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EBOLA: A PUBLIC HEALTH AND LEGAL PERSPECTIVE*

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INTRODUCTION

The 2014 Ebola epidemic is the largest epidemic of Ebola virus disease in history, with current widespread transmission in three countries in West Africa: Guinea, Liberia, and Sierra Leone. As of this writing, there have been four confirmed cases of Ebola in the United States. Public health and healthcare lawyers are addressing complicated legal issues, including concerns related to states' authority to quarantine individuals who are infected with or have been exposed to Ebola, along with issues related to the Emergency Medical Treatment and Labor Act, the privacy and security of information, and vaccine liability.

I. Quarantine and Isolation

Quarantine and isolation are common practices in public health, and both aim to control exposure to infected or potentially infected persons. Both may be undertaken voluntarily or compelled by public health authorities. Although quarantine and isolation have been used interchangeably, they are distinct strategies. Quarantine refers to the separation and restriction of movement of persons who, while not yet ill, have been exposed to an infectious agent and therefore could become infectious. Isolation refers to the separation of persons who have an infectious illness from those who are healthy and the restriction of their movement to stop the spread of that illness.

A. State Legal Authority—Although the federal government does have some quarantine authority, its quarantine powers are limited to situations involving international or interstate transportation or intrastate communicable diseases where the state's response is so ineffective it poses a serious threat to other states. Federal quarantine authority is also limited to certain listed diseases, including viral hemorrhagic fevers such as Ebola.

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Responsibility for public health resides primarily with states, with certain powers often delegated to local public health agencies. This public health authority derives from the police powers granted by state constitutions and reserved to them by the Tenth Amendment to the US Constitution. The public health actions that are available during public health emergencies are determined by statute in each state; therefore, the scope, mechanisms, and procedures of states vary.

In some states, a person can be quarantined through an administrative order; in others, a court order is required before a person can be quarantined. In states that permit quarantine through an administrative order, the responsible party may be either the governor or the public health department. In many states, local public health officials also have significant authority to issue health orders that limit an individual's freedom of movement or prohibit public gatherings to control an epidemic.

While state legal authority to compel isolation and quarantine exists, modern views regarding individual liberties could make some public health officials hesitant to enlist the use of force to restrict movement. This is because the exercise of compulsory public health powers—whether through quarantine, isolation, mandatory vaccination, or compulsory treatment—invariably restricts an individual's liberty and implicates constitutional rights.

B. Reasonableness Requirement—Exercise of compulsory public health powers must provide "due process" and cannot deny "equal protection" to affected individuals. Similarly, courts have historically upheld the requirement that isolation and quarantine orders must be reasonable.

One of the first cases to underscore this reasonableness requirement was *Jew Ho v. Williamson.* In this 1900 case, the US Circuit Court for the Northern District of California overturned two San Francisco quarantine ordinances that had been passed to control an alleged outbreak of bubonic plague. While the city's board of health claimed that an entire area contained within four streets needed to be quarantined, the lines drawn by the ordinances included only homes occupied by Chinese individuals and specifically "left out certain persons, members of races other than Chinese." The court found that the quarantine as it was established was "unreasonable, unjust, and oppressive, and therefore contrary to the laws limiting the police powers of the state and municipality in such matters[,] … that it is discriminating in its character, and is contrary to the provisions of the fourteenth amendment of the constitution of the United States." Ultimately, the court held that the general quarantine could not be continued and could only be applied to people that the board of health had reason to believe were infected by contagious or infectious diseases.

This case is particularly important because it was one of the first to articulate modern principles of public health jurisprudence. It also set the stage for the seminal case in public health, *Jacobson v. Massachusetts*. Relying on principles similar to those outlined in *Jew Ho*, the court in *Jacobson* further articulated the requirement that public health regulations, including quarantine and isolation, must be "reasonable" and balance individual rights.

