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# Legal, Operational, and Practical Considerations For Hospitals and Health Care Providers in Responding to Communicable Diseases Following the 2014 Ebola Outbreak

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# Legal, Operational, and Practical Considerations for Hospitals and Health Care Providers in Responding to Communicable Diseases Following the 2014 Ebola Outbreak

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*This article analyzes some of the potential issues that may arise during epidemics or other public health emergencies. It specifically focuses on legal and operational preparedness experiences at Emory University during the 2014 Ebola crisis. Emory University Hospital was the first health care facility in the U.S. to treat patients diagnosed with Ebola Viral Disease (EVD). Although EVD has particularly frightening symptoms and a high mortality rate, its containment and treatment implicate similar legal, practical, and operational issues as other highly infectious and communicable diseases. These issues include laws related to: isolation and quarantine; travel restrictions; duties to treat highly infectious patients; implications of the federal Emergency Medical Treatment and Active Labor Act (EMTALA); health care workers' rights to a safe working environment, workers' compensation, medical leave; confidentiality protections afforded by the HIPAA Privacy Rule; disability protections for patients under the Americans with Disabilities Act (ADA); and crisis standards of care and*

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*negligence claims. Practical and operational issues are also explored for hospitals and other health providers to consider when facing a public health emergency or other publicized event involving patients with infectious conditions. Hospitals, health care workers, and public health officials can take guidance from these experiences to develop their own response plans in the future.*

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I. INTRODUCTION

It was July 30, 2014, a typical hot and humid summer afternoon at Emory University Hospital (Hospital) in Atlanta, Georgia. Emory’s campus was relatively quiet with students on their summer break.

Emory's Special Containment Disease Unit (SCDU)<sup>1</sup> was empty. Created in 2002 as a two-bed special isolation facility at the request of the Centers for Disease Control and Prevention (CDC), the SCDU was designed to treat CDC employees (either from its main headquarters in Atlanta or the field) exposed to or infected with dangerous pathogens. Since its creation, the SCDU had been used only twice.

The day began like any other for many at Emory Hospital, including Dr. Bryce Gartland, a hospitalist and Vice President of Operations, Bob Bachman, the Hospital's CEO, and Nancy Feistritz, Chief Nursing Officer. They were unaware that officials from the U.S. Department of State visited the SCDU two days earlier. On the morning of July 30, the State Department called infectious disease specialist and SCDU director Dr. Bruce Ribner to ask if Emory would accept and treat Dr. Kent Brantly, an American who contracted Ebola Viral Disease (EVD) while on a medical mission in Liberia.<sup>2</sup> Dr. Ribner quickly announced that Emory was to receive and treat Dr. Brantly, leading to two frenzied days of preparation prior to his arrival on August 2.<sup>3</sup>

EVD is an emerging zoonotic viral disease that originally arose in rural areas of Central Africa. It was first identified in humans in 1976 in a remote hamlet of Zaire (now the Democratic Republic of the Congo) near the Ebola River.<sup>4</sup> Humans contract EVD through direct physical contact with bodily fluids from an infected, *clinically ill* individual.<sup>5</sup> It terrifies affected populations due to its hemorrhagic nature, causing massive bleeding, elimination of waste, and, in many instances, death. No vaccine or other type of therapeutic intervention is currently available

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<sup>1</sup> Four hospitals in the United States (Emory; Nebraska Medical Center in Omaha; the National Institutes of Health in Bethesda, MD; and St. Patrick Hospital in Missoula, MT) have similar high containment units (HCUs) with select beds for isolating patients with highly infectious and dangerous diseases.

<sup>2</sup> Shortly thereafter, Emory was requested to treat a second American on the same medical mission, Nancy Writebol, who arrived at the Hospital on August 5, 2014.

<sup>3</sup> See Maria M. Lameiras, *Ebola: From Microscope to Spotlight*, EMORY MAG., Autumn 2014, at 18, 21, available at [http://www.emory.edu/EMORY\\_MAGAZINE/issues/2014/autumn/print.pdf](http://www.emory.edu/EMORY_MAGAZINE/issues/2014/autumn/print.pdf).

<sup>4</sup> K.A. Alexander et al, *What Factors Might Have Led to the Emergence of Ebola in West Africa?*, PLOS (Nov. 11, 2014), <http://blogs.plos.org/speakingofmedicine/2014/11/11/factors-might-led-emergence-ebola-west-africa/> (citing Team RoaWIS (1978) Ebola haemorrhagic fever in Sudan, 1976. *Bulletin of the World Health Organization* 56: 247).

<sup>5</sup> Carol Clark, *Disrupting the Balance*, EMORY MED., Fall 2014, at 20, 21, available at <http://emorymedicinemagazine.emory.edu/issues/2014/fall/print.pdf>. Three fruit bat species are believed to be EVD's "reservoir," or the organism that carries the pathogen to other wildlife and humans without dying or becoming ill from it. *Id.*

for EVD beyond supportive care.<sup>6</sup> Subsequent outbreaks have occurred sporadically since 1976, but most have dissipated quickly.<sup>7</sup>

The 2014 outbreak in dense, poor urban areas of several West African nations is the exception.<sup>8</sup> Lacking professional medical treatment, widespread transmission has been associated with home care and traditional burial practices that involve a great degree of touch and interaction with the deceased.<sup>9</sup> Hospitals failing to follow infection control procedures, use standard barrier precautions, and employ sufficient, informed, or qualified staff contribute further to EVD's spread.<sup>10</sup> Although the rate of new EVD cases reported to the World Health Organization (WHO) appears to be waning, 22,092 confirmed, probable, and suspected cases of Ebola have been reported as of January 25, 2015, and 8,810 deaths globally.<sup>11</sup>

As noted by CDC Director Dr. Thomas Frieden, “[w]e live in a world where we are all connected by the air we breathe, the water we drink, the food we eat, and by airplanes that can bring disease from anywhere to anywhere in a day.”<sup>12</sup> Although EVD has particularly frightening symptoms and a high mortality rate, its containment and treatment implicate similar legal, practical and operational issues as other communicable diseases. This article analyzes actual and potential legal

<sup>6</sup> *Ebola Virus Disease (EVD) Information for Clinicians in U.S. Healthcare Settings*, CDC, <http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/clinicians.html> (last updated Mar. 16, 2015).

<sup>7</sup> Clark, *supra* note 5, at 21 (“Subsequent outbreaks have also been associated with forested backwaters and have quickly burned themselves out. That is, until the current outbreak in West Africa”).

<sup>8</sup> *Id.*

<sup>9</sup> Scott F. Dowell et al., *Transmission of Ebola Hemorrhagic Fever: A Study of Risk Factors in Family Members, Kikwit, Democratic Republic of the Congo, 1995*, 179 J. INFECTIOUS DISEASES, Supp. 1, 1999, at S87, S90.

<sup>10</sup> Alexander et al, *supra* note 4; Barbara Kerstiöns & Francine Matthys, *Interventions to Control Virus Transmission During an Outbreak of Ebola Hemorrhagic Fever: Experience from Kikwit, Democratic Republic of the Congo, 1995*, 179 J. INFECTIOUS DISEASES, Supp. 1, 1999, at S263, S264-65; J.J. Muyembe-Tamfum et al., *Ebola Outbreak in Kikwit, Democratic Republic of Congo: Discovery and Control Measures*, 179 J. INFECTIOUS DISEASES, Supp. 1, 1999, at S259, S260.

<sup>11</sup> *Update: Ebola Virus Disease Epidemic—West Africa, January 2015*, 64 CDC MORBIDITY & MORTALITY WKLY. REP. 109, 109 (2015). Sierra Leone, Liberia, and Guinea had the most cases, with 7,968, 3,138, and 2,569 EVD patients, respectively. *Id.* For the week ending January 24, 2015, an average of eleven daily confirmed cases were reported from Sierra Leone, less than one from Liberia, and three from Guinea. *Id.*

<sup>12</sup> CDC Director Thomas Frieden, Press Conference on the First Ebola Case Diagnosed in the United States (Sept. 30, 2014) (transcript and audio available at <http://www.cdc.gov/media/releases/2014/t0930-ebola-confirmed-case.html>); see also Press Release, CDC, CDC Announces First Case of Middle East Respiratory Syndrome Coronavirus Infection (MERS) in the United States (May 2, 2014), available at <http://www.cdc.gov/media/releases/2014/p0502-US-MERS.html>.

issues arising during epidemics or other public health emergencies, specifically focusing on Emory's legal and operational preparedness experiences during the 2014 Ebola crisis. Hospitals, physicians, nurses, and public health officials can learn from that experience in developing their own response plans for a future similar crisis.

## II. LEGAL ISSUES ARISING FROM EBOLA AND OTHER PUBLIC HEALTH EMERGENCIES

### A. *Emergency Public Health Legal Authorities in Response to Ebola*

Law is a cornerstone of public health emergency preparedness, funding, and response to emerging threats like Ebola. In December 2014, Congress approved \$5.4 billion to address the Ebola outbreak globally, including specific earmarks to the National Institutes of Health, the CDC, and others.<sup>13</sup> Routine public health powers authorized by law may be used successfully to address emerging infectious disease threats. However, threats like EVD raise the possibility of invoking emergency powers to respond more rapidly in coordinated ways. Formal emergency declarations can affect public health and medical responses by instantly altering the legal environment, depending, in part, on the type of emergency declared.<sup>14</sup> In the U.S., federal and many state (as well as select local) governments may declare states of "emergency,"

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<sup>13</sup> Consolidated and Further Continuing Appropriations Act, 2015, H.R. 83, 113th Cong. (2014); Press Release, Dep't of Health & Human Servs., 35 U.S. Hospitals Designated as Ebola Treatment Centers (Dec. 2, 2014) (*available at* <http://www.hhs.gov/news/press/2014pres/12/20141202b.html>) ("Hospitals with Ebola treatment centers have been designated by state health officials to serve as treatment facilities for patients based on a collaborative decision with local health authorities and the hospital administration. Ebola treatment centers are staffed, equipped, and have been assessed to have current capabilities, training, and resources to provide complex treatments for Ebola patients while minimizing risk to [HCWs]."). In particular, the Defense Advanced Research Projects Agency ("DARPA"), the Pentagon's elite research arm, awarded Emory University up to \$10.8M over three years to direct a project using the blood from survivors of EVD to test a novel way of treating infectious diseases, including not only EVD but potentially seasonal flu and malaria. Julie Steenhuisen, *Blood from Ebola Survivors Could Help Spur New Disease Treatments*, REUTERS (Feb. 4, 2015, 2:45 PM), <http://in.reuters.com/article/2015/02/04/health-ebola-antibodies-idINKBN0L80PP20150204>.

<sup>14</sup> James G. Hodge, Jr. & Evan D. Anderson, *Principles and Practice of Legal Triage During Public Health Emergencies*, 64 N.Y.U. ANN. SURV. AM. L. 249, 250 (2009).

