

# **LEGAL WHITE PAPER**

## **ALTERED STANDARDS OF CARE FOR HEALTH CARE PROVIDERS IN THE PANDEMIC INFLUENZA**

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## I. INTRODUCTION

Pandemic influenza will pose tremendous challenges to health care providers, state public health authorities and the public. All will have to conduct business under the most adverse of circumstances. It will be difficult for providers to meet the customary legal standards of care imposed by state and federal regulatory authorities as well as the common law tort system.

In its report, *Altered Standards of Care and Pandemic Influenza Preparedness: Ethical Issues and Recommendations to the Indiana State Department of Health*, the Indiana University Center for Bioethics (IUCB) proposed two general recommendations regarding altered standards of care in pandemic influenza.<sup>1</sup> The recommendations on altered standards of care are presented in Figure 1. This white paper will explore the legal issues associated with altered standards of care in pandemic influenza.

**Figure 1**  
**IUCB Recommendations for Altered Standards of Care**  
**And Pandemic Influenza Preparedness**

1. The State of Indiana should develop a protocol for altered standards of care, which would take effect for all healthcare institutions upon the declaration of a statewide pandemic influenza emergency by the Governor. Triggers for this declaration should be identified prior to their occurrence. This protocol should specify those healthcare professionals affected by the protocol and should include legal protections for healthcare providers and institutions.
2. The State should begin immediately to engage owners/administrators of all healthcare facilities in discussions about the impact of a statewide protocol for altered standards of care, including the selection of alternate care sites. All efforts should be made to agree to these site acquisitions by consensus and partnership.

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<sup>1</sup> The Indiana University Center for Bioethics (IUCB) provided the Indiana State Department of Health (ISDH) with four Technical Assistance Documents (TAD) to assist the state in its preparation for an influenza pandemic. This report is one of the TADs.

## II. STANDARDS OF CARE

The concept of “standard of care” has several different meanings in different contexts. In medicine, public health and the other health professions, the standard of care refers to accepted standards acknowledged by the profession as defining acceptable and appropriate practice. Increasingly, standards of care are developed by professional organizations, accrediting bodies and government agencies in processes that vary greatly in their democratic characteristics. The standard development efforts are designed to clarify, establish and codify professional standards of care in an organized and accessible manner.<sup>2</sup>

The concept of “standard of care” also has distinct meanings in the law. The term refers to a legal standard that must be followed to avoid liability, sanctions or other legal consequences. Of note, the term, “liability,” is basically equivalent to “legal accountability” and, under civil law, generally involves the payment of compensation. Sanctions are imposed under regulatory law or criminal law. Criminal law also imposes a range of remedies and penalties for violations of various legal standards of conduct established in criminal statutes.

### A. The Standard of Care under Current Law

There are three primary sources of legal standards of care that will be most relevant during pandemic influenza, particularly during the time of the surge. These are: (1) tort standards pertaining to nonconsensual conduct that apply to all people; (2) regulatory standards for both health care facilities and health professionals; and (3) criminal standards that apply to all people. For purposes of this paper, we are not giving attention to applicable criminal standards of conduct although it should be noted that, following Hurricane Katrina, criminal prosecutions were brought against nursing home owners for negligent homicide in not moving their patients before the storm.<sup>3</sup>

#### 1. Tort Standard of Care

There are three predominant bases for liability in tort: (1) liability for intentional conduct; (2) liability for negligent conduct, and (3) strict liability pertaining to certain activities. In intentional conduct, the tortfeasor is intentionally liable if he or she acts

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<sup>2</sup> See Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J. L., MED. & ETHICS 323 (2002).

<sup>3</sup> Adam Nossitier, *Trial Starts for Owners of Nursing Home Hit by Storm*, N.Y. TIMES, Aug. 17, 2007, available at <http://www.nytimes.com/2007/08/17/us/nationalspecial/17nursing.html?partner=rssnyt&emc=rss> (visited Jun. 16, 2008); Adam Nossitier, *Nursing Home Owners Acquitted in Deaths*, N.Y. TIMES, Sept. 8, 2007, available at <http://www.nytimes.com/2007/09/08/us/nationalspecial/08nursing.html?fta=y> (visited Jun. 16, 2008).

with “the purpose of producing that consequence” or “knows to a substantial certainty that the consequence will ensue from the conduct.”<sup>4</sup>

Negligent conduct is a more complex concept and involves risk analysis with respect to one’s conduct vis-à-vis another person. *The Restatement (3rd) Torts* emphasizes a balancing of the risk of injury if precaution is not taken versus the utility of taking precautions that may cost large amounts of money. *The Restatement (3rd) Torts* states:

A person acts with negligence if the person does not exercise reasonable care under all the circumstances. Primary factors to consider in ascertaining whether the person's conduct lacks reasonable care are the foreseeable likelihood that it will result in harm, the foreseeable severity of the harm that may ensue, and the burden that would be borne by the person and others if the person takes precautions that eliminate or reduce the possibility of harm.<sup>5</sup>

The third basis of liability is strict liability which pertains to injuries from abnormally dangerous activities<sup>6</sup> and also from the manufacture and sale of defective consumer products.<sup>7</sup> The basic theory of strict liability is that the injured party need not prove fault on the part of the responsible party once causation is established.

## **2. Relevant State Medical Liability Laws**

Most states have enacted statutes to address tort liability of health care professionals.<sup>8</sup> The standard of care varies by jurisdiction.<sup>9</sup> In addition to setting the standard of care,

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<sup>4</sup> RESTATEMENT (3RD) TORTS, LIABILITY FOR PHYSICAL HARM (BASIC PRINCIPLES), TENTATIVE DRAFT No.1 § 1 (Mar. 28, 2001).