Some states have codified this reasonableness requirement in their quarantine and isolation laws. For example, Connecticut law allows the quarantine of a person refusing to be vaccinated during a public health emergency, but holds that such refusal "shall not be grounds for quarantine or isolation without a reasonable belief that the individual or group of individuals is infected with a communicable disease."

This principle of reasonableness was demonstrated most recently in *Mayhew v. Hickox.* In that case, a nurse who had been potentially exposed to Ebola through her healthcare work in Sierra Leone was placed under mandatory quarantine for twenty-one days upon her return to the United States. The nurse objected to this quarantine, arguing that, because she was asymptomatic and Ebola can be transmitted only by symptomatic individuals, the mandatory quarantine was "not a sound public health decision" and violated her due process rights.

In the case decision, a state court judge in Maine recognized "the potential severe harm posed by transmission of this devastating disease." Nonetheless, the judge lifted her quarantine in favor of less restrictive, direct active monitoring, as outlined in the Centers for Disease Control and Prevention (CDC) guidelines. The court found that the quarantine restriction was not reasonable, noting that "[t]he State [had] not met its burden … to prove by clear and convincing evidence that limiting [Hickox's] movements to … [a greater] degree … is 'necessary to protect other individuals from the dangers of infection.'" This case underscores the principle that actions taken by states to protect the public's health must be reasonable and justified to survive judicial scrutiny.

C. Procedural Legal Issues—Imposition of a quarantine order is a significant action. It removes from the quarantined individual the right to decide where to go and what to do. It is a limitation on the individual's right of free movement by the government and needs to be approached with the same deliberation as any other limitation on liberty by the government.

Under Michigan law, a public health order may be issued by the Governor or the State Director of Community Health if there is "an imminent danger to the health or lives of individuals" in the state. An "imminent danger" exists if "a condition or practice exists which could reasonably be expected to cause death, disease, or serious physical harm immediately or before the imminence of the danger can be eliminated" through other means. Upon a finding of imminent danger, the local health officer may issue a warning to the individual requiring that individual to cooperate with the health officer to prevent or control the transmission of the disease, which may include mandatory testing. The warning must include notice that failure to comply could result in a court order being sought; the individual also has the right to request a hearing.

Under the Texas Communicable Disease Prevention and Control Act, the local health authority can issue quarantine orders and should coordinate public health activity with the Texas Department of State Health Services and the Commissioner of Health. As long as the individual who is the subject of the order complies voluntarily, court action is not required; if the individual objects, an Order for Management of a Person with a Communicable Disease is filed with the district court in the county where the person resides, is found, or is receiving healthcare services. A medical evaluation must be performed and must outline a

diagnosis and the reasons the person poses a threat to self or will continue to endanger the public if control measures are not continued. In the case of a group or area quarantine, the facts must be consistent for all members of the group. The individual who is subject to the control measures order is assigned an attorney if needed, as well as an interpreter.

This brief comparison demonstrates a few differences among the states' approaches to public health laws. Each state addresses public health somewhat differently to meet the unique needs of its citizens. This variability poses some challenges when addressing control of communicable diseases. As the recent Ebola outbreak illustrates, controversy can arise regarding when and how quarantine should be imposed. State policies range from mandatory quarantine of all healthcare workers returning from caring for Ebola patients in West Africa to CDC's recommended tiered approach based on type and extent of exposure. Because the purpose of quarantine is to protect the public from the significant risks posed by serious communicable diseases, the validity of a quarantine order has to be measured against current knowledge of the disease's transmissibility and the likelihood that the individual has had the type of exposure necessary to become infected. Based on current scientific knowledge, Ebola is transmissible only when the patient is symptomatic. Further, because Ebola is not easily transmitted, only certain types of contact are likely to result in transmission of the disease—namely, exposure of mucous membranes or broken skin to infectious body fluids. Quarantine and other public health distancing orders must take into account the scientific realities, rather than fears, to be both respected and upheld by the courts.

