

COMMUNITY PAN-FLU PREPAREDNESS: A CHECKLIST OF KEY LEGAL ISSUES FOR HEALTHCARE PROVIDERS

Informed by a Public Interest Dialogue Session co-sponsored by the American Health Lawyers Association, the U.S. Centers for Disease Control and Prevention, and the Office of Inspector General, U.S. Department of Health & Human Services



"...to serve as a public resource on selected healthcare legal issues"
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—from a declaration of the American Bar Association

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American Health Lawyers Association
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Office of the Inspector General
Washington, DC

NAME Pandemic and H5N1 Flu DATE May 2, 2008

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*A Prescription
for Preparedness*

REFILL

Signature of prescriber *Deborah Belmont*

PREFACE

The American Health Lawyers Association (Health Lawyers) has made a significant commitment to the development of “best practices” for public health emergency legal preparedness through its Public Information Series. *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers* is the most recent addition to the Series. This *Checklist* is a scalable tool designed to assist providers along the continuum of care as well as the broader healthcare and public health communities in taking concrete steps to prepare for an influenza pandemic.

On May 2, 2008, Health Lawyers, with the U.S. Centers for Disease Control and Prevention and the Office of Inspector General of the U.S. Department of Health and Human Services (HHS) convened a public interest dialogue session to discuss the role of the healthcare sector in community pan-flu preparedness. Health Lawyers, the CDC and HHS invited a select group of 52 participants from diverse federal and state governmental jurisdictions, legal disciplines, the provider and payor communities, academia and national associations that focus on public health, healthcare and the law (listed on page 93). Participants shared their best thinking regarding legal impediments and implementation challenges to community pan-flu preparedness and practical solutions to such challenges. Attendees also focused on ways for healthcare providers to coordinate preparedness planning with local, state and federal authorities. These recommendations were incorporated into the *Checklist* to reflect the perspectives of numerous public and private stakeholders in order to make the *Checklist* as practical and relevant as possible.

An inherent challenge in planning for the possibility of a public health emergency is determining what level of preparedness is sufficient. Our country's healthcare system, similar to our economy in general, operates on a just-in-time basis. In order to compete and reduce costs, businesses order or make products only as necessary, rather than maintain vast inventories. Moreover, the interconnectedness of today's global economy means that a disruption in the availability of workers, products, parts or services could affect significantly healthcare entities' surge capacity to accommodate a major disaster. Given the nature of the supply chains, a public health emergency such as an influenza pandemic that closes international borders, causes worker attrition and suspends travel or the transport of commercial goods would disrupt seriously the delivery of everyday essentials. This interdependence highlights the ongoing need for collaboration

within the private and public sectors as well as the importance of applying lessons learned from real world events to our own preparedness efforts. Without a clear understanding in advance of the relevant legal issues, the healthcare sector's preparedness and response efforts will be subject to unnecessary confusion at a time when clarity is needed most.

Health Lawyers' Public Information Series is one of a variety of public interest activities that arise from the Association's mission statement that pledges us “to serve as a public resource on selected healthcare legal issues.” Available on a complimentary basis, the Series is a collection of informative, consumer-friendly guidebooks and fact sheets on health law topics of interest to our members, their clients and the public that benefit individuals and communities by promoting health education and health improvement within the broader healthcare community. As such, these publications—and more importantly the lessons contained therein—can and should be used by healthcare providers as a demonstrable form of community benefit. The Public Information Series is supported in part by generous donations from many Health Lawyers members and members' firms and organizations. On behalf of Health Lawyers' Board of Directors, I wish to thank all of the Health Lawyers members and their firms or organizations who have made a contribution and ask those who have not contributed in the past to consider doing so. These contributions support the drafting of guidance that will help the healthcare system and the country at large be more effective during a crisis. This increased ability to navigate difficult times will ultimately serve patients when they are most vulnerable.