“disaster,”<sup>15</sup> or “public health emergency,”<sup>16</sup> among other classifications. These declarations may empower public and private entities to address public health crises like EVD by:

- Offering public and private sectors greater flexibility to act to protect the public’s health through testing, screening, treatment, and vaccination programs;
- Authorizing use of social distancing measures to control the spread of infectious conditions;
- Allowing temporary suspensions of regulations that may impede emergency responses;
- Enabling efforts among volunteer health providers through limits of, or protections from, claims of liability;<sup>17</sup>
- Facilitating transitions to what the U.S. Institute of Medicine defines as “crisis standards of care” (discussed below);<sup>18</sup> and
- Altering medical licensing standards and scopes of practice to facilitate emergency responses.<sup>19</sup>

Although states of emergency can further public health preparedness, their invocation is unpredictable and precarious. In response to the threat of EVD in 2014, neither the President nor the federal Department of Health and Human Services (DHHS) declared any major states of

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<sup>15</sup> Evan D. Anderson & James G. Hodge, *Emergency Legal Preparedness Among Select U.S. Local Governments*, 3 DISASTER MED. & PUB. HEALTH PREPAREDNESS. S176, S176 (Supp. 2 2009).

<sup>16</sup> DEP’T OF HEALTH & HUMAN SERVS., EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS (ESAR-VHP)—LEGAL AND REGULATORY ISSUES 10–11 (2006).

<sup>17</sup> Sharona Hoffman et al., *Law, Liability, and Public Health Emergencies*, 3 DISASTER MED. & PUB. HEALTH PREPAREDNESS 117, 123 (2009); Sara Rosenbaum et al., *State Laws Extending Comprehensive Legal Liability Protections for Professional Health-Care Volunteers During Public Health Emergencies*, 123 PUB. HEALTH REPS. 238, 238–41 (2008).

<sup>18</sup> HEALTH SYS. RESEARCH, INC., ALTERED STANDARDS OF CARE IN MASS CASUALTY EVENTS: BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES, AGENCY FOR HEALTHCARE RESEARCH & QUALITY PUBL’N No. 05-0043 (2005).

<sup>19</sup> James G. Hodge Jr. et al., *Emergency Legal Preparedness for Hospitals and Health Care Personnel*, 3 DISASTER MED. & PUB. HEALTH PREPAREDNESS S37, S39 (Supp. 1 2009).

emergency.<sup>20</sup> DHHS' Secretary Sylvia Burwell did issue a limited declaration on December 9, 2014<sup>21</sup> to support EVD vaccine development under the Public Readiness and Emergency Preparedness (PREP) Act.<sup>22</sup> Among states, only Connecticut's Governor issued a state of public health emergency, which was declared on October 6, 2014.<sup>23</sup>

Governments' reticence to declare formal states of emergency in response to EVD may seem incredulous given the national attention in the fall of 2014 and Americans' perception of the risks. However, the lack of emergency declarations is understandable for several reasons. First, public health emergency declarations are typically issued in response to known or imminent threats of substantial harms to the population. A handful of domestic cases of a non-airborne, slowly-spreading condition like EVD may frighten the general public, but it does not constitute an imminent threat to the public's health. Second, neither DHHS nor most states had to issue any declaration to apply existing public health powers (*e.g.*, education, testing, screening, treatment, quarantine, isolation, closures) to address EVD. Finally, while emergency laws can help mobilize efforts, they do not provide precise legal guidance. Framed in broad statutory or regulatory language, these laws offer more so a menu of legal powers and options rather than a definitive guide for action. Implementation of emergency powers may be one route to effective response efforts, but are not by definition a panacea. In reality, national, state, and local actors like Emory University Hospital must prioritize legal issues and generate practical solutions in real time to facilitate legitimate public health efforts designed to limit the spread of EVD in balance with communal and individual interests.

### B. *Isolation and Quarantine*

Public health powers to issue quarantine or isolation orders for infectious diseases like EVD are politically controversial and often

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<sup>20</sup> Press Secretary Josh Earnest, Press Briefing in the James S. Brady Press Briefing Room (Oct. 16, 2014) (transcript available at <https://www.whitehouse.gov/the-press-office/2014/10/16/press-briefing-press-secretary-josh-earnest-10162014>) (stating President Obama is not "actively considering [a national health emergency] right now").

<sup>21</sup> Press Release, Sylvia M. Burwell, Sec'y, Dep't of Health & Hum. Servs., Sec'y Burwell Issues Declaration Under PREP Act to Support Dev. of Ebola Vaccines (Dec. 9, 2014), available at <http://www.hhs.gov/news/press/2014pres/12/20141209a.html>.

<sup>22</sup> Public Readiness and Emergency Preparedness (PREP) Act, Pub. L. No. 109-148 (codified in Public Health Service Act, 42 U.S.C. §§ 247d-6d, 247d-6e).

<sup>23</sup> Letter from Daniel P. Malloy, Governor, State of Conn., to the Honorable Denise Merrill, Sec'y of the State, and Clerks of the General Assembly (Oct. 7, 2014), [http://www.governor.ct.gov/malloy/lib/malloy/2014.10.07\\_Declaration\\_of\\_Public\\_Health\\_Emergency.pdf](http://www.governor.ct.gov/malloy/lib/malloy/2014.10.07_Declaration_of_Public_Health_Emergency.pdf).

misunderstood.<sup>24</sup> Quarantine is designed to separate and restrict the movement of persons suspected or known to be *exposed* to an infectious disease.<sup>25</sup> Isolation, on the other hand, separates persons who are suspected or known to be *infected* with an infectious disease.<sup>26</sup> The powers to issue and enforce quarantine and isolation orders are primarily vested in state and local public health agencies.<sup>27</sup> At the federal level, the Public Health Service Act affords the Secretary of DHHS the power to restrict movement of persons with specific infectious diseases, including EVD, into and throughout the United States.<sup>28</sup> Authority to carry out these functions at the federal level is delegated to CDC.<sup>29</sup> CDC can quarantine or isolate persons travelling to the U.S. or across state lines. However, it does not typically exercise these powers.<sup>30</sup> Variations among federal and state law in how and when to implement emergency powers can lead to confusion, especially during exigencies.<sup>31</sup>

Implementation of isolation and quarantine orders entails significant due process protections, including adequate evidentiary proof (often grounded in clear and convincing evidence),<sup>32</sup> sufficient notice, right to a hearing and counsel, and assurances that medical and other needs of affected persons are met.<sup>33</sup> Social distancing measures, including quarantine and isolation, were necessitated by the lack of pharmaceuticals in West Africa, although their effectiveness in

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<sup>24</sup> JAMES G. HODGE, JR., PUBLIC HEALTH LAW IN A NUTSHELL 93–94 (2013).

<sup>25</sup> *Legal Authorities for Isolation and Quarantine*, CDC, <http://www.cdc.gov/quarantine/aboutLawsRegulationsQuarantineIsolation.html> (last updated Oct. 8, 2014) (emphasis added).

<sup>26</sup> HODGE, JR., *supra* note 24, at 94 (2013) (emphasis added).

<sup>27</sup> *Id.* at 93–94; see also *State Quarantine and Isolation Statutes*, NAT'L CONF. OF STATE LEGISLATURES (Oct. 29, 2014), <http://www.ncsl.org/research/health/state-quarantine-and-isolation-statutes.aspx>.

<sup>28</sup> 42 U.S.C. § 264 (2012).

<sup>29</sup> *Legal Authorities for Isolation and Quarantine*, CDC, <http://www.cdc.gov/quarantine/aboutLawsRegulationsQuarantineIsolation.html> (last updated Oct. 8, 2014).

<sup>30</sup> *Id.*

<sup>31</sup> Jim Kuhnhenh, *Where's Czar? Ebola Raises Management Questions*, ASSOCIATED PRESS (Oct. 28, 2014, 5:48 PM), <http://bigstory.ap.org/article/c736c4d56e30479d877e79e7cf87e3e7/wheres-czar-ebola-raises-management-questions>.

<sup>32</sup> Christine M. Grant & Patricia I. Elliott, *21st-Century Scientific Evidence Issues in Public Health Quarantines and Takings*, in SCIENTIFIC EVIDENCE REVIEW: CURRENT ISSUES AT THE CROSSROADS OF SCIENCE, TECHNOLOGY AND THE LAW, MONOGRAPH NO. 7 127, 133 (Christine M. Grant & Helen E. Witt eds. 2006) (“State courts traditionally have given great deference to public health authorities requesting orders of quarantine. However, the claim of authority is not absolute—it can be refuted with facts . . . . Civil confinement usually requires clear and convincing evidence of the need for quarantine, coupled with supervised detention.”).

<sup>33</sup> Lawrence O. Gostin, James G. Hodge, Jr. & Scott Burris, *Is the United States Prepared for Ebola?*, 312 JAMA 2497, 2498 (2014).

combatting EVD varied.<sup>34</sup> Because symptoms may not appear for up to twenty-one days after first exposure,<sup>35</sup> quarantine measures in response to EVD have a finite end point. However, EVD social distancing measures must be stringently enforced to prove effective because of the high morbidity and mortality rates associated with the disease.

Use of social distancing powers is controversial due to the direct infringement on individual liberty and autonomy, among other interests. Quarantine orders, based on *potential* exposure to infectious conditions like EVD, are especially contentious. Mandatory enforcement can negatively impact quarantined individuals (as was the case with those potentially exposed to Thomas Eric Duncan)<sup>36</sup> and contribute to compliance failures.

In October 2014, Maine nurse Kaci Hickox garnered significant media attention when she resisted a quarantine order upon returning to the U.S. from treating EVD patients in Sierra Leone.<sup>37</sup> Hickox only exhibited a minor fever when arriving at Newark Liberty International Airport.<sup>38</sup> However, Governors Andrew Cuomo (New York) and Chris Christie (New Jersey) implemented an automatic quarantine for any health care worker (“HCW”) returning from West Africa who had come in contact with EVD patients (exceeding CDC recommended guidance). Governor Christie worked with state public health agents to place Hickox in a mandatory quarantine setting outside a Newark hospital.<sup>39</sup> After three days, New Jersey reversed the mandatory quarantine and Hickox returned to her home in Maine, where she faced another court ordered quarantine.<sup>40</sup> Still presenting no outward symptoms, Hickox resisted the order,<sup>41</sup> arguing that the automatic quarantines unconstitutionally

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<sup>34</sup> Abhishek Pandey et al., *Strategies for Containing Ebola in West Africa*, 346 *Sci.* 991, 992 (2014).

<sup>35</sup> *Ebola Virus Disease, Signs and Symptoms*, CDC, <http://www.cdc.gov/vhf/Ebola/symptoms/index.html> (last updated Nov. 2, 2014).

<sup>36</sup> After Thomas Eric Duncan’s death in Dallas, Texas, his contacts were subject to a mandatory quarantine. While none of the contacts actually became infected, many were stigmatized or unable to return to work or school. Kevin Sack et al., *Life in Quarantine: 21 Days of Fear and Loathing*, *N.Y. TIMES*, Oct. 19, 2014, at A1.