II. Selected Legal Issues Impacting Healthcare Providers

A. Emergency Medical Treatment and Labor Act—Healthcare providers and their counsel have many other issues to address when faced with this high-intensity, complex communicable disease. One area of concern is the application of the Emergency Medical Treatment and Labor Act (EMTALA) to individuals who present with symptoms and a travel or exposure history consistent with Ebola. The Centers for Medicare and Medicaid Services (CMS) provided an official answer to this in a memorandum dated November 21, 2014, indicating that:

- Each hospital, critical access hospital, and facility with a dedicated emergency department is required to provide an appropriate medical screening exam to any individual who comes to the emergency department, including those who present with symptoms consistent with Ebola.
- This obligation applies whether the individual is brought by ambulance or presents by private transport.
- Every facility is expected to be able to apply appropriate screening criteria, isolate, and notify public health officials when appropriate.
- Stabilizing treatment must be provided. Because stabilizing treatment for Ebola is primarily supportive (IV fluids, oxygen, and normalization of electrolytes), this treatment is within the capabilities of almost all facilities with dedicated emergency departments.

- If public health officials have developed pre-hospital protocols that require probable Ebola patients to be transported to specific hospitals designated as preferred treatment centers for Ebola and other communicable diseases, compliance with those public health protocols "do not present any conflict with EMTALA," even if the ambulance transporting the patient is a hospital-based ambulance, because that directed transport destination is consistent with a community-wide emergency medical services protocol.
- All hospitals and critical access hospitals are expected to be able to institute appropriate isolation protocols to properly care for and protect hospital personnel when caring for possible Ebola patients.
- When appropriate, a patient with an emergency medical condition can be transferred to another appropriate facility for care. This can include transfers to medical centers designated as preferred centers of care for particular diseases, such as Ebola, by public health officials. Such transfers must be made using appropriate means, such as appropriately staffed medical transports, so stabilizing treatment can be continued en route.
- Posting signs that discourage individuals who might have a given disease, such as Ebola, from coming to the emergency department is not appropriate and could violate EMTALA. However, signs that assist individuals in locating the proper place for treatment in the facility are permitted.
- Coordination with public health personnel is expected, and if complaints regarding EMTALA violations are received, CMS will take into consideration the direction provided to the facility by public health personnel when evaluating compliance with EMTALA obligations.

B. Privacy and Security of Information—Understandably, when a newsworthy medical event occurs, the public is interested, and the media seek to respond to that interest by providing the public all of the information they can obtain. It is the responsibility of medical professionals and those who, under the Health Insurance Portability and Accountability Act (HIPAA), are deemed either covered entities or business associates to protect the privacy of patients under their care and provide information only for the purposes and to the extent either authorized by the patient or permitted under law. Because the Ebola outbreak generated debate regarding the extent to which certain patient-identifiable information could be shared, the Department of Health and Human Services (HHS) Office for Civil Rights issued on November 1, 2014, a bulletin regarding "HIPAA Privacy in Emergency Situations."

Certain identifiable disclosures may be made without the patient's authorization:

- Disclosures for treatment purposes: for treating that patient, or treating another patient; includes coordination of care and care management, consultation among providers, and referral of patients for treatment.
- Disclosures to a public health authority: such as CDC, or a state or local public health authority.

- Disclosures as directed by a duly authorized public health authority to a foreign government.
- To persons at risk of contracting or spreading the disease, if a state law permits or directs such disclosure.
- To "prevent or lessen" an imminent danger "to the health or safety of another person or the public," to the extent consistent with state law and ethical requirements.

The healthcare entity should try to obtain the patient's agreement before making certain identifiable disclosures; however, if doing so is not possible, due, for example, to the patient's condition, the following disclosures may be made:

- Disclosures to family members or others involved in the patient's care or to locate or notify family of the patient's location.
- Notification to disaster relief organizations, such as the Red Cross, when appropriate.
- Directory information, including confirmation that the patient is in the hospital, and limited information regarding condition, unless the patient objects; or, if the patient is incapacitated, if it is consistent with any known patient preference and is thought to be in the patient's best interest.

