radiation monitors
- Must provide signs and warning labels
Personal Protective Equipment

- 29 CFR 1910.132-.138
- Hierarchy of OSHA-preferred methods of dealing with hazards in the workplace is to (i) eliminate the hazard, when possible; (ii) minimize the hazard through engineering controls or changes in procedures; and (iii) use personal protective equipment (PPE)
- Must select appropriate PPE, train employees, maintain integrity of PPE
Medical and First-Aid Standard

• 29 CFR 1910.151

• OSHA requires employers to provide medical and first-aid personnel and supplies commensurate with the hazards of the workplace. The details of a workplace medical and first-aid program are dependent on the circumstances of each workplace and employer.

Other Standards & Guidelines

- Ergonomic hazards
- Tuberculosis
- Chemical hazards
- Influenza
- Latex
- Workplace violence
Sector-Specific Information

- Clinicians
  https://www.osha.gov/dts/c很差/clinicians/index.html

- Home healthcare

- Hospitals

- Laboratories
  https://www.osha.gov/SLTC/laboratories/index.html

- Medical and Dental Offices
  https://www.osha.gov/Publications/osha3187.pdf

- Nursing Homes & Personal Care Facilities
American With Disabilities Act Requirements
ADA Requirements

• Infectious diseases are likely to be considered "disability" under the Americans with Disabilities Act (ADA) so an employer’s ability to make disability-related inquiries or to require medical examinations may be limited unless they are job-related and consistent with business necessity.

• Generally:
  − Must have a reasonable belief, based on objective evidence
  − That the employee’s ability to perform essential job functions will be impaired by a medical condition or that the employee will pose a direct threat to others due to a medical condition
  − An employer may not send an employee home because of a disability unless the employee poses a direct threat to the health and safety of others
ADA Requirements

- U.S. Equal Employment Opportunity Commission (EEOC), which enforces the ADA, did not issued Ebola-specific guidance.

- However, the 2009 EEOC guidance concerning the H1N1 influenza pandemic that (although there are significant differences between H1N1 and Ebola) poses and answers Ebola relevant questions like: How much information can be asked about an employee’s health? When can an employee be asked to stay home? Can temperatures be taken?
ADA Requirements

- That guidance incorporates CDC recommendations and sets forth ADA-compliant practices that clarify when it is permissible to obtain medical information and/or to send employees home for health reasons

- A case-by-case determination
National Labor Relations Board Requirements
NLRB Requirements

- National Labor Relations Act protects the right of employees, whether or not they are members of a union, to engage in “concerted activity” for “mutual aid or protection.” 29 U.S.C. § 157

- Separately, it protects the rights of unionized employees to cease working if they, in “good faith” are concerned over “abnormally dangerous conditions for work.” 29 U.S.C. § 143. For both union and non-union employees, a refusal to work because of safety concerns could be protected concerted activity
NLRB Requirements

- National Labor Relations Board (NLRB) interpretation: Employee commentary on social media can be protected concerted activity, e.g., discussion about workplace safety on Facebook might be protected (discussions that could identify particular patients may violate patient privacy rights).

- The NLRA also requires employers of unionized employees to “meet at reasonable times and confer in good faith with [the union concerning] terms and conditions of employment.” 29 U.S.C. § 158(d). An employer may be obligated to bargain with the union concerning safety issues and/or changes that are made in the workplace to address Ebola-related concerns.
NLRB Requirements

- Employers should consult with counsel about the permissible scope of policies before disciplining employees for violating internal rules
What Health Care Companies Can Do

• Regulatory requirements should be tracked and communicated to healthcare institutions

• Trade associations may want to advocate to agencies that they modify their proposed or final regulations and guidance to reflect the unique characteristics of infectious material

• Industry may want to assess developing voluntary industry standards/practices

• Healthcare companies should consider requiring their suppliers to certify prior compliance

• Perform an audit or review to ensure that equipment and material supplier’s products are in compliance
Questions & Answers
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