<sup>37</sup> Jess Bidgood & Dave Philipps, *Judge in Maine Eases Restrictions on Nurse*, *N.Y. TIMES*, Nov. 1, 2014, at A18.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> Temporary Order, *Mayhew v. Hickox*, No. CV-2014-36 (Me. Dist. Ct. Oct. 30, 2014).

<sup>41</sup> In view of the media and trailed by a police car, Hickox went for a bike ride with her boyfriend to publicly defy the quarantine order. Sydney Lupkin & Aaron Katersky, *Talks with Ebola Nurse Kaci Hickox Fail, Governor to Use ‘Full Authority’*, *ABC NEWS* (Oct. 30, 2014, 10:13 AM), <http://abcnews.go.com/Health/talks-ebola-nurse-kaci-hickox-fail-governor-full/story?id=26569596>.

infringed on her liberty interests and discouraged HCWs from providing aid in EVD affected countries.<sup>42</sup> State officials in Maine defended the quarantine as a public health necessity<sup>43</sup> authorized by its quarantine law.<sup>44</sup> When challenged, the Maine District Court relaxed the court order, allowing Hickox to move about freely, submit to self-monitoring, and report any upcoming travel.<sup>45</sup> Ultimately, Hickox never contracted EVD. Her case illustrates the potential pitfalls and inconsistencies related to quarantine and isolation powers or other social distancing measures.

### C. *Travel Restrictions*

Like social distancing measures, government restrictions on individual travel and movement implicate fundamental liberties. Yet these powers are vital to maintaining the public's health and often explicitly authorized by law.<sup>46</sup> Travel restrictions and screening are exercised at the federal and state levels. Federal regulations may limit persons with EVD from traveling between states.<sup>47</sup> States may also have their own authority to restrict one's travel within and outside its borders for public health purposes.<sup>48</sup> Furthermore, federal oversight of passport approval,<sup>49</sup> immigration law,<sup>50</sup> transportation regulations,<sup>51</sup> and "Do Not Board" requirements<sup>52</sup> may restrict the entry or exit of persons into and out of the U.S.

Federal powers to restrict travel are broad, but federal officials have been reluctant to completely prohibit travel to and from the affected EVD regions. WHO has consistently recommended against closing borders in response to EVD, in part because border closures make it "difficult to transport supplies, personnel, and other resources."<sup>53</sup> Some

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<sup>42</sup> Bidgood & Philipps, *supra* note 37, at A18.

<sup>43</sup> *Id.*

<sup>44</sup> ME. REV. STAT. ANN. tit. 22 § 810 (2004).

<sup>45</sup> Order Pending Hearing, *Mayhew v. Hickox*, No. CV-2014-36 (Me. Dist. Ct. Oct. 31, 2014).

<sup>46</sup> HODGE, JR., *supra* note 24, at 48.

<sup>47</sup> 42 C.F.R. § 70.3 (2014).

<sup>48</sup> *See, e.g.*, MICH. COMP. LAWS ANN. § 30.410 (2012).

<sup>49</sup> 22 U.S.C. § 211a (2012).

<sup>50</sup> 8 U.S.C. § 1182(a)(1)(A) (2012).

<sup>51</sup> 14 C.F.R. § 382.21 (2014).

<sup>52</sup> *Federal Air Travel Restrictions for Public Health Purposes—United States, June 2007–May 2008*, 57 CDC MORBIDITY & MORTALITY WKLY. REP. 1009, 1009–12 (2008).

<sup>53</sup> *WHO Urges Countries to Avoid Actions that Compromise Ebola Response Efforts*, WORLD HEALTH ORG. (Aug. 28, 2014), <http://www.afro.who.int/en/media-centre/pressreleases/item/6929-who-urges-countries-to-avoid-actions-that-compromise-ebola-response-efforts.html>.

members of Congress<sup>54</sup> called for President Obama to close the U.S. border to West African nations, but he repeatedly refused.<sup>55</sup> CDC Director Dr. Thomas Frieden warned that border closures have the potential to drive Ebola cases underground, causing the outbreak to spread undetected and continue indefinitely.<sup>56</sup> CDC has warned Americans to avoid nonessential travel to Liberia, Guinea, and Sierra Leone,<sup>57</sup> but does not limit the provision of resources to those countries.

Rather than instituting mandatory travel restrictions in response to EVD (as some countries have required), U.S. authorities have opted for tighter screening protocols intended to prevent disease spread and allow aid to continue to reach the affected countries. On October 8, 2014, CDC announced enhanced screening measures at five U.S. airports to detect, assess, and respond to potential Ebola cases.<sup>58</sup> Additionally, CDC issued recommended guidance regarding the screening and monitoring of persons with potential Ebola exposure.<sup>59</sup> However, states are not required to follow CDC's guidance. Accordingly, many opted to enforce their own more or less restrictive protocols.<sup>60</sup> Other institutions may also opt (as Emory did) to implement their own guidelines accounting for specific

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<sup>54</sup> See Steven Nelson, *Congressman: Close Border to Ebola Countries*, US NEWS (July 30, 2014, 11:52 AM), <http://www.usnews.com/news/articles/2014/07/30/congressman-close-border-to-ebola-countries>; Sarah Ferris, *Dems Call for Ebola Flight Ban*, THE HILL (Oct. 9, 2014, 4:03 PM), <http://thehill.com/policy/healthcare/220317-dems-call-for-obama-to-ban-flights-from-ebola-countries>; Arlette Saenz & John Parkinson, *4 Things Some DC Lawmakers Want Obama to Do About Ebola*, ABC NEWS (Oct. 17, 2014, 12:02 PM), <http://abcnews.go.com/blogs/politics/2014/10/4-things-some-dc-lawmakers-want-obama-to-do-about-ebola/>.

<sup>55</sup> President Barack Obama, Remarks by the President After Meeting on Ebola (Oct. 6, 2014) (transcript available at <https://www.whitehouse.gov/the-press-office/2014/10/06/remarks-president-after-meeting-ebola>) (“Because of the measures that we’ve put in place, as well as our world-class health system and the nature of the Ebola virus itself -- which is difficult to transmit—the chance of an Ebola outbreak in the United States is extremely low.”).

<sup>56</sup> Tom Frieden, *CDC Chief: Why I Don't Support a Travel Ban to Combat Ebola Outbreak*, FOX NEWS (Oct. 9, 2014), <http://www.foxnews.com/opinion/2014/10/09/cdc-chief-why-dont-support-travel-ban-to-combat-ebola-outbreak/>.

<sup>57</sup> *Travel Health Notices*, CDC, <http://wwwnc.cdc.gov/travel/notices> (last updated Mar. 6, 2015).

<sup>58</sup> Press Release, CDC, Enhanced Ebola Screening to Start at Five U.S. Airports and New Tracking Program for all People Entering U.S. From Ebola-affected Countries (Oct. 8, 2014) (available at <http://www.cdc.gov/media/releases/2014/p1008-ebola-screening.html>) (describing enhanced screening at airports in New York, NY, Washington, DC, Newark, NJ, Chicago, IL, and Atlanta, GA).

<sup>59</sup> *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*, CDC, <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html> (last updated Dec. 24, 2014).

<sup>60</sup> *State Ebola Protocols*, CDC, <http://www.cdc.gov/phlp/publications/topic/ebola.html> (last updated Mar. 9, 2015).

workplace-related factors (e.g., students, faculty, researchers and other non-HCW employees).<sup>61</sup>

#### D. Duty to Treat

Do physicians and other medical professionals have a duty to treat patients with highly infectious and dangerous diseases? What rights of employees to safety or other concerns must be considered in deciding to accept and treat a patient with a dangerous disease? Does a safety concern of a HCW ever outweigh any obligation to treat a patient?

Emory's team of physicians, nurses, lab technologists, chaplains, and others enthusiastically expressed willingness to accept and treat U.S.-bound patients with EVD as reflected in the comments provided by Dr. Kent Brantly during a press conference on the day of his discharge with the entire Emory care team present on stage.<sup>62</sup> Although Emory Hospital never faced the issue of having a physician or employee refuse to treat a highly infectious patient, HCWs' resistance to treat highly infectious patients could be a critical factor in other cases, especially in facilities lacking personnel who are prepared to handle patients with diseases like EVD.<sup>63</sup>

In *Bragdon v. Abbot*,<sup>64</sup> the U.S. Supreme Court clarified that a medical professional may not categorically refuse to treat disabled patients (as defined in the Americans with Disabilities Act of 1990 (ADA)) for discriminatory reasons. Notwithstanding ethical principles,<sup>65</sup> medical professionals can refuse to treat patients in a number of circumstances as a general rule under common law.<sup>66</sup> In *Childs v. Weis*,<sup>67</sup>

<sup>61</sup> *Guidelines for Travel to Countries Affected by Ebola Virus Disease*, EMORY UNIV. (Nov. 7, 2014), [http://global.emory.edu/support/travel/ebola\\_travel\\_policy.html](http://global.emory.edu/support/travel/ebola_travel_policy.html).

<sup>62</sup> Dr. Kent Brantly, Press Conference Announcing Discharge of Dr. Kent Brantly & Nancy Writebol (Aug. 21, 2014) (video available at <http://www.wsbtv.com/news/news/ebola-patients-released-emory-university-hospital/ng6jR/>) [hereinafter Emory August 21 Press Conference].

<sup>63</sup> See Manny Fernandez, *Dallas Nurse Contracts Ebola Virus, Elevating Response and Anxiety*, N.Y. TIMES, Oct. 13, 2014, at A1.

<sup>64</sup> *Bragdon v. Abbott*, 524 U.S. 624 (1998).

<sup>65</sup> While the law may impose no, or a limited, duty on physicians to treat patients with AIDS and other infectious diseases, physicians' moral and ethical obligations are more well-established. Ann Bitton Gazvy & James V. Hertzler, *To Treat or Not to Treat: Healthcare Providers' Duties*, 126 N.J. Law., Feb. 1989, at 52.

<sup>66</sup> See, e.g., *Anderson v. Houser*, 523 S.E.2d 342 (Ga. Ct. App. 2000); see also Polly J. Price, *Ebola and the Law in the United States: A Short Guide to Public Health Authority and Practical Limits* 17 (Emory Legal Studies Research Paper No. 14-299), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2538187](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2538187); Christopher C. White, *Health Care Professionals and Treatment of HIV-Positive Patients: Is There an Affirmative Duty to Treat Under Common Law, the Rehabilitation Act, or the Americans with Disabilities Act?*, 20 J. LEGAL MED. 67, 77 (1999).

a lower court expressed this “no duty” rule.<sup>68</sup> Since the physician/patient relationship is essentially contractual in nature and no obligation to treat arises until its creation,<sup>69</sup> medical professionals can terminate an existing physician/patient relationship with proper notice and transition to an alternative provider.<sup>70</sup> However, refusal to treat can result in professional sanctions by the governing licensing boards in a particular state.<sup>71</sup>

Even if EVD patients are likely considered disabled under the ADA, a physician can defend a decision to deny treatment if the patient presents a significant risk to the physician’s health.<sup>72</sup> The ADA does not require that a person benefit from services where such individual poses a “direct threat” to the health or safety of others, meaning a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures or by the provision of auxiliary aids or services.<sup>73</sup> There is no standard definition of “significant risk”, as each situation must be determined on a case-by-case basis balancing objective and prevailing medical standards and science with a physician’s judgment.