Other than disclosures for treatment purposes, all disclosures should be limited to the minimum information necessary to accomplish the intended purpose. Further, although non-covered entities/business associates may release information publicly, the covered entity and business associates remain bound by HIPAA to respect the patient's rights to privacy; even information that is in the public domain must be treated as confidential. The safeguards that are in place in normal operations must, to the greatest extent possible, remain operational during a public health emergency.

In some public health emergencies, partial HIPAA waivers may be authorized by the secretary of HHS. The authority to issue a partial waiver of the HIPAA Privacy Rule does not arise until the President has issued a declaration of an emergency and the secretary issues a declaration of public health emergency; in that situation, a HIPAA waiver may be authorized that waives Privacy Rule requirements related to requests of confidential communications, "privacy restrictions," "notice of privacy practices," and the right "to opt-out of the facility directory." Note that even under a HIPAA waiver, compliance with many requirements of the Privacy Rule remains mandatory; only specific provisions are waived.

C. Vaccines and Limitations of Liability—An Ebola vaccine being evaluated in Switzerland temporarily suspended testing activities on December 11, 2014, after some participants complained of joint pain. The vaccine's manufacturer hopes to resume testing after January 5, 2015. However, as this demonstrates, liability concerns are common with vaccines and have been said to potentially impede their rapid development and deployment. With the goal of supporting enhanced development of Ebola vaccines, Sylvia Matthews Burwell, Secretary of HHS, issued on December 10, 2014, a declaration under the Public

Readiness and Emergency Preparedness Act granting immunity under US law for liability claims related to the development, manufacturing, distribution, and administration of vaccines against the Ebola virus. This grant of immunity is effective only with respect to liability claims brought within the United States for three vaccine candidates:

- The Recombinant Replication Deficient Chimpanzee Adenovirus Type 3-Vectored Ebola Zaire Vaccine, known as ChAd3-EBO-Z, manufactured by GlaxoSmithKline;
- The BPSC1001 vaccine, known as rVSV-ZEBOV-GP, made by BioProtection Services Corporation, a subsidiary of Newlink Genetics; and
- The Ad26.ZEBOV/MVA-BN-Filo vaccine manufactured by Janssen Corporation, a subsidiary of Johnson & Johnson/Bavarian Nordic.

Many clinical trials for these Ebola vaccines will be conducted in Africa, and it is possible that similar grants of immunity will be enacted in these jurisdictions.

CONCLUSION

The Ebola outbreak has provided a spotlight on important public health issues that healthcare lawyers should be aware of and prepared to address. Ebola remains active in West Africa, and thus remains a threat worldwide, given the global economy. Meanwhile, other emerging diseases—many of which are much more transmissible than Ebola—continue to pose threats globally. Seasonal influenza is just beginning, and avian influenza, Middle East respiratory syndrome, sudden acute respiratory syndrome, antibiotic-resistant and re-emerging pathogens, and as-yet identified pathogens all pose the risk of serious communicable diseases that could require the use of control measures such as quarantine and isolation.

The variation in quarantine laws and procedures demonstrates the need for public health legal counsel to familiarize themselves with their jurisdiction’s requirements for issuing orders and be prepared to ensure that all procedural and other requirements are met, including due process requirements. In addition to familiarizing themselves with legal issues related to EMTALA, privacy and security, and vaccine liability concerns, counsel should review client pandemic preparedness plans. Training on both clinical and operational factors and legal requirements is also critical. These steps will help reduce ambiguity about available public health measures, streamline administrative procedures, and ensure that individuals’ rights are respected. These steps will also help ensure that the public health, healthcare, and legal systems can respond to new threats both rapidly and reasonably.