<sup>5</sup>*Id.* at § 3.

<sup>6</sup>*Id.* at § 24.

<sup>7</sup>*Id.* at § 1.

<sup>8</sup> See, e.g., ALA. CODE §§ 6-5-540 *et seq.* (2008), ALASKA STAT. §§ 09.55.530 *et seq.* (2008), ARIZ. REV. STAT. §§ 12-561 *et seq.* (2008), ARK. CODE §§ 16-114-201 *et seq.* (2008), COLO. REV. STAT. §§ 13-64-101 *et seq.* (2007), 18 DEL. LAWS §§ 6801 *et seq.* (2008), D.C. CODE ANN. §§ 16-2801 *et seq.* (2008), FLA. STAT. §§ 766.101 *et seq.* (2008), GA. CODE ANN. §§ 9-9-60 *et seq.* (2008), HAW. REV. STAT. §§ 671-1 *et seq.* (2008), IDAHO CODE §§ 6-1001 *et seq.* (2008), ILL. COMP. STAT. §§ 5/2-1701 (2008), IND. CODE §§ 34-18-1-1 *et seq.* (2008), IOWA CODE §§ 147.135 *et seq.* (2008), KAN. STAT. ANN. §§ 60-3501 *et seq.* (2006), KY. REV. STAT. ANN. §§ 304.40-250 *et seq.* (2008), LA. REV. STAT. ANN. §§ 40:1299.39 *et seq.* (2008), ME. REV. STAT. ANN. 24 §§ 2851 *et seq.* (2008), MD. CODE ANN. §§ 3-2A-01 *et seq.* (2008), MASS. GEN. LAWS ch. 231 §§ 60B *et seq.* (2008), MO. REV. STAT. §§ 538.205 *et seq.* (2008), MONT. CODE ANN. §§ 27-6-101 *et seq.* (2007), NEB. REV. STAT. §§ 44-2801 *et seq.* (2008), NEV. REV. STAT. §§ 41A.003 *et seq.* (2007), N.H. REV. STAT. ANN. §§ 507-C1 *et seq.* (2008), N.M. STAT. ANN. §§ 41-5-1 *et seq.* (2008), N.C. GEN. STAT. §§ 99-21.50 *et seq.* (2008), OHIO REV. STAT. §§ 2323.41 (2008), 40 PA. STAT. §§ 1303.501 *et seq.* (2007), S.C. CODE ANN. §§ 15-79-110 *et seq.* (2007), TENN. CODE ANN. §§ 29-26-1 *et seq.* (2008), TEX. CIV. PRAC. & REM. CODE §§ 74.001 *et seq.* (2007), UTAH CODE ANN. §§ 78-14-1 *et seq.* (2008), VA. CODE ANN. §§ 8.01-581.1 *et seq.* (2008), W. VA. CODE §§ 55-7B-1 *et seq.* (2008),

states have enacted statutes establishing pre-trial procedural requirements, damage caps, and other reforms in an effort to reform the adjudication of malpractice cases.<sup>10</sup> Indiana has had such a medical malpractice reform since 1975.<sup>11</sup>

A majority of states has adopted a “national” standard of care but a significant minority still adheres to the “locality rule,” which focuses on local custom to determine the appropriate level of care. The locality rule, developed over one hundred years ago, was intended to protect rural and small town physicians who were presumed to be less informed and well equipped than colleagues in large cities.<sup>12</sup> The standard of care enunciated under the strictest version of the locality rule measures the conduct of a physician against that of other physicians in the same field operating within the same community. Although most jurisdictions initially adopted the strict locality rule, many subsequently adopted a “modified locality rule” which is characterized as the degree of care, skill and proficiency commonly exercised by ordinarily careful, skillful and prudent physicians at the same time the treatment was provided and in similar localities.

States are moving toward a national standard of care which evaluates whether the physician has exercised the “care and skill expected of a reasonably competent physician in specialty in the same or similar circumstances.”<sup>13</sup> Most states adopting the national standard consider locality as one of several factors to be considered to determine whether a physician has acted reasonably under the circumstances.<sup>14</sup> Some states, however, apply a variation of the “locality rule,” or apply both standards of care depending on whether the physician is a specialist. The District of Columbia and 29 states have adopted the national standard of care and 21 states continue to maintain some version of the “locality rule.”<sup>15</sup>

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WIS. STAT. §§ 654.001 *et seq.* (2007). Michelle Huckaby Lewis, John K. Gohagan, and Daniel J. Merenstein, *The Locality Rule and the Physician’s Dilemma: Local Medical Practices vs the National Standard of Care*, 279 JAMA 2633 (2007).

<sup>9</sup>*Id.*

<sup>10</sup> State Medical Malpractice Tort Laws, National Conference of State Legislatures (2005) available at <http://www.ncsl.org/standcomm/sclaw/medmaltorttable205.htm> (visited June 6, 2008).

<sup>11</sup> IND. CODE §§ 34-18-1-1 *et seq.* (2008).

<sup>12</sup> See, e.g., Vergara v. Doan, 593 N.E.2d 185 (Ind. 1992); Hall v. Hibun, 466 So. 2d 856 (Miss. 1985) (both cases discuss history of locality rule and cite to applicable standards of care in various states at the time of publication).