In *Bragdon*, the Supreme Court noted “the importance of prohibiting discrimination against persons with a recognized disability while protecting others from significant health and safety risks, resulting, for instance, from a contagious disease.”<sup>74</sup> A physician’s belief, even in good faith, that a significant risk existed to his or her health would not necessarily provide relief from liability under the ADA. However, in the event of a new, unknown pathogen that lacks medical objectives or scientific information regarding transmission risks, a physician or other

<sup>67</sup> Childs v. Weis, 440 S.W.2d 104 (Tex. App. 1969).

<sup>68</sup> *Id.* at 107 (“Since it is unquestionably the law that the relationship of physician and patient is dependent on contract, either express or implied, a physician is not . . . liable for arbitrarily refusing to respond to a call of a person even urgently in need of medical or surgical assistance provided that the relation of physician and patient does not exist . . .”).

<sup>69</sup> White, *supra* note 66, at 78.

<sup>70</sup> Termination of the physician/patient relationship must be carefully and appropriately accomplished with adequate notice to avoid claims of patient abandonment. AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS 261, OP. 8.115—TERMINATION OF THE PHYSICIAN-PATIENT RELATIONSHIP (2008); *Can My Physician Terminate My Care or Discontinue Seeing Me?*, GA. COMPOSITE MED. BD., <http://medicalboard.georgia.gov/can-my-physician-terminate-my-care-or-discontinue-seeing-me> (last visited Mar. 22, 2015).

<sup>71</sup> Price, *supra* note 66, at 17-18; White, *supra* note 66, at 93 n.173.

<sup>72</sup> Ariel R. Schwartz, Note, *Doubtful Duty: Physicians’ Legal Obligation to Treat During an Epidemic*, 60 STAN. L. REV. 657, 671 (2007).

<sup>73</sup> 42 U.S.C. § 12182(b)(3) (2012); Schwartz, *supra* note 72, at 671.

<sup>74</sup> See Schwartz, *supra* note 72, at 671 (citing *Bragdon*, 524 U.S. at 649; Sch. Bd. of Nassau Cty. v Arline, 480 U.S. 273, 287 (1987)).

health provider might legitimately posit that there is a “significant risk” outweighing any obligation to treat under the ADA or other ethical and moral principles.

*E. Emergency Medical Treatment and Active Labor Act*

One exception to the general “no duty to treat” principle discussed above is a provider’s obligation to treat and stabilize patients in emergency settings. If a patient presents in a hospital emergency room (ER), this assessment, treatment, and stabilization requirement is well-established under the federal Emergency Medical Treatment and Active Labor Act (EMTALA).<sup>75</sup> EMTALA requires hospitals that receive federal funds (through Medicare and Medicaid) to provide stabilizing treatment to patients presenting with emergency conditions in the ER without regard for the patient’s ability to pay. Once the patient is stable, they may be appropriately admitted or transferred for further care.

EMTALA focuses solely on the hospital’s obligations to assess whether an “emergency” exists (e.g., childbirth is considered an emergency) and, if so, provide stabilizing care and treatment.<sup>76</sup> As a result, hospitals must treat patients with highly infectious and communicable diseases if the conditions are deemed to be an emergency (such as EVD). Absent an EMTALA waiver pursuant to a federally-declared emergency, EMTALA requires stabilizing treatment even in the face of potential threats to the health and safety of HCWs. Separate federal standards under the Occupational Safety and Health Act (OSHA), discussed below, may also apply.

EMTALA obligations extend to physicians by way of (1) employment of physicians by the hospital or health system, (2) a contract between a physician and a hospital under which the physician agrees to provide ER services, or (3) in the context of many community hospitals, by the physician’s staff privileges. For example, as noted by Ariel Schwartz, “if an on-call physician negligently acts inconsistent with the hospitals’ EMTALA obligations,”<sup>77</sup> or violates hospital medical staff bylaws, the physician and the hospital may face liability under EMTALA and up to a \$50,000 penalty. Additionally, the physician may be liable via contract, which may include possible expulsion from the medical staff pursuant to medical staff bylaws.<sup>78</sup>

Hospitals have limited flexibility in how they satisfy their EMTALA obligations during emergencies. DHHS’ policies may allow hospitals to

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<sup>75</sup> 42 U.S.C. §§ 1395dd(a)–(b) (2012).

<sup>76</sup> *Id.*

<sup>77</sup> Schwartz, *supra* note 72, at 679.

<sup>78</sup> § 1395dd(d)(1); Schwartz, *supra* note 72, at 679.

avoid EMTALA sanctions for direction, relocation, or transfer of patients prior to screening or stabilization in limited circumstances pursuant to a Section 1135 waiver.<sup>79</sup> Hospitals can also transfer patients in non-emergency situations. The federal Centers for Medicare and Medicaid Services (CMS) issued the following guidelines in 2002:

CMS does not require that a hospital's medical staff provide on-call coverage 24 hours/day, 365 days/year. If there comes a particular time that a hospital does not have on-call coverage for a particular specialty, that hospital lacks capacity to treat a patient needing that specialty service and it is therefore appropriate to transfer the patient because the medical benefits of the transfer outweighs the risks . . . Medicare does not set requirements on how frequently a hospital's medical staff of on-call physicians is expected to provide on-call coverage . . . We are also aware that there are some hospitals that have limited financial means to maintain on call coverage all of the time . . . CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on-call coverage that is within their capability.<sup>80</sup>

In many cases, patients may present in a non-emergent state or in settings other than a hospital ER, such as an outpatient physician clinic. Even though EMTALA is not implicated, providers should have clear protocols in place, including: (1) questions used to screen patients concerning potential exposure; (2) isolation of patients if answers to the screening questions are positive; (3) procedures for testing for EVD (or other communicable diseases); (4) transfer protocols, agreements to transfer to the hospital ER, or procedures for admission to the hospital; and (5) if there is no specialized service in the facility, a transfer to a facility that can treat the patient.

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<sup>79</sup> *Public Health Emergency Declaration Q&As*, DEP'T OF HEALTH & HUMAN SERVS., <http://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx> (last updated Apr. 24, 2013).

<sup>80</sup> Schwartz, *supra* note 72, at 680 (citing Memorandum from Dir., Survey & Certification Group., Dep't of Health & Human Servs., to Associate Reg'l Adm'rs 2 (June 13, 2002), available at <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter02-34.pdf>).

*F. Right to a Safe Working Environment, Workers' Compensation, and the Family Medical Leave Act*

Related to, and balanced with, the duty to treat is the right of employees in the workplace to a safe working environment mandated by OSHA.<sup>81</sup> After the initial decision was made to accept the first two patients, Emory's next and equally important question was how to provide that care safely—both for the patients and for the HCWs on the care team. As part of Emory's SCDU, the Environmental Health and Safety Officer was constantly present and led the OSHA response requirements and personal protective equipment (PPE) training with the HCWs. As discussed below, Emory's adherence to clinical protocols and safety measures were critical both to successful treatment and to assuring employees of their own personal safety.

Generally, employers have to provide a workplace free from "recognized hazards that are causing or are likely to cause death or serious physical harm" to employees.<sup>82</sup> When dealing with a highly infectious disease like EVD, OSHA expects employers to develop a program based upon a "hazard assessment" of potential exposure at the worksite, including: (1) conducting employee awareness and other trainings regarding the potential hazard, (2) creating protocols and procedures requiring the issuance of PPE if necessary to prevent infection and transmission, (3) providing a means of reporting infection and medical surveillance for infected employees, (4) maintaining appropriate documentation of all of the foregoing, (5) preserving and maintaining patient medical records, and (6) appropriately recording with OSHA any occupationally-related infections.<sup>83</sup>

Similarly, employees must comply with safety and health standards and regulations.<sup>84</sup> Employees can refuse to work when there is a

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<sup>81</sup> 29 U.S.C. § 654 (2012); *see also* John B. Flood, *Revisiting the Right to Refuse Hazardous Work Amidst the Anthrax Crisis of 2001*, 5 U. PA. J. LAB. & EMP. L. 545, 567 (2003); *Refusing to Work Because Conditions are Dangerous*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/as/opa/worker/refuse.html> (last visited Mar. 22, 2015) (public guidance issued by OSHA discussing an employee's right to refuse work).

<sup>82</sup> 29 U.S.C. § 654 (2012).

<sup>83</sup> OCCUPATIONAL SAFETY & HEALTH ADMIN., OSHA 3122-06R, PRINCIPAL EMERGENCY RESPONSE AND PREPAREDNESS REQUIREMENTS AND GUIDELINES (2004).

<sup>84</sup> 29 U.S.C. § 143 (2012) ("Nothing in this chapter shall be construed to require an individual employee to render labor or service without his consent, nor shall anything in this chapter be construed to make the quitting of his labor by an individual employee an illegal act; nor shall any court issue any process to compel the performance by an individual employee of such labor or service, without his consent; nor shall the quitting of labor by an employee or employees in good faith because of abnormally dangerous conditions for work at the place of employment of such employee or employees be deemed a strike under this chapter.").

reasonable apprehension of death or serious physical harm and no less drastic alternative is available.<sup>85</sup> Related to significant health hazards that may result from treating EVD patients, employees could also refuse to work because they believe that their health is in imminent danger due to the actual presence or reasonable probability of the disease. Such employees are engaged in “protected activity” under the Act<sup>86</sup> and thus not subject to adverse action by the employer for refusal to work unless the employer can establish through “objective” evidence that (1) there is no hazard or (2) its response plan will protect employees from exposure.

Like any employer, hospitals must also address issues relating to the potential for workers’ compensation benefits and the applicability of the Family and Medical Leave Act (FMLA).<sup>87</sup> With respect to workers’ compensation benefits, in the event that an employee contracts EVD as a result of occupational exposure (in other words, the illness arises out of and in the course of employment as proven by the employee through competent medical evidence), the employee may be entitled to receive temporary total disability benefits in lieu of wages, reasonable and necessary medical treatment, and an award for any resulting permanent disability (e.g., reduced respiratory capacity). An employer should evaluate whether it has adequate worker’s compensation insurance coverage and coverage limits that include occupational diseases.

If an employee contracts the disease and it is not occupationally related, the employee may be entitled to disability benefits if the employer provides such benefits. Again, the employer should carefully evaluate the extent of benefits and any exclusions. The employer must consider whether EVD is going to involve significant medical issues by determining (1) whether the employee is infectious; (2) what type of treatment is necessary; (3) whether the employee presents a health risk to others; and (4) when the employee can safely return to work.<sup>88</sup> Employers should also identify competent medical professionals with expertise in infection control that can advise on all medically related

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<sup>85</sup> *Whirlpool Corp. v. Marshall*, 445 U.S. 1 (1980); *see also Stepp v. Review Bd. of the Indiana Emp’t Sec. Div.*, 521 N.E. 2d 350 (Ind. Ct. App. 1988) (employee who refused to perform tests on fluids with AIDS warning label was properly suspended and discharged); *Marshall v. N.L. Indus., Inc.*, 618 F. 2d 1220, 1224 (7th Cir. 1980) (discharge of an employee in response to the employee’s good faith refusal to expose himself to conditions he reasonably believes are dangerous is discriminatory).