Special thanks are extended to my fellow co-authors who generously contributed their time and expertise to this publication: David Abelman, Esq.; Joanne R. Lax, Esq.; Melissa L. Markey, Esq.; Matthew S. Penn, Esq.; Paul W. Radensky, M.D., J.D.; Jeffrey Rubin, Ph.D., CEM; Richard L. Shackelford, Esq.; Marilyn Thomas, Esq.; August J. Valenti, M.D.; and Lisa Diehl Vandecaveye, Esq. I also wish to extend my sincere appreciation to Cynthia M. Conner, Vice President of Professional Resources and Bianca L. Bishop, Managing Editor, for their ongoing support of the Public Information Series. I am deeply grateful to Sheri Denkensohn, Esq., Special Assistant to the Inspector General, and Lewis Morris, Esq., Chief Counsel to the Inspector General, Office of Inspector General, HHS, for their invaluable assistance in planning the Public Interest Dialogue Session. I also wish to thank Katherine E. Wone,

Manager of Public Interest, and Maggie Russell, Public Affairs Coordinator, for their intensive staff work to coordinate the session. Health Lawyers also wishes to acknowledge the contributions of Montrece McNeill Ransom, J.D., Senior Public Health Analyst, Public Health Law Program of the U.S. Centers for Disease Control and Prevention, and Anthony D. Moulton, Ph.D., Director of the Public Health Law Program of the U.S. Centers for Disease Control and Prevention, in co-sponsoring the public interest dialogue session. Finally, Health Lawyers is grateful to Sara Rosenbaum, J.D., Chair of the Department of Health Policy and the Harold and Jane Hirsh Professor of Health Law and Policy at the George Washington University School of Public Health and Health Services for graciously agreeing to host this event.

If you have suggestions for future publications in Health Lawyers' Public Information Series, please contact Kerry B. Hoggard, CAE, PAHM, Vice President of Membership and Public Interest, at (202) 833-0760 or khoggard@healthlawyers.org or Katherine E. Wone, Manager of Public Interest, at (202) 833-0787 or kwone@healthlawyers.org.



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If you don't know where you are going, any road will get you there.

– Lewis Carroll

Anyone who is familiar with the United States healthcare system today realizes that as much as any institution in our modern society, it represents an intersection of technology, innovation, healing, crisis, chaos, outcome measurement, unintentional injury, ethics and serious financial challenge—all in one package. It is difficult to imagine that any event or special circumstance could suddenly overshadow or dominate all of these features and redefine the practice of medicine and nursing care as we know it.

We know well how a *regional* natural disaster can overwhelm a local healthcare system until the reinforcements of federal and state resources arrive. If the disaster creates physical damage to facilities and the basic infrastructure (*e.g.*, electrical power and communication), the recovery challenge is more difficult and prolonged. Yet, even in such a scenario, recovery resources from many venues are, at worst, just hours to days away. Even the local healthcare system in the eye of a hurricane or earthquake proceeds towards a rapid and orderly recovery with outside reinforcements.

Imagine today, however, an ultimate crisis—one that is nationwide, occurring in all regions at about the same time. Envisage it as global in nature, also, with much of the world immersed in responding to this singular crisis. Such a crisis would unfold over months, not hours or days, and not with the same relative speed of an earthquake, hurricane, tsunami, tornado, bridge collapse or explosion—all situations where recovery begins almost immediately. This disaster not only would build over weeks before it began to subside, but it also would circle back in one or two additional waves over the next 8 to 12 months. It would not immediately be clear when the final recovery stage begins.

Sound like science fiction? It's not. I'm talking about the next influenza pandemic. Similar to earthquakes, hurricanes and tsunamis, influenza pandemics are inevitable. There have been 10 in the past 300 years, and the next one may be just around the corner.

While pandemic preparedness activities in many communities have slowed as planners experience severe bouts of fatigue, we cannot be lulled into the

false hope that not preparing for the next pandemic means it will not happen. It is going to happen—we just do not know when, where it will start, or exactly how fast it will cover the globe.

This is why *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers* should become required reading and a critical strategic planning resource for every healthcare and public health agency, organization, and practitioner. It details the realistic and daunting issues that the next pandemic will thrust upon the healthcare system in every one of our communities. I am absolutely convinced that wise communities who embrace this document and use it as a primary guide for pandemic preparedness planning ultimately will save lives and be judged by their citizens as having done everything possible to get ready for one of Mother Nature's inevitable and most catastrophic assaults on our population.

For those who still believe that next pandemic simply will not occur or will be far more adequately and easily handled than previous pandemics because of our modern healthcare system, think again. You owe it to yourself, your loved ones and your communities to wake up and learn the facts.