<sup>13</sup> Sara Rosenbaum, *The Impact of United States Law on Medicine as a Profession*, 298 JAMA 1546 (2003) (quoting *Shilkret v. Annapolis Emergency Hospital Ass’n*, 349 A.2d 249, 249-50 (1975)).

<sup>14</sup> See Vergara, 593 N.E.2d at 187.

<sup>15</sup> Lewis et al., *supra* note 8.

Until 1992, Indiana followed the modified locality rule. That year, in *Vergara v. Doan*,<sup>16</sup> the Indiana Supreme Court established the following standard: "[A] physician must exercise that degree of care, skill and proficiency exercised by reasonably careful, skillful, and prudent practitioners in the same class to which he belongs, acting under the same or similar circumstances." In so doing, the Indiana Supreme Court adopted the national standard of care for Indiana.

### 3. Regulatory Standards of Care

The health care sector is one of the most regulated areas in the economy of the United States. A myriad of state and federal regulatory regimes govern both health care professionals and facilities to achieve a variety of regulatory objectives. These regulatory schemes involve both licensure and accreditation requirements.

Licensure and accreditation norms generally set regulatory standards for competence and, increasingly, quality of services. Licensure for both professionals and facilities tends to both define the characteristics of the profession or facility and establish criteria and standards for meeting these definitive characteristics. Accreditation is basically the same as licensure except that the survey and certification function is carried out by a private organization. Often, as is the case with hospitals, accreditation by a private accrediting body, i.e., the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), will be deemed to meet the conditions of state licensure and also the conditions of participation for third party payers.<sup>17</sup> The conditions required under licensure and accreditation may be one source to which a court looks as it determines whether or not a defendant has met the standard of care.

The federal Medicare program and joint federal-state Medicaid programs have an array of statutory and regulatory prescriptions governing health care providers to ensure that program beneficiaries receive high quality care for which payment is made.<sup>18</sup> These standards are similar to licensure and accreditation standards in terms of the conduct they require on the part of providers. Given the experience in Hurricane Katrina, the Centers for Medicare and Medicaid Services (CMS), the agency within the Department of Health and Human Services (DHHS) which administers the Medicare, Medicaid, and SCHIP programs, waived many of these standards because of the extraordinary difficulties compliance would have imposed on providers.<sup>19</sup>

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<sup>16</sup> Vergara, 593 N.E.2d at 185.

<sup>17</sup> See Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?* 57 L & CONTEMP.PROBS. 47, 50-57 (1994).

<sup>18</sup> See Eleanor D. Kinney, *The Medicare, Medicaid and SCHIP Programs Meet the Challenges of Public Health Emergencies* 58 ADMIN. L. REV. 559 (2006).

<sup>19</sup> Kaiser Comm'n on Medicaid and the Uninsured, *A Comparison of the Seventeen Approved Katrina Waivers* (2006), available at <http://www.kff.org/medicaid/upload/7420.pdf> (visited Apr. 14, 2006). See also Priscilla D. Keith, *Access to Care Issues Consumers Continue to Face as a Result of Katrina*, 2 ABA

Specifically, CMS waived liability for hospital emergency rooms under the Emergency Medical Treatment and Labor Act (EMTALA)<sup>20</sup> for transferring patients to other facilities for assessment if the original facility was located in an area where a public health emergency had been declared. CMS also waived certain Health Insurance Portability and Accountability Act (HIPAA) privacy requirements<sup>21</sup> so that providers could talk to family members about a patient's condition when patients were unable to grant that permission to the provider.

## **B. Professional Development of the Content of the Standard of Care**

It is important to appreciate that the ultimate source of legal standards of care, particularly with respect to tort liability, are professional norms.<sup>22</sup> Since the 1980s, the medical profession and its medical specialties have engaged in the development of more formal standards of care in all areas of medical practice.<sup>23</sup>

Further, the current standard of care in tort accommodates the fact that there may be legitimate variations in the conditions under which services are delivered with language such as “in like or similar circumstances.”<sup>24</sup> Certainly a state agency, with its authority to promulgate public health regulations, could establish standards of care by regulation if that agency’s enabling legislation authorizes standard setting activities.<sup>25</sup>

Thus, it is appropriate to rely on the flexibility of current standards to develop protocols in conjunction with stakeholders. To the extent that they have been developed in a fairly transparent and democratic process, model protocols will be authoritative in establishing the appropriate standard of care. Indeed, governmental agencies have often adopted privately set standards in their regulatory programs.<sup>26</sup>

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Health eSource (Dec. 2005), available at <http://www.abanet.org/health/esource/vol2no4/> (visited Jun. 16, 2008).

<sup>20</sup> 42 U.S.C. § 1395dd(d)(1).

<sup>21</sup> *Id.* at §§ 1320d-1329d-8; Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002).

<sup>22</sup> See Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, *supra* note 2.

<sup>23</sup> See *id.*

<sup>24</sup> See note 16 *supra* and accompanying text.

<sup>25</sup> See Eleanor D. Kinney, *Administrative Law Approaches to Medical Malpractice Reform*, 49 ST. LOUIS U. L. J. 45 (2005).

<sup>26</sup> See Eleanor D. Kinney, *Behind the Veil Where the Action Is: Private Policy Making and American Health Care*, 50 ADMIN. L. REV. 145 (1999).

### III. STATE AUTHORITY AND ALTERED STANDARDS OF CARE

The major sources of law that govern state public health matters are statutes according states the authority to protect and promote public health within the state. Most states also have specific statutes that authorize the governor of the state to declare an emergency and assume extraordinary powers to address the emergency. These statutes often immunize emergency and public health workers from liability for negligent conduct during the emergency.