<sup>86</sup> 29 U.S.C. § 660(c) (2012); *see also* U.S. DEP’T OF LABOR, AUDIT REPORT NO. 05-97-107-10-105, NATIONWIDE AUDIT OF OSHA’S SECTION 11(C) DISCRIMINATION INVESTIGATIONS (1997).

<sup>87</sup> 29 U.S. C. § 2601 (2012); 29 C.F.R. pt. 825 (2014).

<sup>88</sup> Mark A. Lies II et al., *Ebola and Employer Liability Issues*, SEYFARTH SHAW LLP (Oct. 10, 2014), <http://www.environmentalsafetyupdate.com/osha-compliance/ebola-and-employer-liability-issues/>.

issues, including worker's compensation.<sup>89</sup> Under the FMLA, eligible employees may be entitled to up to twelve weeks of unpaid leave if the employee or a spouse, child, or parent has a "serious health condition," like EVD. This is especially important considering that both Emory and CDC issued guidelines mandating a twenty-one-day period of isolation for persons with EVD.<sup>90</sup>

Emory carefully considered all of these laws in preparing for the arrival of its EVD patients. Providing a safe working environment was critical. Emory also determined that FMLA would be fully utilized if applicable and requested (which it was not). With respect to workers' compensation benefits, Emory determined that any worker who contracted EVD would be entitled to workers' compensation related to their medical expenses, time away from work, and post-traumatic syndrome disease at a rate of one-hundred percent (higher than the sixty-six percent rate required in Georgia for disability<sup>91</sup>). Fortunately, this benefit was not utilized at Emory. With respect to a potential claim for "fear of contracting EVD," such claims were to be adjudged ineligible for workers' compensation unless the employee actually contracted the disease. This also was never an issue at Emory, but could be in a different setting and circumstances.

### G. *HIPAA Privacy Rule and Other Issues of Confidentiality*

When treating patients with a highly infectious, lethal disease that is the subject of massive media attention, a paramount obligation is to maintain the confidentiality of patient information under federal and state law, including the Health Insurance Portability and Accountability Act ("HIPAA")<sup>92</sup> and the accompanying Privacy Rule.<sup>93</sup> Despite the fact that the identities and images of the patients treated at Emory (and indeed elsewhere nationally) were universally published, Emory patients were classified as "no information" patients, meaning that specifics of their condition, or even their identities, were carefully protected and managed in all public communications. In communications with the news media,

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<sup>89</sup> *Id.*

<sup>90</sup> *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*, CDC, <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html> (last updated Dec. 24, 2014) [hereinafter *CDC Guidelines*]; John Fox, Bill Bornstein & Susan Grant, *Emory Healthcare Ebola Preparedness Protocols*, EMORY HEALTHCARE, <http://www.emoryhealthcare.org/ebola-protocol/ehc-message.html> (last visited Mar. 22, 2015) [hereinafter *Emory Protocols*].

<sup>91</sup> Georgia Workers' Compensation Act, O.C.G.A. § 34-9-261 (2014)

<sup>92</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1938.

<sup>93</sup> 45 C.F.R. §§ 160, 164.102-164.106, 164.500-164.534 (2014).

the Emory care team never used the patients' names until Dr. Brantly's news conference prior to his discharge from the Hospital. These actions appeared mysterious to the media, but Emory's respect for confidential information was maintained throughout. In public communications, Emory's team educated the media and the public on the disease itself, attempting to dispel fears, misunderstandings, and inaccuracies.

Heightened risks to patient privacy and the need to control communications were recognized immediately at Emory. Its Chief Privacy Officer was one of the first administrative employees brought onto the team with other clinical care and operations personnel.<sup>94</sup> Efforts to ensure HIPAA Privacy Rule compliance included several email "blasts" to all Emory healthcare employees reminding them of the obligations to ensure patient privacy, and warning about sharing any information even if no identifiable patient information was used. Employees were reminded not to talk about or discuss patient information in public areas (cafeterias, lobbies, etc.) and not to post anything about patients on any social media websites. Emory also activated an additional control on its electronic medical records system so workers who tried to access the EVD patients' records were stopped by an electronic message asking the employees to affirmatively check a box attesting that they were authorized to view the information before the system permitted them to continue. Audit trials were conducted to see if anyone accessed the records without permission. Similar audits at the University of Nebraska's Medical Center led to the discovery and termination of two workers who violated privacy requirements by reviewing information about one of the EVD patients treated there.<sup>95</sup>

In November 2014, DHHS issued a special Bulletin specifically related to HIPAA Privacy in Emergency Situations in light of the EVD outbreak.<sup>96</sup> DHHS sought to clarify that while the protections of the Privacy Rule are not set aside in an emergency, there are "ways to ensure that appropriate uses and disclosures of the information still may be made when necessary to treat a patient, to protect the nation's public health, and for other critical purposes."<sup>97</sup>

DHHS clarified that protected health information may be disclosed (1) to a public health authority; (2) at the direction of a public health

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<sup>94</sup> *Hospitals with Ebola Patients are Under Great Pressure to Ensure Their Privacy*, 14 REP. ON PATIENT PRIVACY, Nov. 2014, at 1, available at [http://aishealth.com/sites/all/files/marketplace\\_pdf\\_samples/samplerpp.pdf](http://aishealth.com/sites/all/files/marketplace_pdf_samples/samplerpp.pdf).

<sup>95</sup> *Id.* at 4.

<sup>96</sup> Memorandum from the Dep't of Health & Human Servs., Bulletin: HIPAA Privacy in Emergency Situations (Nov. 2014) (available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/emercencysituations.pdf>).

<sup>97</sup> *Id.*

authority or to a foreign government acting in collaboration with a public health authority; (3) to “persons at risk” of contracting or spreading the disease; (4) to family, friends and others “involved in an individual’s care and for notification;” (5) to anyone “as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public” consistent with applicable law; and (6) to the media or others not involved if the patient has not objected to or restricted the release of this information, or the patient is incapacitated and the disclosure is believed to be in the best interests of the patient and consistent with any prior expressed preferences of the patient.<sup>98</sup> With respect to the permitted disclosure to the media, patient consent is key. Also, anyone disclosing patient information may only share the “minimum necessary” information to accomplish the purpose of disclosure.<sup>99</sup>

#### H. *Americans with Disabilities Act*

As hospitals decide whether to accept and treat patients with EVD or similar communicable diseases in the future,<sup>100</sup> patient disability status will be an important consideration. Generally, persons with communicable or otherwise infectious diseases may satisfy the requirements of Section 504 of the Rehabilitation Act of 1973 (Rehab Act),<sup>101</sup> the ADA (involving health care and human service providers and institutions),<sup>102</sup> and the ADA Amendments Act of 2008 (ADAAA),<sup>103</sup> and may therefore be protected against discriminatory acts, including the decision by a provider not to accept or treat a covered individual. These statutes all prohibit covered entities (such as hospitals) from discriminating against (i.e., refusing to treat) persons with disabilities in

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<sup>98</sup> *Id.*

<sup>99</sup> *Id.* (“In general, . . . affirmative reporting to the media or the public at large about an identifiable patient, or the disclosure to the public or media of specific information about treatment of an identifiable patient, such as specific tests, test results or details of a patient’s illness, may not be done without the patient’s written authorization (or the written authorization of a personal representative who is a person legally authorized to make health care decisions for the patient). See 45 CFR 164.508 for the requirements for a HIPAA authorization.”).

<sup>100</sup> The decision to accept and treat these Ebola patients at Emory was clinically based, and therefore did not focus on legal analysis. Nevertheless, under different circumstances or with another disease, the issue may play a larger role in the decision process.

<sup>101</sup> Rehabilitation Act of 1973, Pub. L. No. 93-112, 87 Stat. 355, 394 (1973) (codified as amended at 29 U.S.C. § 794).

<sup>102</sup> Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990) (codified as amended at 42 U.S.C. §§ 12101-12213 (2012)).

<sup>103</sup> ADA Amendments Act of 2008, Pub. L. No. 110-325, § 2, 122 Stat. 3553, 3553-54 (2008).

providing benefits and services, or conducting programs and activities on the basis of their disability. This leads to the ultimate question of whether an infectious disease such as EVD is, in fact, a “disability.”<sup>104</sup>

The Rehab Act (later incorporated into the ADA) protects individuals defined as potentially benefitting from rehabilitation services.<sup>105</sup> Amendments in 1974 expanded the definition of “handicapped individuals” to include any person who (1) has a physical or mental impairment which substantially limits one or more of such person’s major life activities; (2) has a record of such an impairment; or (3) is regarded as having such as impairment.<sup>106</sup> These definitional terms, including what constituted a “physical or mental impairment” are not defined by the Rehab Act<sup>107</sup> and were subsequently refined by DHHS,<sup>108</sup> although DHHS unequivocally stated that the list was “not comprehensive” and that certain terms in the statute (i.e. whether the condition “substantially limits” a person’s major life activities) were not “capable of definition.”<sup>109</sup>

What constitutes a handicap or a disability has been the subject of considerable litigation following the passage of the Rehab Act and its amendments, and particularly following the precedent-setting case of *School Board of Nassau County v. Arline*.<sup>110</sup> In *Arline*, the Supreme Court held that an individual with a contagious disease (in this case, tuberculosis) is considered handicapped and thus entitled to protection under the Rehab Act. The Court’s ruling in *Arline* has played a pivotal role in the development of federal disability law, especially as applied to persons diagnosed and living with HIV and AIDS because of the communicable nature of HIV.<sup>111</sup>

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<sup>104</sup> Office for Civil Rights, *Your Rights Under Section 504 and the Americans with Disabilities Act*, DEP’T OF HEALTH & HUMAN SERVS., <http://archive.hhs.gov/ocr/504ada.html> (last visited Mar. 24, 2015).

<sup>105</sup> Rehabilitation Act of 1973, Pub. L. No. 93-112, 87 Stat. 355, 394 (1973).

<sup>106</sup> Rehabilitation Act Amendments of 1974, Pub. L. No. 93-651, 89 Stat. 2–5 (1974) (codified at 29 U.S.C. §§ 706, 780, 790 (1974)).

<sup>107</sup> Nor were definitional terms subsequently defined in the ADA in 1990. Further regulations provide guidance as to what constitutes a “physical or mental impairment” to include a “physiological disorder or condition” that affects “one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs,) cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin and endocrine.” 29 C.F.R. § 1630.2(h)(1) (2014).

<sup>108</sup> 45 C.F.R. pt. 84 (2014).