The inevitability of the next influenza pandemic is clear. Pandemics date back to our earliest recorded human history. Over the past 300 years, it has been an average of 24 years between pandemics with a range of 10 to 49 years. Needless to say, it has been 40 years since the last pandemic of 1968. None of these numbers means the next pandemic is going to occur tomorrow. But it could. Or then, perhaps if we are fortunate, we will have another 10 to 15 years to prepare. None of us know. I just would not bet my family's lives on having a lot of time to get better prepared. How bad will the next pandemic be in terms of morbidity and mortality? Again, none of us has a clue. Could it be caused by the ever-mutating H5N1 virus and resemble the 1918 pandemic or even worse? Maybe! Or the next pandemic virus strain could be one that is not even on our radar screens of today.

The effects of the next pandemic will be unlike anything witnessed in our human history. First given that 6.5 billion people inhabit the earth today, even a very mild pandemic (*i.e.*, the one we experienced in 1968) will kill upwards of 7 to 10 million people. If it is similar to a 1918 pandemic, upwards of 180 million people or more could die. Compare that to the approximate 30 million people who have died of HIV/AIDS in the last 30 years.

In addition, the next pandemic will be the first to occur in the global just-in-time economy. We live in a world where many of the critical products that we count on everyday arrive by fast freighter from Asia and are delivered to our hospitals, businesses and homes “just-in-time.” We have limited or no surge production and delivery capacity for most everything we use today. Every indication we have now is that international borders will be closed by panic-stricken leaders or, at a minimum, trade and travel will be seriously curtailed. Our group is currently examining the grave effects that the next pandemic will have on our nation’s health if many of the generic, but critical life-saving drugs cannot be manufactured and delivered from such places as China and India. More than 90 percent of these medications are currently manufactured off-shore and are delivered to the United States by ship. Those drugs will not be available if the pandemic takes its toll on workers in these foreign countries, if the long and thin supply chains that support the manufacturing of these drugs are interrupted, or if international trade and travel is even moderately compromised. We’re talking about generic drugs that we use everyday but take for granted. They include drugs such as insulin, albuterol, atropine, ones on the crash cart in emergency departments and most antibiotics. Frankly, the collateral morbidity and mortality from such medication shortages could be huge. The list of critical products that I believe will be at serious risk during the next pandemic due to supply-chain disruption include all of the infection control-related equipment (*e.g.*, masks, respirators, gloves and gowns), food, equipment parts, and even caskets.

If electricity generation is compromised due to the interruption of coal mining and rail delivery to generation plants — which could realistically happen given the very tight and thin supply chain for coal today — a cascade of terrible events will unfold. . . no water supplies because pumps will not work, no sewage systems, no refrigeration and even no oil due to the refineries having to shut down. As

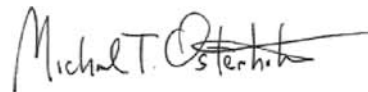
tough as it is for us to think about and even plan for these events, we must.

While this document may be viewed by many as something that healthcare lawyers should read and consider as they advise their clients, I know that would be a major mistake. Everyone from our federal, state and local government leaders and their staff professionals involved in emergency management and preparedness, healthcare system administrators, public health officials, and even those in business continuity and preparedness planning should closely examine the comprehensive and carefully researched direction this *Checklist* provides and plan accordingly.

Make no mistake about it: We will be judged harshly if one day the next pandemic occurs and it is found we were negligent in not better preparing for what was clearly predicted and detailed by the information in this *Checklist*.

“It’s no use saying, ‘we’re doing our best.’ You have got to succeed in doing what is necessary.”

– Sir Winston Churchill



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Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers

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I. INTRODUCTION

The Spanish influenza pandemic of 1918–1919 caused 20 to 40 million deaths worldwide, and is considered to be the most devastating epidemic in recorded human history. Now, scientists and world health officials are warning the public to expect another pandemic to occur.

A recent study suggests that U.S. hospitals would face difficulties in providing care and would suffer significant financial losses in the event of a pandemic.¹ A flu pandemic similar to the one in 1918 could cost U.S. hospitals \$3.9 billion, but a human-to-human outbreak of the H5N1 avian influenza strain could dwarf that estimate. The report estimated the lost revenue to hospitals from a 1918-style pandemic would come from deferred elective cases and uncompensated care for flu victims. That report stated that the average community hospital would lose \$353,985 by deferring cases over an eight-week pandemic period. At the same time, the effects of the pandemic would include uncompensated costs of \$430,607 per hospital to treat the influx of flu patients, the researchers said.² This projected \$3.9 billion loss across all U.S. hospitals could create severe financial strains in the healthcare

system, the researchers stated, adding that “some hospitals may not have sufficient cash on hand to cover these losses.”³