In 2006, Indiana revised its laws regarding public health and other emergencies to provide the governor with emergency powers, including rulemaking powers, and to waive liability for negligent conduct in certain instances.<sup>27</sup> Under Indiana law, the governor has the power to declare a state of emergency, which triggers authorizations to engage in many emergency response activities.<sup>28</sup>

Two model acts are widely circulated and worthy of note. The first, the Model State Emergency Health Powers Act developed by the Center for Law and the Public's Health at Georgetown University School of Law and the Johns Hopkins School of Public Health in collaboration with the Centers for Disease Control and Prevention (CDC)<sup>29</sup> has been somewhat controversial politically.<sup>30</sup> The second is the Turning Point Model State Public Health Act,<sup>31</sup> developed by a collaborative group of public health policy makers and academics funded by the CDC and The Robert Wood Johnson Foundation.

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<sup>27</sup> 2008 IND. ACTS 138.

<sup>28</sup> IND. CODE § IC 10-14-3-12.

<sup>29</sup> The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, *Model State Emergency Health Powers Act* (2001) available at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> (visited Mar. 22, 2008). See Lawrence O. Gostin, et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 JAMA 622 (2002).

<sup>30</sup> See Sue Blevins, *The Model State Emergency Health Powers Act: An Assault on Civil Liberties in the Name of Homeland Security* (Jun. 10, 2002), available at <http://www.heritage.org/Research/HomelandSecurity/HL748.cfm> (A critique from the conservative Heritage Foundation); George J. Annas, *Bioterrorism and Public Health Law* (letter), 288 JAMA 2685 (2002); George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 NEW. ENG. J. MED. 1337 (2002). See also National Conference of State Legislatures, *The Model State Emergency Health Powers Act: A Checklist of Issues* (June 2002), available at <http://www.ncsl.org/programs/health/modelact.pdf> (visited Jun. 18, 2008).

<sup>31</sup> Lawrence O. Gostin and James G. Hodge, Jr., *Turning Point Collaborating for a New Century in Public Health: Model State Public Health Act, A Tool for Assessing Public Health Laws* (Public Health Modernization National Excellence Collaborative 2002), available at [http://www.turningpointprogram.org/Pages/pdfs/statute\\_mod/MSPHAfinal.pdf](http://www.turningpointprogram.org/Pages/pdfs/statute_mod/MSPHAfinal.pdf) (visited Jun. 16, 2008). See Benjamin Mason Meier, James G. Hodge, Jr. and Kristine M. Gebbie, *Contrasting Experiences of State Public Health Law Reform Pursuant to the Turning Point Model State Public Health Act*, 122 PUBLIC HEALTH REPORTS 559 (2007); James G. Hodge, Jr., Lawrence O. Gostin, Kristine Gebbie, and Deborah L.

## A. Setting the Altered Standard of Care for a Public Health Emergency

As states do not currently set the standard of care for medical treatment but rely on professional organizations and individuals to do so, states do not need statutory authority to “alter” the standard of care. Under current law, states can convene relevant stakeholders to discuss and develop an altered standard of care pursuant to the conventional processes for developing standards described above.<sup>32</sup>

Under a state’s authority to act in public health emergencies and to issue rules and orders to proceed in such emergencies, the state could issue an order recognizing that the previously developed protocol will be the altered standard of care in the public health emergency. Ostensibly, the governor could declare a previously developed protocol as the altered standard of care in the emergency at hand, although the governor need not take this step to assure that the protocols be authoritative. Nevertheless, such a rule - or even a declaration - would be useful in litigating cases and establishing the standard of care to be used in the situation. The Indiana Code gives the governor the power to issue rules and orders in the event of a public health emergency.<sup>33</sup> Similarly, the Turning Point Model Public Health Act accords such authority as well.<sup>34</sup>

The most effective way to confer authority on a protocol establishing altered standards of care in subsequent litigation is to develop the protocol before the emergency using the ideal process described above. Such a process would involve convening the major stakeholders from around the state to develop the protocol in a transparent and democratic process involving broad consultation with interested parties and the public.

Also, the protocols would gain authority if they reflected consideration of other authoritative sources. The Agency for Healthcare Quality and Research has developed a useful guide for developing protocols for an altered standard of care.<sup>35</sup> The American Health Lawyers Association has also developed a tool to assist states in legal preparation

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Erickson, *Transforming Public Health Law: The Turning Point Model State Public Health Act*, 33 J. L., MED. & ETHICS 77 (2006).

<sup>32</sup> See notes 22-26 *supra* and accompanying text.

<sup>33</sup> IND. CODE § 10-14-3-22 (2008).

<sup>34</sup> Turning Point Public Health Act § 6-102(d)(1) (2002), *supra* note 29. The Model State Public Health Emergency Powers Act contains a comparable provision. The Model State Public Health Emergency Powers Act § 403(a)(1) (2001), *supra* note 29.

<sup>35</sup> Agency for Healthcare Research and Quality, *Altered Standards of Care in Mass Casualty Events*, (Apr. 2007), available at <http://www.ahrq.gov/research/altstand/altstand.pdf> (visited Jun. 17, 2008). See also Agency for Healthcare Research and Quality, *Providing Mass Medical Care with Scarce Resources: A Community Planning Guide* (Feb. 2007), available at <http://www.ahrq.gov/research/mce/> (visited Jun. 18, 2008).

for a public health emergency that specifically identifies key issues involved with developing protocols for altered standards of care.<sup>36</sup>

## **B. Modifying Liability Rules for Conduct during a Public Health Emergency**

State statutes that accord immunities from civil liability for health care providers and workers in emergency situations can greatly facilitate the implementation of altered standards of care. While such statutes are not necessary, they clarify that health care providers will not be civilly liable for negligence in a declared public health emergency. Such statutory provisions are important to provide legal “cover” in the event that stakeholders develop protocols for altered standards of care that depart from the standard of care for negligence in the usual business environment.