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5. 42 C.F.R. § 70.2.
6. *Selected Federal Legal Authorities Pertinent to Public Health Emergencies*, CTRS. FOR DISEASE CONTROL & PREVENTION: PUBLIC HEALTH LAW PROGRAM 8–9 (Aug. 2014), *available at* http://www.cdc.gov/phlp/docs/ph-emergencies.pdf (citing Exec. Order Nos. 13295, 13375, and 13674 as establishing the current list of communicable diseases for which an individual can be apprehended, detained, examined, or conditionally released by federal public health authorities under 42 C.F.R. §§ 70 and 71 as "cholera; diphtheria; infectious tuberculosis; plague; smallpox; yellow fever; viral hemorrhagic fevers;" "'influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic[;]'" and "'[s]evere acute respiratory syndromes'").
7. *See, e.g.*, ALA. CODE §§ 22.12.1–22.12.29; ARK. STAT. ANN. §§ 14-262-101–109 (West 2010).
8. *See, e.g.*, ARK. STAT. ANN. §§ 14-262-101–109 (court order).
9. *See, e.g.*, ALASKA STAT. § 26.23.020 (2004); CONN. GEN. STAT. § 368e-19a-221 (2003).
10. *See, e.g.*, ARK. STAT. ANN. §§ 14-262-101–109; CAL. HEALTH & SAFETY CODE §§ 120175-120250, 120195–120235 (1996); COLO. REV. STAT. § 25-1-506 (2008).
11. *See, e.g.*, MICH. COMP. LAWS ANN. § 333.2453 (West 2012).
12. *See U.S. CONST.* amend. XIV, ("[N]or shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.").
13. Jew Ho v. Williamson, 103 F. 10 (N.D. Cal. 1900).
14. *Id.* at 24. Additionally, the court questioned whether the bubonic plague was at all present, as no living cases had been examined and there had been no evidence of "transmission of the disease from any of those who have died." *Id.* at 25. Ultimately, the court did not issue a final decision on the question of whether the bubonic plague existed but did state that "the evidence in this case seems to be sufficient to establish the fact that the bubonic plague has not existed, and does not now exist, in San Francisco." *Id.* at 26.
15. Jew Ho, 103 F. at 26.
16. *Id.* at 26–27.
17. Jacobson v. Mass., 197 U.S. 11 (1905).
18. *Id.* at 29, 38 ("Before closing this opinion we deem it appropriate, in order to prevent misapprehension as to our views, to observe—perhaps to repeat a thought already sufficiently expressed, namely—that the police power of a state, whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression.").
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27. *Id.* at § 333.2251(5)(b).
28. MICH. COMP. LAWS ANN. § 333.5203(1).
29. *Id.* at § 333.5203(3).

30. TEX. HEALTH & SAFETY CODE ANN. § 81.083(b) (West 2013).
31. TEX. HEALTH & SAFETY CODE ANN. § 81.151.
32. Id.
33. *Id.* at § 81.151(e); § 81.083(k).
34. *Id.* at § 81.153.
35. Gregory Sunshine, Dawn Pepin, Marty Cetron & Matthew Penn, *State and Territorial Ebola Screening, Monitoring, and Movement Policy Statements—United States, August 31, 2015*, 64(40) MORBIDITY AND MORTALITY WKLY. REP. 1145 (2015).
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38. Id.
39. Id.
40. *Id.* at 2.
41. Id.
42. *Id.* at 2–3.
43. See id.
44. See id.
45. *See* id.
46. *Id.* at 2.
47. Id.
48. *Id.* at 3–4.
49. The Health Insurance Portability and Accountability Act of 1996, as amended, and the implementing regulations. The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1939 (1996) (codified as amended in scattered sections of 42 U.S.C.).
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52. *Id.* §§ 501, 164.512(b)(1)(i).
53. *Id.* § 164.512(b)(1)(i).
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