Government planning assumptions also suggest that, if a pandemic were on the 1918 scale, hospitals would find it difficult to treat all the patients who required care. For example, according to the study, the average community hospital has twenty ventilators available and – by deferring cases – could have eighty-one free beds.⁴ But at the height of a 1918-style pandemic, 42 patients would need ventilators and 290 would need beds.⁵ All this is based on extrapolations of planning assumptions from DHHS, which were predicated on the 24% mortality rate from infections in the 1918 flu. If the pathogen involved is a humanized version of the H5N1 avian flu strain, then “the severity and duration of a pandemic could be greater than [the government] assumes,” according to the research.⁶ Globally, the World Health Organization (WHO) claims that 336 confirmed cases of H5N1 influenza in humans have occurred as of December 4, 2007, of which 207 have been fatal.⁷

* The authors wish to express their sincere appreciation to Catherine S. Stern, Esq., an associate at King & Spalding, LLP, for her assistance in preparing the sections relating to Altered Standards of Care and Avoiding Liability and Temporary Licensing and Credentialing of Healthcare Workers. Additionally, the authors wish to recognize the contributions of Caroline Chapman, J.D., Eunice Lee, and Jason Libby, legal interns at the Illinois Department of Public Health, for their assistance in preparing the section relating to Ethical Considerations in a Pandemic. Finally, the authors are deeply grateful to Beth Kelsch, Esq., Legal Counsel, MaineHealth, for her invaluable assistance in reviewing the footnotes to ensure that all of the citations contained in this publication are accurate and authorities cited correctly.

1 Jason Matheny et al., *Financial Effects of an Influenza Pandemic on U.S. Hospitals*, 34 J. HEALTH CARE FIN., Fall 2007, at 58 – 63.

2 *Id.* at 62.

3 *Id.*

4 *Id.*

5 *Id.*

6 *Id.*

7 *Id.*

The report suggests that hospitals need to have a financial plan in place to cope with such an event, because “the expected negative financial impact on hospitals of a severe pandemic is significant.” Furthermore, hospitals should include financial departments in pandemic planning, and the report suggested that federal policymakers should look for ways to ensure that hospitals do not become insolvent during a pandemic.⁸

This publication will examine the key legal issues that arise in the context of pandemic influenza along the healthcare continuum, and address a broad range of issues faced by pre-hospital providers, physicians, other community health professionals, acute care facilities, and long term care facilities. This publication also will discuss the important relationship between healthcare providers and the public health authority during a pandemic. By identifying the key legal issues in checklist form, this new publication will provide a scalable tool to assist providers and the broader healthcare community to take concrete preparedness steps with respect to a pandemic, and thus translate “preparedness on paper” into “preparedness in practice.”⁹

For the purposes of this outline, the term “influenza pandemic” refers to a widespread emerging virus to which humans have little or no immunity, and shall be deemed to include all strains of influenza including H5N1.

In planning for any influenza pandemic, healthcare employers need to address their responsibilities and obligations during three phases of emergency man-

agement: (i) preparation; (ii) response; and (iii) recovery.

- Preparedness involves planning how to respond in the event that an emergency or disaster occurs and includes the establishment of effective emergency operations plan, training of personnel, and identification of back-up supply and service providers. It also encompasses the *immediate* response needs and recovery activity.
- Response is the phase of emergency management in which activities are taken to provide emergency assistance to victims of the event, and/or reduce the likelihood of secondary damage. It also includes monitoring of potential hazardous situations, activation of alert phase procedures, activation of the community’s Emergency Operation Plan, personnel call-back, activation of back-up systems, establishing contact with community emergency services, and damage control.
- Recovery refers to activities taken to restore the organization or operations or both to pre-emergency condition, and includes providing continuing care, addressing staff needs, obtaining extended services and supplies, performing facility repairs and constructions, maintaining the financial viability of the organization, replenishing emergency kits and supplies, and evaluating the effectiveness of the emergency response.