Once an emergency has been declared, Indiana law deems all emergency care workers , who are working in a governmental function to be not liable in tort for their actions, except where there is willful misconduct, gross negligence, or bad faith.<sup>37</sup> The Indiana Code provides specific immunity for both health care workers and facilities as long as they refrain from willful misconduct and gross negligence.<sup>38</sup>

Under Indiana law, health care workers are also accorded immunity from liability for negligence in public health emergencies if they are licensed health care professionals operating under circumstances of a declared disaster.<sup>39</sup> However, such health care workers are not immune from civil liability if damages result from gross negligence or willful misconduct.<sup>40</sup> Facilities are also accorded immunity from “civil liability” in times of declared public health emergencies.<sup>41</sup> Similarly, the Turning Point Model Public Health Act contains similar provisions regarding tort liability of health care providers and workers.<sup>42</sup>

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<sup>36</sup> Am. Health Lawyers Ass’n, *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers* (2008), available at [http://www.healthlawyers.org/Content/NavigationMenu/Public\\_Interest\\_and\\_Affairs/Public\\_Information\\_Series/Pan-Flu08.pdf](http://www.healthlawyers.org/Content/NavigationMenu/Public_Interest_and_Affairs/Public_Information_Series/Pan-Flu08.pdf) (visited Aug. 5, 2008).

<sup>37</sup> IND. CODE § 10-14-3-15 (2008).

<sup>38</sup> *Id.* at § 34-30-13.5.

<sup>39</sup> *Id.* at § 34-30-13.5-1.

<sup>40</sup> *Id.* at § 34-30-13.5-2.

<sup>41</sup> *Id.* at § 34-30-13.5-3.

<sup>42</sup> Turning Point Public Health Act § 6-105(b) (2002), *supra* note 29. The Model State Public Health Emergency Powers Act contains a comparable provision. The Model State Public Health Emergency Powers Act § 804 (b) (2001), *supra* note 29.

## IV. CHALLENGES

The challenges for the state, providers and the public will be legion during a pandemic, particularly during the pandemic's surge. The surge is the point in an epidemic when the most people are infected and the demand for medical resources and services will be the greatest. DHHS has developed computer programs that states and providers can use to estimate the demand for services and resources during the surge.<sup>43</sup> Also, hospitals customarily estimate what their surge capacity is for any public health emergency.<sup>44</sup>

Hospitals, nursing homes, home health-care services, and other health care institutions are ill-prepared for a surge at any level much less in the numbers expected in the event of pandemic influenza. Although many hospitals could operate at 125 percent capacity or more, for up to 72 hours, most cannot maintain this level of service beyond 3 days.<sup>45</sup>

An important issue is whether alternative sites, such as hotels, schools, offices and churches, will be used for the delivery of care during the surge and at other times.<sup>46</sup> Such unorthodox facilities probably could not provide services at the customary standard of care.

### A. Triage Methodologies

Triage in a public health emergency is the process by which first responders will sort victims so that the most serious cases are treated before those with conditions not likely to deteriorate rapidly. This decision-making process will inevitably implicate legal doctrines pertaining to the standard of care.<sup>47</sup> In the United States, health care and health law have traditionally focused on the individual patient. Generally, a physician owes a duty to provide the best care to and seek the best outcome for each patient regardless of who is in the waiting room. Failure to provide such care may subject the practitioner to malpractice liability, professional penalties, and/or, in the most egregious cases, criminal sanctions. However, in the event of pandemic influenza and a huge number of ill patients, physicians will necessarily focus on maximizing population outcomes rather

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<sup>43</sup> CDC, *Pandemic Influenza Resources, Flu Surge 2.0*, available at <http://www.cdc.gov/flu/tools/flusurge/> (visited Jun. 17, 2008).

<sup>44</sup> See J. Lee Jenkins, Robert E. O'Connor and David C. Cone, *Medicine Differentiating Large-scale Surge versus Daily Surge*, 13 ACAD. EMERG. MED. 1169 (2006).

<sup>45</sup> Agency for Healthcare Research and Quality, *Reopening Shuttered Hospitals to Expand Surge Capacity*, app. at D-47 (2006).

<sup>46</sup> *Id.*

<sup>47</sup> James G. Hodge, Jr., *Legal Triage during Public Health Emergencies and Disasters*, 58 ADMIN. L. REV. 627 (2006).

than improving the health of individuals.<sup>48</sup> The medical community will shift to a “public health” orientation which focuses on ensuring the health and safety of the population as a whole.<sup>49</sup> Significantly, the goal of providing optimal care to the population may require compromising best practices or providing less than optimal care to individual patients. This approach, ethically intolerable or legally suspect under “normal” conditions, may be necessary and appropriate under disaster scenarios.<sup>50</sup> Consequently, pre-pandemic development of protocols for appropriate triage processes is essential. Protocols must address issues such as who gets access to limited resources like ventilators versus less intensive or palliative care.