<sup>109</sup> 45 C.F.R. pt. 84 app. A.

<sup>110</sup> *Sch. Bd. of Nassau Cnty. v. Arline*, 482 U.S. 273 (1973).

<sup>111</sup> Donald H.J. Hermann, *The Development of AIDS Federal Civil Rights Law: Anti-Discrimination Law Protection of Persons Infected With Human Immunodeficiency Virus*, 33 IND. L. REV. 783 (a comprehensive analysis and retrospective of the application of the public health laws and federal and state decisions relating to persons with HIV

Whether an individual infected with EVD or another highly infectious disease has a disability and therefore qualifies for protection under the ADA has not been settled or even addressed.<sup>112</sup> It would appear that such an individual would satisfy the first two requirements of a “disability,” (1) having “a physical or mental impairment that substantially limits one or more major life activities”, and (2) having a “record of such impairment,”<sup>113</sup> but whether the third prong of that test (“regarded and treated as though they have an impairment”), is uncertain. Although the mortality rates of EVD have been enormously high in West Africa during the 2014 outbreak, all but one patient treated for EVD in the United States have survived and been declared free of the disease and not a threat to the public.<sup>114</sup>

The ADA specifies that it does not apply to impairments that are “transitory and minor,” defining “transitory” as “an impairment with an actual or expected duration of 6 months or less.”<sup>115</sup> While the life cycle of EVD appears to be less than six months (either ending in death or being declared disease-free), the long-term health effects on persons who are declared disease free are unknown and still undergoing scrutiny.<sup>116</sup>

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infection and AIDS); see *Bragdon*, 524 U.S. at 642 (a person with asymptomatic HIV is entitled to claim protection under the ADA since it constituted an “impairment” that substantially limits the “major life activity” of reproduction and therefore cannot be denied medical treatment. However, HIV is not always a *per se* disability under the ADA); see also *Sussle v. Sirina Protection Sys. Corp.*, 267 F. Supp. 2d 285 (E.D.N. Y. 2003) (although Hepatitis C is a “physical impairment” and thus a disability, plaintiff failed to demonstrate that the impairment substantially limited a major life activity).

<sup>112</sup> Schwartz, *supra* note 72, at 669.

<sup>113</sup> 42. U.S.C. § 12102(1)(A)-(B) (2012); see also *The ADA: Questions and Answers*, EQUAL EMP’T OPPORTUNITY COMM’N, <http://www.eeoc.gov/eeoc/publications/adaqa1.cfm> (last visited Mar. 24, 2015) (“The first part of the definition makes clear that the ADA applies to persons who have substantial, as distinct from minor, impairments, and that these must be impairments that limit major life activities such as seeing, hearing, speaking, walking, breathing, performing manual tasks, learning, caring for oneself, and working. An individual with epilepsy, paralysis, a substantial hearing or visual impairment, mental retardation, or a learning disability would be covered, but an individual with a minor, non-chronic condition of short duration, such as a sprain, infection, or broken limb, generally would not be covered. The second part of the definition would include, for example, a person with a history of cancer that is currently in remission or a person with a history of mental illness. The third part of the definition protects individuals who are regarded and treated as though they have a substantially limiting disability, even though they may not have such an impairment.”).

<sup>114</sup> Bruce Ribner, Statement at News Conference (Aug. 21, 2014) (transcript *available at* [http://news.emory.edu/stories/2014/08/ebola\\_press\\_conference\\_ribner\\_statement/campus.html](http://news.emory.edu/stories/2014/08/ebola_press_conference_ribner_statement/campus.html)).

<sup>115</sup> 42. U.S.C. § 12102(3)(B).

<sup>116</sup> Kelsey Ryan, *Ebola Survivors Face Long Term Health Effects*, THE WICHITA EAGLE, <http://www.kansas.com/news/local/article3952318.html> (last updated Nov. 15, 2014, 11:21 AM).

For example, one long-term effect currently being researched is the medical condition of uveitis, an inflammation of the inner workings of the eye. Researchers previously found that survivors of a 1995 EVD outbreak in the Democratic Republic of the Congo developed eye pain and vision problems after having the virus.<sup>117</sup> Additionally, chronic arthralgia—pain in the joints—was also common in people living in Gabon with EVD antibodies present in their blood.<sup>118</sup> Due to its potential long-term effects, EVD could potentially be defined as a medical condition that is not “transitory.”

Assuming that the issue of transience is resolved, another issue is whether a person with EVD would be regarded as having an impairment or a substantially limiting disability, even though they may not actually have, or currently be suffering from, such an impairment. In its interpretation of this prong of the definitional test of a “disability,” the Equal Employment Opportunity Commission states that “this provision would protect a severely disfigured qualified individual from being denied employment because an employer feared the ‘negative reactions’ of others.”<sup>119</sup> The fearful and negative public reaction to the EVD outbreak in the United States may have devastating effects even to third parties who themselves were not infected with EVD but who simply had contact with infected (though asymptomatic) patients.<sup>120</sup> While important to consider, it is too early at this stage to predict the legal outcome if a patient who has been previously infected with EVD, survives, and then faces some sort of discriminatory action.<sup>121</sup>

### I. Crisis Standards of Care

Crisis standards of care (CSC) substantially alter how health care facilities operate and deliver care as necessitated by widespread or catastrophic disaster.<sup>122</sup> Operating under such standards shifts the focus

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<sup>117</sup> Kapay Kibadi et al., Late Ophthalmologic Manifestations in Survivors of the 1995 Ebola Virus Epidemic in Kikwit, Democratic Republic of the Congo, 179 J. INFECTIOUS DISEASES, Supp. 1, 1999, at S13, S13.

<sup>118</sup> Ryan, *supra* note 116.

<sup>119</sup> *The ADA*, *supra* note 113.

<sup>120</sup> See Erik Ortiz, *Ohio Bridal Shop Visited by Ebola Nurse Amber Vinson Is Closing Down*, (Jan. 9, 2015, 9:29 AM), <http://www.nbcnews.com/storyline/ebola-virus-outbreak/ohio-bridal-shop-visited-ebola-nurse-amber-vinson-closing-down-n282861>.

<sup>121</sup> See Schwartz, *supra* note 72, for a comprehensive analysis of a physician’s duty to treat in an epidemic, focusing in particular on SARS, HIV-AIDS, avian influenza, and Ebola.

<sup>122</sup> INST. OF MED. OF THE NAT’L ACADS., GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REP. 18 (Bruce M. Altevogt et al. eds., 2009), available at [http://www.nap.edu/openbook.php?record\\_id=12749&page=R1](http://www.nap.edu/openbook.php?record_id=12749&page=R1).

of care from the individual patient to the population.<sup>123</sup> Normally, providing care at such a level potentiates legal claims against health care providers, but a formal declaration at the state level offers legal powers and protections for those providers.<sup>124</sup> Caring for the few domestic EVD patients to date required efforts from hundreds of HCWs acting of their own volition and access to specialized isolation facilities and supplies.<sup>125</sup> Without an approved treatment for EVD, administration of readily available, routine medical treatments satisfies existing standards of care,<sup>126</sup> even though some patients recovered after receiving experimental treatments such as ZMapp and Brincidofovir.<sup>127</sup> In 2012, the Institute of Medicine described how scarcity of personnel, space, and medications when treating infectious diseases, like EVD, can necessitate shifts from conventional standards of care to CSC.<sup>128</sup> Presently, the United States has the capacity to concurrently treat only a small number of EVD patients in specialized isolation facilities.<sup>129</sup> A domestic EVD outbreak would likely spread resources thin, temporarily transforming

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<sup>123</sup> COMMITTEE ON GUIDANCE FOR ESTABLISHING STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS, INST. OF MED. OF THE NAT'L ACADS., CRISIS STANDARDS OF CARE: A SYSTEMS FRAMEWORK FOR CATASTROPHIC DISASTER RESPONSE 42 (2012), *available at* <http://www.phe.gov/coi/Documents/Committee%20on%20Guidance%20for%20Est%20SC%20for%20Use%20in%20Disaster%20Situations%20Atlanta%20Conf.pdf> [hereinafter JOINT PREPAREDNESS CONFERENCE 2012]; INST. OF MED., CRISIS STANDARDS OF CARE: A SYSTEMS FRAMEWORK FOR CATASTROPHIC DISASTER RESPONSE 33 (Dan Hanfling et al. eds., 2012), *available at* [http://www.nap.edu/openbook.php?record\\_id=13351](http://www.nap.edu/openbook.php?record_id=13351) [hereinafter Hanfling et al.] (While the focus under CSC becomes the needs of the population, the purpose of establishing these standards is to ensure that “the best possible care is given to individuals and the population as a whole”).

<sup>124</sup> JOINT PREPAREDNESS CONFERENCE 2012, *supra* note 123 (situational circumstances and a declaration from a state government indicating that CSC “will be in effect for a sustained period” offers health care providers additional legal protections in determining how to best allocate scarce resources.).

<sup>125</sup> James G. Hodge, Jr. et. al, *Law and the Public's Health: Law, Medicine, and Public Health Preparedness: The Case of Ebola*, 130 PUB. HEALTH REP. 167, 167-68 (2015).

<sup>126</sup> Makikio Kitamura, *U.S. Ebola Patient Brantly to Be Released From Hospital*, BLOOMBERG BUS. (Aug. 31, 2014, 3:39 AM), <http://www.bloomberg.com/news/articles/2014-08-21/u-s-ebola-patient-brantly-to-be-released-from-hospital> (Supportive care at specialized isolation facilities remains the standard treatment for EVD. This includes keeping the patient hydrated, replacing lost blood, and fighting opportunistic infections with antibiotics.).

<sup>127</sup> JAMES G. HODGE, JR., NETWORK PUB. HEALTH. L., EMERGENCY LEGAL PREPAREDNESS CONCERNING EBOLA: A PRIMER, (Dec. 1, 2014), *available at* [https://www.networkforphl.org/\\_asset/dzf8u4/Ebola-Outbreak-2014---Network-Overview.pdf](https://www.networkforphl.org/_asset/dzf8u4/Ebola-Outbreak-2014---Network-Overview.pdf).

<sup>128</sup> Hanfling et al., *supra* note 123.

<sup>129</sup> *See US Has Capacity for 11 Ebola Patients at Specialized Hospitals*, ABC NEWS (Oct. 16, 2014, 4:47 PM), <http://abcnews.go.com/Health/us-capacity-11-ebola-patients-specialized-hospitals/story?id=26251721>.

basic clinical standards of care.<sup>130</sup> With changes to medical CSC comes a corresponding shift in legal standards of care and the potential for decreased risks of liability related to triaging public health and medical services.<sup>131</sup>

### J. General Principles of Potential Negligence Claims

Liability risks pose ongoing concerns for HCWs and health care entities on the frontline of the EVD emergency responses as they attempt to navigate patient care.<sup>132</sup> Liability may arise from a health care provider's actions or even a failure to act. Medical malpractice and wrongful death claims may be brought if a physician fails to diagnose, or misdiagnoses, delays treatment, or uses unapproved treatments without first obtaining adequate consent.<sup>133</sup> For instance, the initial handling of the EVD case of Thomas Eric Duncan<sup>134</sup> in Dallas, Texas led to threats of litigation and a settlement after physicians failed to diagnose his EVD during his initial visit to the hospital emergency room.<sup>135</sup> Health care entities may also be at an increased liability risk for failing to have proper emergency procedures in place for, or adequately training employees to handle, infectious diseases like EVD.<sup>136</sup>

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<sup>130</sup> Hodge, Jr., et al, *supra* note 127, at 168.