This checklist is organized around the traditional Incident Command System (ICS) structure, providing a scalable approach to emergency management that offers a model for the immediate (and hopefully

8 *Id.* See also Trust for America’s Health, *Ready or Not? Protecting the Public’s Health from Diseases, Disasters and Bioterrorism* (December 2007), available online at healthyamericans.org/reports/bioterror07/ (last visited Feb. 21, 2008). The Trust for America’s Health (TFAH) is a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community, and working to make disease prevention a national priority. The 2007 report finds that significant progress has been made in the nation’s preparedness on some measures; nevertheless, concerted action is needed in important areas. Current capabilities fall short of the report’s stated goals in a number of areas, from ensuring an adequate stockpile of pandemic influenza countermeasures to having a public health workforce large enough and trained enough to respond to an emergency, federal, and state policies. Almost half of U.S. states do not provide sufficient legal protection from liability for healthcare volunteers who respond to the nation’s call for assistance in an emergency. In many other areas, a lack of transparency makes it hard for the American people and their elected representatives to know whether their government is protecting them. The variation in preparedness among the states, although not as great as in past years, means that where one lives still determines how well one is protected. Furthermore, just as the nation is beginning to see a return on the federal investment in preparedness, funding to states and localities to maintain and improve their preparedness is declining. Overall, federal funding for state and local preparedness will have declined by 25% in three years if the President’s Fiscal Year 2008 request is approved. Further, unless Congress and the President act, funding for states and localities for pandemic influenza preparedness will expire in 2008. Health emergencies pose some of the greatest threats to the nation; acts of bioterrorism and natural outbreaks of disease are challenging to detect and contain. In addition, natural disasters often cause health problems that are difficult to predict and prepare for. Since 2003, TFAH has issued the *Ready or Not? Protecting the Public’s Health from Diseases, Disasters, and Bioterrorism* report to examine the progress that has been made to improving America’s ability to respond to health threats and help identify ongoing areas of vulnerability. Some of the key areas of concern TFAH has raised include the need to: (i) increase accountability; (ii) strengthen leadership; (iii) enhance surge capacity and the public health workforce; (iv) modernize technology and equipment; and (v) improve community engagement.

9 General issues relating to emergency preparedness are discussed in two AHHA publications – *Emergency Preparedness, Response and Recovery Checklist: Beyond the Emergency Management Plan* and *Lessons Learned from the Gulf Coast Hurricanes* – both of which can be downloaded on a complimentary basis at www.healthlawyers.org/checklist and www.healthlawyers.org/lessonslearned (last visited Feb. 21, 2008) respectively.

short-term) ad hoc restructuring of an organization around functional, rather than administrative, lines to meet the demands of the emergency situation. ICS identifies key roles within an organization, including responsibilities for each role, and assigns individuals and resources to those roles based on their availability as needed during an emergency. The ICS structure's scalability enables its use in the full range of emergencies that may disrupt a healthcare provider's operations. The ICS employs an Incident Commander with four "sections" that report to the commander: (i) Operations; (ii) Planning; (iii) Logistics; and (iv) Finance, each with its own "chief." The Incident Commander is responsible for assigning Section Chiefs as incident needs demand. Section Chiefs are responsible for staffing and managing their respective

sections.¹⁰ The ICS often is described as a "rainbow chart" approach to response, given that the four "sections" operating under the control of the Incident Commander often are color-coded in planning documents. Command and these four Sections comprise the five essential functions of ICS. Regardless of whether each function is individually *staffed* (e.g., an Incident Commander and Operations, Planning, Logistics, and Finance/Administration Section Chiefs), all five functions *always* are addressed within an ICS organization.

A final note: Each healthcare provider is unique; the following checklist questions will need to be adapted to address the specific needs and capabilities of a particular healthcare professional or entity and the community.

¹⁰ By custom in the healthcare environment, each of these five key roles (i.e., the Incident Commander and her/his four chiefs) has an assigned color, as will be indicated in this checklist. See HOSPITAL INCIDENT COMMAND SYSTEM (2006).

II. INCIDENT COMMAND (ORANGE)

Emergency planning is a prerequisite for effective disaster preparation; unless these elements are considered, evaluated, and addressed in advance, response to public emergencies such as pandemic influenza will be severely handicapped. Emergency planning has four phases: (i) preparedness; (ii) mitigation; (iii) response; and (iv) recovery.

- Preparedness involves training; development of plans, policies, and procedures; establishment of locations for emergency command centers; repositioning of equipment and supplies; installation and testing of generators; contracting for and setting up technology disaster-recovery centers (*i.e.*, “hot sites”); establishing agreements with other local providers and community organizations for transfer of patients and other assistance in an emergency; drills and exercises that test the ability to implement these measures and their efficacy; and similar activities.
- The mitigation phase involves identification of risks and reduction of those risks through prior action, such as securing air intakes from potential biological contaminants, bolting down heavy equipment and furniture in case of earthquake, relocation of essential utilities from locations prone to flooding, assessing and obtaining appropriate insurance coverages.
- Response to an incident involves activation of the institution’s ICS or Hospital Emergency Incident Command System (now referred to as the Hospital Incident Command System or HICS) in order to deal with an emergency.
- Recovery activities are designed to return the organization from emergency operations to normal status, including demobilization of the additional resources brought into play in the response phase. Recovery also includes implementing needed repairs, granting furloughs for staff who handled the emergency, return of patients to closed units, applications for available emergency relief funding, and similar steps.