Yet a 2006 literature review by a Canadian team of researchers found no current triage protocols for critical care in an influenza pandemic.<sup>51</sup> The Canadian team and others have since proposed triage protocols that differ in many respects but offer policymakers a starting point for pre-pandemic planning.<sup>52</sup> The proposals outline inclusion and exclusion criteria and identify the levels of treatment that are appropriate based thereon. Most focus on symptoms and avoid subjective criteria like age and lifestyle. These tools will assist first responders in making difficult decisions that allow for the optimal allocation of limited resources.

Experts agree that successful implementation of a triage methodology requires public discussion prior to the onset of a public health emergency.<sup>53</sup> A public that is aware of and has the opportunity to participate in a forum addressing these very difficult issues will be less likely to view the decisions as unfair or motivated by suspected partiality. Although frightening to many people, the responsible path is to reach a consensus on triage well before the state is confronted with a public health disaster.

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<sup>48</sup> Kristi I. Koenig, et al., *Surging to the Right Standard of Care*, 13 ACAD. EMERG. MED. 195 (2007).

<sup>49</sup> Elizabeth Weeks, *Lessons from Katrina: Response, Recovery and the Public Health Infrastructure*, 10 DEPAUL J. HEALTH CARE L. 251, 257 (2007).

<sup>50</sup> *Id.* at 284; *See also.*, Hillary R. Ahle, *Symposium: Sharing a New Direction in Law and Medicine: An International Debate on Culture, Disaster, Biotechnology and Public Health: Anticipating Pandemic Avian Influenza: Why the Federal and State Preparedness Plans are for the Birds*, 10 DEPAUL J. HEALTH CARE LAW 213, 248-249 (2007).

<sup>51</sup> Michael D. Christian, et al., *Development of a Triage Protocol for Critical Care during an Influenza Pandemic*, 175 CMAJ 1377 (2006).

<sup>52</sup> *Id.* *See* Tia Powell, et al., *Allocation of Ventilators in a Public Health Disaster*, 2 DISASTER MED. AND PUB. HEALTH PREPAREDNESS 20 (2008); Daniel Talmor, et al., *Simple Triage Scoring System Predicting Death and the Need for Critical Care Resources During Epidemics*, 35 CRIT. CARE MED. 1251 (2007); Kristy Challen, et al., *Physiological-Social Score (PMEWS) vs. CURB-65 to Triage Pandemic Influenza: A Comparative Evaluation Study Using Community-Acquired Pneumonia as a Proxy*, 7 BMC HEALTH SERVS. RESEARCH 33 (2007). *See also.*, John L. Hick and Daniel O’Laughlin, *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*, 13 ACAD. EMER. MED. 223 (2006).

<sup>53</sup> *See* Ahle, *supra* note 50, at 248-249.

In addition to potential tort liability, standards of care are established in criminal law and anti-discrimination law. Specifically, criminal statutes, and also the common law torts of reckless and intentional conduct, will apply in cases in which decisions about access to life-saving treatment is withheld.

Of note, if people perceive that additional criteria such as social utility of individuals have been used in triage decisions, health care providers may be liable for discrimination under federal and state civil rights laws. Federal and state civil rights laws prohibit discrimination in public accommodations and access to government programs on the basis of race, religion, gender, and national origin.<sup>54</sup>

## **B. Standard of Care for the Distribution of Vaccines and Antivirals**

As with any other health care service, the decision to allocate vaccines and antiviral medications are governed by tort and regulatory standards of care. Thus, attention should be given to what are the appropriate protocols for the distribution of these products during pandemic influenza as part of the broader inquiry on altered standards of care.

As a legal matter, the federal government has the nearly exclusive authority to regulate drugs, biologics and medical devices and does so through the Food, Drug and Cosmetic Act (FDCA).<sup>55</sup> In national planning for pandemic influenza, the federal government, through its various emergency planning documents, has recognized a predominant federal role for the distribution of vaccines and biologics.<sup>56</sup>

Further, federal law also addresses tort liability for injuries associated with pharmaceutical products, including vaccines, and medical devices.<sup>57</sup> Also, in recent years, there have been several cases before the United States Supreme Court involving whether federal regulatory law on labeling preempts state tort liability based on a failure to adequately warn of dangers associated with the product.<sup>58</sup> In 2006, the FDA asserted in drug labeling regulation, that the FDCA preempted state tort law when it came to

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<sup>54</sup> See 42 U.S.C. § 2000a(a) (1999) (federal civil rights authorities); 15 AM.JUR.2D, Civil Rights § § 223-231 (2000) (state civil rights authorities).

<sup>55</sup> 21 U.S.C. §§ 501-573.

<sup>56</sup> See U.S. Dep't Health & Human Services, *HHS Pandemic Influenza Implementation Plan* (Nov. 2006), available at <http://www.hhs.gov/pandemicflu/implementationplan/> (visited Jun. 18, 2008). See also PandemicFlu.Gov, *Federal Planning & Response Activities*, available at <http://www.pandemicflu.gov/plan/federal/index.html#implementation> (visited Jun. 18, 2008).

<sup>57</sup> See Joseph Nicosia III, Note, *Avian Flu: The Consumer Costs of Preparing for Global Pandemic*, 18 LOY. CONSUMER L. REV. 479, 494 (2006).