<sup>131</sup> James G. Hodge, Jr., *The Evolution of Law in Biopreparedness*, 10 *BIOSECURITY & BIOTERRORISM* 38, 38–48 (2012); Hanfling et al., *supra* note 123 (legal standards of care are not required to change in conjunction with medical standards of care, but emergency planners should “consider whether additional liability protections are warranted in their jurisdictions”).

<sup>132</sup> Sharona Hoffman, *Responders' Responsibility: Liability and Immunity in Public Health Emergencies*, 96 *GEO. L. J.* 1913, 1918 (2008).

<sup>133</sup> Hodge Jr., et al, *supra* note 127, at 169.

<sup>134</sup> Greg Botelho, *U.S. Ebola Patient: The Travels and Health Travails of Thomas Eric Duncan*, CNN (Oct. 2, 2014, 9:29 PM), <http://www.cnn.com/2014/10/01/health/us-ebola-patient/> (Mr. Duncan was the first domestically diagnosed Ebola case. Texas Health Presbyterian Hospital Dallas, the hospital where he was eventually diagnosed and treated is not one of the four United States hospitals with specialized HCUs to isolate and treat patients with highly infectious and dangerous diseases).

<sup>135</sup> Justin Moyer, *Dallas Hospital Settles With Family of Ebola Patient Thomas Eric Duncan, Disputes Media Accounts of His Treatment*, WASH. POST (Nov. 13, 2014), <http://www.washingtonpost.com/news/morning-mix/wp/2014/11/13/dallas-hospital-settles-with-family-of-ebola-patient-thomas-eric-duncan-disputes-media-accounts-of-his-treatment/> (After an initial visit to the Dallas hospital, Duncan, who presented with a fever that spiked to 103 degrees Fahrenheit, was sent home with antibiotics despite CDC guidance to look for “for patients who had traveled to areas with “active” Ebola transmission and had temperatures above 101.5 degrees.”).

<sup>136</sup> Jeffery P. Clark et al., *Ebola Preparedness: Mission Critical for Hospitals and Health Systems*, REINHART (Oct. 21, 2014), available at [http://www.reinhartlaw.com/Documents/LE\\_20141021Revised-FINAL.pdf](http://www.reinhartlaw.com/Documents/LE_20141021Revised-FINAL.pdf).

Implementing CSC in a hospital setting requires difficult decisions centered on testing, screening, and treatment.<sup>137</sup> Using new or experimental drugs to treat patients further implicates liability risks. To obviate the potential for negligence claims, health care entities should ensure proper development, implementation, and testing of clinical protocols for diagnosing and treating infectious disease.<sup>138</sup> Providing hospital employees with proper access to PPE and adequate training ensures all protocols are followed safely.<sup>139</sup> As for patient treatment, health care providers should comply with appropriate standards of care, obtain proper patient consent, and seek FDA approval prior to administering any new or experimental treatment.<sup>140</sup> As discussed throughout, Emory's team was dedicated to careful and coordinated preparation, education of both its HCWs and other employees during the entire experience, constant refinement of clinical protocols,<sup>141</sup> and promotion of a culture that is characterized as "patient and family centered."<sup>142</sup>

Health care providers do not have a comprehensive liability protection. However, state and federal governments offer a bevy of specific immunities, high burdens of proof for civil malpractice claims,<sup>143</sup> and other protections<sup>144</sup> from acts of negligence by HCWs and

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<sup>137</sup> James G. Hodge, Jr., Gregory Measer & Asha M. Agrawal, "Top 10" Issues in Public Health Legal Preparedness and Ebola, ABA HEALTH ESOURCE, Nov. 2014, available at [http://www.americanbar.org/publications/aba\\_health\\_esource/2014-2015/november/top10.html](http://www.americanbar.org/publications/aba_health_esource/2014-2015/november/top10.html).

<sup>138</sup> Clark et al., *supra* note 136.

<sup>139</sup> *Id.*; *Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)*, CDC, <http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html> (last updated Feb. 12, 2015).

<sup>140</sup> Hodge, Jr. et al, *supra* note 127, at 169; Elaine Schattner, *Ebola, Experimental Drugs and Informed Consent: Should Those At Risk Simply Take What The Doctor Orders?*, FORBES (Aug. 31, 2014, 8:03 PM), <http://www.forbes.com/sites/elaineschattner/2014/08/31/ebola-experimental-drugs-and-informed-consent-should-those-at-risk-simply-take-what-the-doctor-orders/>.

<sup>141</sup> Lameiras, *supra* note 3, at 21, 23.

<sup>142</sup> EMORY HEALTHCARE, CARE OF THE PATIENT WITH EBOLA VIRUS DISEASE (2014), available at <http://www.emoryhealthcare.org/ebola-protocol/pdf/overview-of-ebola.pdf>.

<sup>143</sup> Jessica Dye, *Ebola Lawsuits Would Face High Hurdles in Texas*, REUTERS (Oct. 7, 2014, 7:02 AM), <http://www.reuters.com/article/2014/10/07/us-health-ebola-usa-liability-idUSKCN0HW0W920141007>. In Texas, a malpractice claim due to emergency room error requires plaintiffs show hospital staff were "willfully and wantonly negligent." *Id.* In Duncan's case, this would involve showing that "the staff had to have consciously put [the patient] or others at extreme risk by releasing him" instead of just showing a mistake was made. *Id.*

volunteers that supplement the hospital's planning and preparations for insulating itself against liability.<sup>145</sup> Other protections may shield against some negligence claims directed at hospitals or other select entities. For example, the Emergency Management Assistance Compact, agreed to by all states, insulates public agents at the state or local level against liability claims.<sup>146</sup> These protections apply typically only for a limited time, however, and may require emergency declarations to trigger their benefits.<sup>147</sup> Moreover, they do not apply to liability claims based on gross negligence, willful or criminal acts, or potential failures to plan.<sup>148</sup>

Concerning pharmaceutical companies, liability can arise in the manufacturing, testing, development, distribution, or administration of new drugs or vaccines, especially in real-time emergencies. However, these entities may be immunized from liability via the PREP Act.<sup>149</sup> DHHS Secretary Sylvia Burwell issued a PREP Act declaration on December 9, 2014, in support of the development of three different EVD vaccines to combat the EVD outbreak internationally and prevent a future domestic outbreak.<sup>150</sup>

### III. OPERATIONAL, CLINICAL, AND PRACTICAL ISSUES: EMORY'S EBOLA EXPERIENCE

#### A. *Hazardous Waste, Environmental Safety, and Transport and Disposal of Waste*

In preparing to receive Emory's first two EVD patients, Dr. Gartland did not anticipate the significance of the Hospital's proximity to CDC headquarters.<sup>151</sup> CDC assumed responsibility for the ultimate disposal of the enormous amounts of hazardous waste generated in caring for the

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<sup>144</sup> TRUST FOR AMERICA'S HEALTH (TFAH), TFAH LIABILITY PROTECTIONS RELEVANT STATUTES (2008), available at <http://healthyamericans.org/reports/bioterror08/pdf/legal-preparedness-law-review-of-state-statutes-and-codes.pdf>.

<sup>145</sup> Rosenbaum et al., *supra* note 17, at 238-41.

<sup>146</sup> Emergency Management Assistance Compact, Pub. L. No. 104-321, 110 Stat. 3877 (1996).

<sup>147</sup> HODGE, JR., *supra* note 24, at 244.

<sup>148</sup> See James G. Hodge, Jr. & Erin Fuse Brown, *Assessing Liability for Health Care Entities That Insufficiently Prepare for Catastrophic Emergencies*, 306 JAMA 308, 309 (2011).

<sup>149</sup> Public Readiness and Emergency Preparedness (PREP) Act, Pub. L. No. 109-148, 119 Stat. 2818 (2005) (codified in Public Health Service Act at 42 U.S.C. §§ 247d-6d, 247d-6e).

<sup>150</sup> Burwell, *supra* note 21.

<sup>151</sup> Emory University Hospital is on the same side of Clifton Road in Atlanta as CDC headquarters, separated only by a few academic buildings owned by Emory University.

EVD patients. Emory Hospital's close proximity "along" the street to CDC greatly facilitated compliance with U.S. Department of Transportation (DOT) Hazardous Materials Regulations<sup>152</sup> for transporting hazardous waste.<sup>153</sup> Because wastes from EVD patients are considered "hazardous material" under the DOT, they are subject to stringent procedures and regulations set forth by local, state, and federal agencies.<sup>154</sup> Such wastes must be appropriately incinerated, autoclaved, or otherwise inactivated to prevent further potential for infection. Strict compliance with regulations is mandatory, even for "off-site" commercial transport (including final transport for disposal).<sup>155</sup>

Due to EVD's clinical pathway, Emory's team prioritized waste disposal, but no one foresaw the need to properly dispose of nearly 40 bags of waste per day for the two patients.<sup>156</sup> Contracts were prepared with outside vendors and additional equipment was ordered and installed prior to the patients' arrivals since existing equipment at the Hospital was insufficient to address the initial disposal needs of the SCU and other units. As well, the Hospital arranged with CDC for the ultimate disposal of the waste.

In the future, responding hospitals must be prepared to quickly address similar challenges to best ensure the safety of the patients, HCWs, and other staff. While another epidemic or public health emergency caused by a different pathogen may not present the same waste disposal challenges as EVD, health providers should have access to an expert in these issues or on staff. Advance contracts with medical

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<sup>152</sup> 49 C.F.R. pts. 171-180 (2014).

<sup>153</sup> 40 C.F.R. § 260.10 (2014) (definition of "off-site" location for purposes of the hazardous waste regulations from the Department of Transportation); 40 C.F.R. § 262.20(f) (An EPA hazardous waste manifest is not required when transporting hazardous waste across the street or along a street, provided your organization owns property along the road on which you are transporting it. However, if the waste is a DOT hazardous material, a DOT bill of lading is required whenever you are transporting hazardous materials in commerce. In the event of a discharge, the hazardous waste generator is required to comply with the requirements for transporters at 40 C.F.R. § 263.30 (immediate action) and § 263.31 (discharge clean up)); *see also On-Site and Off-Site Transportation of Hazardous Waste [40 CFR 260.10]*, ENV'T'L RES. CTR. (May 16, 2007), <http://www.ercweb.com/resources/viewreg.aspx?id=6976>.