A key tool in emergency planning is the Hazard Vulnerability Assessment (HVA). Using the HVA, the organization identifies the foreseeable risks it faces, classifies them as high or low likelihood, and assesses their potential effect on the organization. The result of this process reveals a prioritization of emergencies to plan for, which enables the organization to devote its attention to the high-likelihood, high-effect risks.

The Incident Commander has overall authority and responsibility for operations during an emergency event. The Incident Commander’s main job is to allocate resources and ensure safety. Any function not otherwise assigned is the responsibility of the Incident Commander. In addition to the four ICS roles, each of which is described in its own section, the Incident Commander has these direct reports: Liaison Officer, Public Information Officer (PIO), Communications Officer, Safety/Security Officer, and Recorder/Transcriber.

Depending upon a hospital’s emergency plan and the nature, scope, and size of an event (including its timing and who may be on-site during the disaster), the assignments of responsibility during an event under the ICS may not necessarily be consistent with an institution’s traditional organizational structure. For example, during an event that occurs on a weekend, the chief financial officer (CFO) may not be physically available to assume functional responsibility for some of the financial recordkeeping that must be accomplished, so under the ICS this responsibility must be assigned and assumed using existing available resources, until new incident needs arise or new staffing resources arrive and are reassigned.¹¹

In a small event that lasts a few hours, a single individual may serve several roles at once. For example, one person may fill the roles of Incident Commander and Operations Chief for a short period. Events that last longer and/or have a larger scope call for a more complete implementation of the ICS, with all or nearly all principal roles being filled at some point.

A. Activation of the Emergency Operations Center (EOC)

1. Has the organization reviewed its appointments for command staff to ensure that the best command appointments for the unique characteristics of an influenza pandemic have been made?
2. Has the organization established strict, epidemiologically sound principles for determining whether individuals should be admitted into the EOC?
3. Has the organization established treatment/triage capabilities in the EOC with monitoring for influenza-like illness, exhaustion, mental fatigue and stress-related illnesses?
4. Has the organization established capability for a virtual EOC to minimize the risk of infection to the command structure? If so, has the organization coordinated the virtual EOC capabilities with the local, regional and state EOC?

¹¹ *Id.*

INCIDENT COMMAND (ORANGE)

5. Has the organization conducted drills for each successive level of command staff so that all succession personnel have drilled in their positions?
6. Has the organization conducted drills that simulate transfer of command among command staff members over a significant period of time? Has the drill simulated the effects of illness within the command staff?
7. Has the organization specified in the Emergency Management Plan, and in affected policies and procedures, whether it will comply with the directions of the local, regional and/or state-wide EOC?
8. Has the organization worked with local schools, colleges and other agencies to provide information to students on the basics of disaster preparedness, the National Incident Management System and the ICS?
9. Has the organization worked with local media and other communications resources to explain the role and function of Incident Command in disasters?

III. OPERATIONS (RED)

The Operations Chief reports directly to the Incident Commander and is responsible for accomplishing incident objectives during the emergency, regardless of whether they are clinical, related to maintaining facility integrity or business continuity, dealing with a security issue or a hazardous materials release or a combination thereof.¹² The Operations Chief is responsible for whatever services are applied to address the objectives provided by Command, and frequently oversees a fairly large number of operational leaders responsible for specific areas (*e.g.*, decontamination, emergency services, inpatient services, and the operating room).¹³ Some key checklist issues facing the Operations Chief include the following.

A. Consent to Treatment

The ability to consent to one's own healthcare is a basic precept of American law. Failure to obtain informed consent may result in claims for battery or malpractice. The likely chaos of a pandemic presents special difficulties in obtaining legally valid consent.

1. Assisting with Community Preparations Before an Influenza Pandemic Outbreak to Minimize Liability and Ease Operations During an Outbreak

Healthcare organizations and providers should take steps to prepare their communities for an influenza pandemic. Simple, but important, steps may help ease consent issues that will arise during a pandemic.