<sup>58</sup> See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); *Warner-Lambert v. Kent*, 128 S.Ct. 1168, 170 L.Ed.2d 51 *aff'd per curiam*; *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006); *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008); *Levine v. Wyeth* (Vt., 2006), cert. granted, 128 S.Ct. 1118 (2008); *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3rd Cir. 2008).

product labeling.<sup>59</sup> Of note, the Turning Point Model State Public Health Act would immunize administrators of vaccines from civil and criminal liability in a public health emergency.<sup>60</sup>

### **C. Workforce Management and Altered Standards of Care**

Rampant absenteeism among health professionals during pandemic influenza could result in under-staffing to such an extent that ordinary legal standards of medical care will not be met. As an altered standard of care is developed, the issue of absenteeism should be addressed. In addition, a discussion of the appropriate use of volunteer health professionals during pandemic influenza and the creation of standards may help ensure a legal environment that will not discourage their much-needed assistance.

#### **1. Absenteeism of Employed Health Care Workers**

The federal government has estimated that pandemic influenza could affect 40 percent of the total workforce at its peak, and that the rate of absenteeism at that time may well be immobilizing.<sup>61</sup> Potential reasons for employee absenteeism during pandemic influenza include illness or death, mandatory or voluntary isolation or quarantine, necessary care of children when schools have been closed, an inability to get to work due to halted public transportation, obligations to care for a sick family member, or a fear of either contracting or spreading influenza at the workplace.<sup>62</sup>

In a national 2006 survey of the U.S. population conducted by the Harvard School of Public Health, 57 percent of Americans said they would cooperate with public health officials if instructed to stay home from work, and 35 percent said they would not.<sup>63</sup> Also this survey reported that 22 percent of employed adults expressed concern that their employer would require them to work even if they were sick.<sup>64</sup> More recently, in 2002, a national survey of physicians found that only 55 percent of respondents believed that they had an obligation to care for patients in an epidemic during which their own health

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<sup>59</sup> Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922(Jan. 24, 2006) (21 CFR Parts 201, 314, and 601).

<sup>60</sup>Turning Point Model State Public Health Act § 6-105, *supra* note 31.

<sup>61</sup> U.S. Department of Labor Occupational Safety and Health Administration, *Guidance on Preparing Workplaces for an Influenza Pandemic*, available at [http://www.osha.gov/Publications/influenza\\_pandemic.html](http://www.osha.gov/Publications/influenza_pandemic.html) (visited Mar. 29, 2008).

<sup>62</sup> *Id.*

<sup>63</sup> Harvard School of Public Health, *In the Case of an Outbreak of Pandemic Flu: Large Majority of Americans Willing to Make Major Changes in Their Lives*, available at <http://www.hsph.harvard.edu/news/press-releases/2006-releases/press10262006.html> (visited April 12, 2008).

<sup>64</sup> *Id.*

might be endangered.<sup>65</sup> Such fears of health professionals are not unfounded. In the 2003 SARS epidemic, health professionals were disproportionately infected with SARS in Vietnam, Hong Kong and Canada.<sup>66</sup>

Many strategies have been proposed and/or implemented in response to this threat of health professional absenteeism. The American Medical Association (AMA) has adopted several new policies focusing on physician responsibilities during such emergency situations. One AMA policy, adopted in June 2004, states that “physicians have an obligation to provide urgent medical care during disasters . . . even in the face of greater than usual risks to their own safety, health or life.”<sup>67</sup> This responsibility is limited, however, by the recognition that “the physician workforce . . . is not an unlimited resource . . . [and] physicians should balance immediate benefits to individual patients with ability to care for patients in the future.”<sup>68</sup>

In Maryland, for example, health professionals are required to report to work during medical emergencies or risk imprisonment.<sup>69</sup> The Model State Emergency Health Powers Act authorizes licensure revocation by requiring that health professionals provide care during a public health emergency “as a condition of licensure, authorization, or the ability to continue to function as a health care provider.”<sup>70</sup> Another approach is to offer incentives discouraging absenteeism. In Vietnam and Canada, for example, health care workers received additional pay for caring for SARS patients.<sup>71</sup>

Absent legislative or regulatory action at the federal and state level, there is a huge body of law regulating employment relationships that will apply in the event of pandemic influenza, just as it applies at any time. This body of law pertains to worker protections, wage and hour policies, workers compensation and other matters that address the

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<sup>65</sup> G. Caleb Alexander and Matthew K. Wynia, *Ready and Willing? Physicians’ Sense of Preparedness for Bioterrorism*, 22 HEALTH AFF. 189, 195 (2003). See also Ariel R. Swartz, *Doubtful Duty: Physicians’ Legal Duty to Treat During An Epidemic*, 60 STAN. L. REV. 657 (2007).

<sup>66</sup> Mark A. Rothstein, *Are Traditional Public Health Strategies Consistent with Contemporary American Values?* 77 TEMP. L. REV. 1775, 185-186 (2004).

<sup>67</sup> American Medical Association, *Policy E-9.067: Physician Obligation in Disaster Preparedness and Response*, [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/E-9.067.HTM](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-9.067.HTM) (visited Jun. 17, 2008).

<sup>68</sup> *Id.*

<sup>69</sup> University of Maryland Center for Health and Homeland Security, *Maryland Public Health Emergency Preparedness Legal Handbook* (2005), available at <http://www.umaryland.edu/healthsecurity/dos/Handbook%209-9-05.pdf>. (visited Jun. 18, 2008).

<sup>70</sup> The Model State Emergency Public Health Powers Act § 608(a) (2001), *supra* note 29.

<sup>71</sup> *Id.* at 186.

employment relationship. Many of the problems of absenteeism may be addressed by these laws.