<sup>154</sup> 29 C.F.R. § 1910.1030 (2014) (bloodborne pathogens standard); *see, e.g.*, GA. COMP. R. & REGS. 391-3-4 (2005); GA. CODE ANN. §§12-8-20 (2004); *Fact Sheet: Safe Handling, Treatment, Transport and Disposal of Ebola-Contaminated Waste*, OCCUPATIONAL SAFETY & HEALTH ADMIN., [https://www.osha.gov/Publications/OSHA\\_FS-3766.pdf](https://www.osha.gov/Publications/OSHA_FS-3766.pdf). [hereinafter *OSHA Ebola Fact Sheet*].

<sup>155</sup> *OSHA Ebola Fact Sheet*, *supra* note 154.

<sup>156</sup> U.S. ARMY INST. OF PUBLIC HEALTH, STANDARD OPERATING PROCEDURE EBOLA VIRUS DISEASE WASTE MANAGEMENT IN THE MEDICAL TREATMENT FACILITY 13,18 (2014), *available at* <http://phc.amedd.army.mil/PHC%20Resource%20Library/EVDWasteManagementonMTFSOP.docx>.

waste vendors should be regularly reviewed to assure vendors are qualified to address pathogen-related waste disposal issues. Finally, developing relationships with local and state officials regarding waste disposal helps obviate misunderstandings and assures compliance with complex waste management regulations.

### *B. Supply Chain and Vendor Agreements*

For Emory and other hospitals facing an infectious disease emergency, supply chain issues and availability of equipment and supplies are critical. For EVD patients, having a sufficient supply of personal protective equipment (PPE) is essential to effective treatment. Emory's clinical protocols, noted below, required HCWs to don a new set of PPE every time they entered a patient's room,<sup>157</sup> resulting in large quantities of PPE being used daily. Hospitals must carefully review their vendor contracts and their capacity to ramp up deliveries for critical supplies without sudden price increases, substitutions, or special delivery fees. Resource alternatives should be prearranged in case the normal supply chain is interrupted or a vendor cannot meet demand. Inventoried supplies critical to EVD treatment (or any infectious disease during an emergency or epidemic) must be secured. In the event of a supply shortage, conservation and prioritization distribution plans should be developed.

### *C. Clinical Protocols*

Guidelines for the care and treatment of patients with EVD continue to evolve as the science surrounding the disease progresses. Hospitals and health systems must remain up to date on real-time developments. Relevant CDC guidelines,<sup>158</sup> for example, are comprehensive, accessible, and continually updated. Emory determined that "all of American health care needs some level of preparedness for Ebola and other types of communicable diseases . . ." <sup>159</sup> To this end, Emory developed its own clinical protocols, utilizing lessons learned from its own experience while incorporating guidelines issued by CDC and others "with the hope that [they] can help other health systems develop their own Ebola readiness plans."<sup>160</sup>

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<sup>157</sup> *Emory Protocols*, *supra* note 90.

<sup>158</sup> *CDC Guidelines*, *supra* note 90.

<sup>159</sup> *Emory Protocols*, *supra* note 90.

<sup>160</sup> *Id.*

*D. Emory's Care Transformation Model and Patient Centered Care*

To limit the number of individuals exposed to EVD at Emory, every HCW in direct contact with EVD patients was knowledgeable in how to handle patients' every need—from drawing blood and taking vital signs to administering medications and cleaning up bodily fluids. Safety precautions involved in donning and doffing of PPE entailed almost 70 total separate steps<sup>161</sup> and considerable time. As a result, Emory's care team determined that once a HCW entered a patient's room, the worker would be physically present for the entire shift without exiting the room.

This model of care demands a unique culture, one Emory began cultivating in 2007 when the current state of performance was assessed for safety, evidence-based decision-making, anticipation of needs, and teamwork among caregivers. Emory Hospital surveyed patient and family perceptions of their involvement in care decisions. As leaders and staff assessed the organizational culture and perception of care through directed focus groups, it became apparent that employees, patients, and families doubted the Hospital's ability to meet the quality promise to patients of "impeccable clinical outcomes, delivered safely with outstanding service."<sup>162</sup> This assessment necessitated a "culture transformation"<sup>163</sup> for Emory to meet its promise of quality care to patients centered on five essential attributes: (1) patient- and family-centered care, (2) shared decision making, (3) cultural competency and diversity, (4) fair and just culture, and (5) transparency (see Figure 1. Care Transformation Model below).

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<sup>161</sup> *Emory Protocols*, *supra* note 90 at Support Document 10: Standard Operating Procedures: SCU.

<sup>162</sup> *About Us*, EMORY HEALTHCARE, <http://www.emoryhealthcare.org/employment/about-us.html> (last visited Mar. 26, 2015).

<sup>163</sup> Interview by Jane E. Jordan with Susan M. Grant, Chief Nurse Exec. & Chief Patient Servs. Officer, Emory Healthcare (Feb. 1, 2015).

Figure 1. Care Transformation Model<sup>164</sup>

The new culture, focused on the interests of the patient and his or her family, supported the EVD care team in its goal to put aside any egos and work together. For example, none of Emory’s physicians refused to take blood or clean up bodily waste. As two nurses stated,

We had to be a family, we relied on each other to be safe . . . There were no egos—there couldn’t be . . . We all really worked and functioned as a team. It was truly collaborative, not just among the nurses, but the staff, the physicians, the lab . . . We all had a lot on our minds, more than just what was happening in the isolation unit, so we had to take care of each other.<sup>165</sup>

The Hospital also addressed emotional support for the care team. Chaplains were available at all times for team members. Daily “huddles” allowed members to share any mistakes witnessed and lessons learned during the day. While “soft” issues such as culture and emotional support

<sup>164</sup> *Id.* Patients and the “promise” of quality are seated on a platform of Patient- and Family-Centered Care, illustrating that patients are at the source of control. The attributes that staff and leadership identified that would transform the culture and care was placed on the platform: transparency, fair and just culture, cultural competence, shared decision-making and patient- and family-centered care. Teamwork ribbons link the attributes.

<sup>165</sup> Lamerias, *supra* note 3, at 25 (quoting Sharon Vanairsdale, Clinical Nurse Specialist, and Carolyn Hill, Nursing Unit Director for the SCDU).

are often downplayed in preparing for an epidemic or public emergency, Emory's success was tied to its appreciation of these issues.

#### *E. Team Preparedness and Drills*

Emory's treatment of four EVD patients to date has been grounded in excellent clinical care, adherence to the highest levels of safety, appreciation of relevant legal principles, and its dedicated care team. The Hospital's response was also positively impacted by twelve years of planning and practice, including biannual "preparedness" drills. In establishing its SDCU in 2002, Emory determined that it would also be prudent to establish an enterprise-wide program, known as the Office of Critical Event Preparedness and Response (CEPAR).<sup>166</sup> CEPAR is dedicated to assuring coordinated emergency responses to diseases, natural disasters, or other emerging threats. Still, any facility treating patients with a communicable disease must "expect the unexpected."<sup>167</sup> Preparedness requires comprehensive team readiness to address the non-clinical issues that invariably arise. While the specific composition of this larger team depends on the circumstances, essential non-clinical competencies would likely include:

- Public Relations/Communications/Crisis Management
- Hospital Operations
- Risk Management
- Security/Facilities Management/Transportation
- Environmental Safety
- Compliance/Privacy
- Legal
- Customer Service/Patient Relations/Pastoral Care
- Human Resources

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<sup>166</sup> CEPAR: *Office of Critical Event Preparedness and Response*, EMORY UNIV., [www.emergency.emory.edu](http://www.emergency.emory.edu) (last visited Mar. 26, 2015). "CEPAR serves as the center for Emory enterprise-wide planning for and coordinated response to catastrophic events affecting Emory and the broader community." *Id.*

<sup>167</sup> Alexander Isakov et al., *Safe Management of Patients with Serious Communicable Diseases: Recent Experience With Ebola Virus*, 161 ANNALS INTERNAL MEDICINE 829, 829–30; see also *Emory Protocols*, *supra* note 91, for a compilation of Emory's protocols and external resources used in the treatment of EVD patients.

These preparedness teams must be assembled *before* an emergency occurs to avoid wasting invaluable time. In Emory's case, clinical, legal, and administrative preparedness prior to the patients' arrivals was critical to its successful clinical outcome, as well as uniting these disparate operational units around a common goal.

*F. Public Relations, Communications, and Education*

Once the non-clinical team is in place and a situation presents, practical issues involving public relations and communications must be addressed both internally and for the external public. Messaging of events, especially those implicating "fear factors," is critical. Institutions must educate the public to try to dispel these fears and circumvent associated tendencies to panic or engage in irrational decisions. As Emory did, other institutions should consider:

- Agreeing in advance on consistent external messaging;
- Identifying a spokesperson with substantive knowledge who engenders trust of employees, patients, and the public;
- Educating the media on the facts surrounding patient treatment while protecting patient confidentiality;
- Demonstrating effective coordination with external community partners;
- Developing a communications strategy addressing issues on timing and notice to internal management and other leaders (e.g., governing board of trustees); and
- Disseminating information to employees on and off the care team effectively.

Although Emory's senior management was involved and supportive, the Hospital's most visible spokespersons were clinicians and care providers who made public appearances to educate the media about medical and scientific facts of EVD, including how it is (and is not) transmitted. The clear and simple message, "We can fear, or we can care," was intended to allay the public's anxiety.<sup>168</sup> Emory's governing

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<sup>168</sup> Susan M. Grant, Op-Ed., *I'm the Head Nurse at Emory. This is Why We Wanted to Bring the Ebola Patients to the U.S.*, WASH. POST (Aug. 6, 2014), <http://www.washingtonpost.com/local/healthcare/i-m-the-head-nurse-at-emory-this-is-why-we-wanted-to-bring-the-ebola-patients-to-the-u-s/2014/08/06/>

boards, employees, and staff knew about events before media publication, where possible, through town hall-style meetings, emails, and information sessions. Emory's website<sup>169</sup> was consistently updated after the arrival of the first two EVD patients, including public posting of its clinical protocols (utilizing protocols from CDC and others).<sup>170</sup>

#### IV. CONCLUSION

Domestic concerns over EVD have waned as most U.S. patients, largely HCWs infected while working in West African countries, have been successfully treated. Though limited in its duration, the EVD crisis in 2014 exposed the sad truth that many American hospitals and other health care providers may not be clinically, operationally, or practically prepared to handle the impact of a highly lethal, contagious disease despite years of preparedness funding and efforts to assure readiness. Lessons learned can be universally implemented to circumvent negative health impacts of future infectious disease threats. Every health provider must commit to developing an implementable preparedness plan, engaging in routine preparedness exercises and training, and remaining on guard for the next inevitable communicable to menace the health of patients and the public.

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washingtonpost.com/posteverything/wp/2014/08/06/im-the-head-nurse-at-emory-this-is-why-we-wanted-to-bring-the-ebola-patients-to-the-u-s/.

<sup>169</sup> *Ebola*, EMORY NEWS CTR., <http://news.emory.edu/tags/topic/ebola/index.html> (last updated Mar. 9, 2015).

<sup>170</sup> *Emory Protocols*, *supra* note 91.