- a. Has the organization taken steps to coordinate with public health and non-governmental organizations (*e.g.*, the American Red Cross and medical groups focused on pediatrics and emergency medicine) to train parents in the community regarding issues related to consent to treatment for their children in the event of an influenza pandemic or other mass-casualty situations?
- b. Has the organization coordinated with public health and non-governmental organizations to encourage parents of patients with significant healthcare issues to develop a small notebook or item that is easily carried in a pocket which describes their child's diagnoses, medications, allergies, and other information necessary to ensure the best care for the child in an emergency?

c. Has the organization developed and distributed emergency cards (*e.g.*, the CDC's personal medical information form, called the "Keep It With You Personal Medical Information Form")¹⁴ on a regular basis to patients that include the patient's medical history, medications, allergies, and consent-to-treatment provisions?

- Has the organization instructed the recipients to keep the cards with them at all times, if possible?
 - Has the organization distributed the emergency cards to parents of minors? Has the organization instructed parents that all members of a household should have their own personalized emergency cards?
 - Has the organization instructed parents to maintain a copy of their children's emergency cards at the location where the child spends most of his or her time (*e.g.*, at school or day-care)?
- d. If permitted in the organization's jurisdiction, has the organization taken steps to inform parents of documents that they can use to delegate decision-making rights regarding the care of their minor child to another individual that they trust for situations in which the parents are incapacitated or unavailable?
- If so, have parents been informed of the need to continually update such forms, because the forms often are valid only for a limited period of time to ensure that the information is current?
- ##### 2. Obtaining Consent When the Patient is Unable to Consent

An individual infected with the influenza virus may be incapacitated and unable to consent to her own treatment, or to treatment for her minor child. Many states have statutes that define those individuals who are authorized to consent for an incompetent patient. Exceptions to the requirement for consent have been established, and the most commonly recognized exception is care in the event of an emergency—where the patient is unable to consent, no surrogate decision-maker is available, and delay in treatment could result in death or serious disability. In such cases, consent to treatment may be implied, on the theory that a reasonable person would agree to treatment in such circumstances.

¹² *Id.*

¹³ *Id.*

¹⁴ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Keep It With You Personal Medical Information Form*, www.bt.cdc.gov/disasters/hurricanes/katrina/pdf/kiwy.pdf (last visited Feb. 21, 2008).

- a. Under the organization’s state laws, who is permitted to grant consent to medical treatment as a surrogate decision-maker for an incapacitated individual?
 - May a spouse, parent, or sibling act as a surrogate decision-maker? Does the statute list other family members or non-family members that may fulfill this role?¹⁵
 - Are healthcare professionals required to seek the listed surrogate decision-makers in a particular order?¹⁶
 - What limitations, if any, does the law impose on the decision-making authority of a surrogate decision-maker?¹⁷ Do the limitations vary based on who the surrogate decision-maker is?
- b. Who is permitted under state law to consent to medical treatment for a minor?
 - Does the organization’s state law list individuals other than parents or guardians who are permitted to grant consent for minors to receive medical care (*e.g.*, adult siblings)?¹⁸
 - If so, how broad are the provisions?¹⁹
 - Is the state itself permitted to consent to emergency care for minors?²⁰
- c. Does the organization’s state law allow “mature minors” to consent to their own medical treatment?
 - If so, at what age is a minor considered to be “mature” under the statute?²¹
 - What other requirements does the statute impose?
- d. Do the organization’s state laws require that healthcare organizations follow a statutory procedure for recognizing a surrogate?
 - Is there a priority requirement? For example, must a spouse be unavailable before a healthcare organization may turn to a parent?
 - What documentation is required to appear in a patient’s medical record about the selection and reliance on a surrogate decision-maker under the statute?²² Does it vary depending on who is acting as the surrogate decision-maker?
 - Are the physicians and employees within the healthcare organization familiar with these procedures?
 - Does the organization have a process for informing temporary licensed healthcare professionals of these procedures? If so, does the process include informing temporary licensed personnel who have arrived to assist the organization in response to an influenza pandemic about the applicable procedures?

15 See, *e.g.*, TEX. HEALTH & SAFETY CODE ANN. § 313.004 (listing as surrogate decision-makers, in addition to a patient’s spouse and adult child, a majority of the patient’s reasonably available adult children, the patient’s parents, and available clergy).