## 2. Use of Volunteer Healthcare Professionals

There are three important legal issues with the use of volunteer professionals: provider liability for volunteer conduct in the delivery of services; provider liability for injury to volunteer professionals; and the portability of out-of-state volunteer professional licenses. These issues are analyzed extensively in an article by Professor James G. Hodge and colleagues.<sup>72</sup>

Following the terrorist attacks of September 11, 2001, Congress authorized the DHHS to fund the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP); under this system, 37 jurisdictions currently have operational advance registration systems and the remaining jurisdictions have plans to become fully operational in the future.<sup>73</sup>

Although ESAR-VHP may allow for the rapid identification of qualified volunteers, licensure requirements will still have to be relaxed in order for volunteers to practice. Most states and territories have agreed to provide for reciprocity of licensure between jurisdictions for healthcare professionals. In addition, the Emergency Management Assistance Compact (EMAC), developed by the National Emergency Management Association, allows for reciprocity between member jurisdictions regarding the credentialing of volunteers for the duration of an emergency.<sup>74</sup> The Turning Point Model State Public Health Act also has extensive provisions regarding the licensure and appointment of health care personnel during a public health emergency.<sup>75</sup>

Indiana law specifically allows for volunteer workers from other jurisdictions to practice and authorizes the use of the Indiana Worker's Compensation program in the event of volunteer injury.<sup>76</sup> In addition, the Indiana Code allows for mutual aid agreements, both among counties and between states.<sup>77</sup>

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<sup>72</sup> James G. Hodge, Jr., at al., *Volunteer Health Professionals and Emergencies: Assessing and Transforming the Legal Environment*, 3 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE & SCIENCE 216 (2005).

<sup>73</sup> The Department of Health and Human Services, *Office of the Assistant Secretary for Preparedness and Response: FY 2009 Online Performance Appendix*, available at <http://www.hhs.gov/budget/09budget/asprfy09opa.pdf> (visited Jun. 18, 2008).

<sup>74</sup> National Emergency Management Association, Proposed Model Intrastate Mutual Aid Legislation (2004), <http://emacweb.org/docs/NEMA%20Proposed%20Intrastate%Model-Final.pdf>.

<sup>75</sup> Turning Point Model State Public Health Act § 6-104 (d), *supra* note 31.

<sup>76</sup> IND. CODE § 10-14-3-15 (2008).

<sup>77</sup> *Id.* at § 10-14-3-16.

## V. IUCB RECOMMENDATIONS ON ALTERED STANDARDS OF CARE

**Recommendation 1: The State of Indiana should develop a protocol for altered standards of care, which would take effect for all healthcare institutions upon the declaration of a statewide pandemic influenza emergency by the Governor. Triggers for this declaration should be identified prior to their occurrence. This protocol should specify those healthcare professionals affected by the protocol and should include legal protections for healthcare providers and institutions.<sup>78</sup>**

An important issue regarding the recommended protocol is its legal authority. A statutory enactment will assure legal authority and impact. Also, if there is requisite statutory authority to promulgate regulations, a state agency could conceivably promulgate a regulation pursuant to its statutory authority to issue licenses that would modify the standard of care under specified conditions.

Also, since professional standard setting is essentially determined by external professional norms, and accounts for permissible variations in the circumstances in which professional services are delivered, protocols developed by professionals with state support and in a transparent, inclusive and democratic process will be quite authoritative as the standard of care in civil litigation.

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<sup>78</sup> The relevant IUCB report provided:

“It is necessary for any decisions about altering the standards of providing healthcare to patients in Indiana to be statewide and uniform. As a part of this protocol, it is critical for the State to identify relevant laws and regulations that may need to be altered or suspended during an emergency in order to provide legal protections to healthcare institutions, providers, staff, and volunteers. Doing so may increase healthcare workers’ and healthcare institutions’ compliance with the recommended alterations by removing the fear of litigation that may result from following altered standards of care. It also may help to ensure that these altered standards are implemented consistently statewide.

Expert panel members expressed concern about the extent to which the State would be able to provide protection. Members emphasized the need to clarify how such protections would be implemented, as fear of litigation would be a major concern for healthcare providers and undoubtedly would influence their adherence to altered standards protocol. For further discussion on this topic, please refer to the document regarding legal issues during an influenza pandemic that was produced by individuals from the Indiana University School of Law-Indianapolis.”

**Recommendation 2: The State should begin immediately to engage owners/administrators of all healthcare facilities in discussions about the impact of a statewide protocol for altered standards of care, including the selection of alternate care sites. All efforts should be made to agree to these site acquisitions by consensus and partnership.<sup>79</sup>**

Engaging stakeholders in the protocol development process is essential to enhancing the credibility of protocols with courts. In addition, attention should be paid to the process by which protocols are developed. Specifically, they should be developed in a transparent and democratic process that includes all relevant stakeholders including consumers.

In preparing this protocol, the State should initiate listening tours, focus groups, forums and other opportunities to engage the public on issues involving vaccine distribution and triage protocols in the event of an influenza pandemic. An aware and informed public will likely be more supportive of medical decisions that may appear harsh but are focused on utilizing limited medical resources to the maximum potential for population health outcomes.

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<sup>79</sup> The relevant IUCB report provided:

“The key to a smooth transition from the current system to any system that amends the standards of care is the emphasis on early planning. The use of partnership instead of coercion may result in less resistance and greater compliance to the use of alternate care facilities. In addition, it is recommended that such facilities be insured and the owners compensated to the most reasonable extent possible for their cooperation so that they do not suffer large financial or property losses. Finally, such facilities should be located in readily accessible sites to ensure ease of access for citizens.”