16 See, *e.g.*, *Id.* (ranking the listed surrogate decision-makers in a particular order); GA. CODE ANN. § 31-9-2(a)(6) (ranking the following persons in the following order of priority if there is no advance directive, it is not a parent or legal guardian consenting for his or her minor child and the patient does not have a spouse: (i) any adult child for his or her parents; (ii) any parent for his or her adult child, (iii) any adult for his or her brother or sister; or (iv) any grandparent for his or her grandchild).

17 See, *e.g.*, TEX. HEALTH & SAFETY CODE ANN. § 313.004 (prohibiting a surrogate decision-maker listed in the statute from consenting to (i) voluntary inpatient mental health services, (ii) electro-convulsive treatment, or (iii) the appointment of another surrogate decision-maker); GA. CODE ANN. § 31-9-2(b) (requiring any surrogate decision-maker listed in the statute to act in “good faith to consent to surgical or medical treatment or procedures which the patient would have wanted had the patient understood the circumstances under which such treatment or procedures are provided”).

18 See, *e.g.*, ARIZ. REV. STAT. ANN. § 36-2271 (requiring the written consent of a parent or legal guardian before a healthcare institution may perform surgery on a minor and not listing any additional individuals who may provide consent).

19 See, *e.g.*, MISS. CODE ANN. § 41-41-3 (listing, in descending order of priority, those persons who are authorized to consent to care on behalf of a minor, and then including a broad statement authorizing any “adult who has exhibited special care and concern for the minor and who is reasonably available” to act and give consent for a minor if none of the persons listed in the statute are available).

20 See, *e.g.*, GA. CODE ANN. § 15-11-14 (allowing the Georgia Department of Human Resources to authorize emergency care for children who are at imminent risk of abuse or neglect or who are under the emergency custody of the department).

21 See, *e.g.*, ALA. CODE § 22-8-4 (allowing a minor who is either 14 years of age or older, has graduated from high school, is married or having been married is divorced, or is pregnant to give effective consent to “any legally authorized medical, dental, health or mental health services for himself or herself”); ALA. CODE § 22-8-5 (allowing any minor who is either married, was married and then divorced, or has a child to give effective consent for his or her child).

22 See, *e.g.*, TEX. HEALTH & SAFETY CODE ANN. §313.005 (listing the prerequisites for consent, including the requirement that the attending physician record the date and time of a surrogate decision-maker’s consent to medical treatment on behalf of a patient and also sign the patient’s medical record, in addition to the requirement that the surrogate decision-maker countersign the patient’s medical record or execute an informed consent form).

- e. Does the organization’s state law provide for situations where no surrogate decision-maker listed in the statute is available?
- If so, to what situations does the law apply?
 - Must the healthcare organization first undergo reasonably diligent efforts to locate a guardian or statutorily listed surrogate decision-maker, or does the statute describe a different standard?²³ Does the statute specifically list what efforts the organization must first undertake?
 - Who does the statute designate as default surrogates, if anyone? May the attending physician act as a default surrogate? May the attending physician, in consultation with other physicians, act as a default surrogate?²⁴
 - What documentation or other requirements must the organization follow when a default surrogate is designated?
 - What medical services may be provided under this decision-making? Are the services limited to those that are “medically necessary,” or does a different standard apply?
- f. Has the organization’s state enacted laws authorizing the court to appoint an individual to make healthcare decisions for another?
- If so, what process is required under the statute?²⁵
 - Has the organization worked with local courts to establish procedures that permit its staff to participate in hearings via video-conference?
 - Does the organization have the ability to encrypt or otherwise protect the privacy of videoconference proceedings?
- g. Do the organization’s informed-consent laws provide for exceptions to informed-consent requirements and procedures in emergency situations?²⁶
- If so, what constitutes an “emergency” or a situation in which consent does not have to be obtained?²⁷
 - Does the exception specifically apply to cases of communicable diseases (*e.g.*, influenza pandemic outbreaks), or is the standard based on the risk to the life or health of the patient?²⁸
 - Does the statute list procedures that the organization must follow when relying upon the emergency informed-consent statute?
 - What medical services may be provided in such an emergency situation? What limitations are placed on the medical services that may be provided?
- h. Has the organization determined how its process for choosing and informing surrogate

23 See, *e.g.*, ARIZ. REV. STAT. ANN. § 36-2271 (providing an exception to the requirement that a parent or legal guardian provide written consent for surgery to be performed on a minor when the parent or legal guardian cannot be located or contacted after reasonably diligent effort).

24 See, *e.g.*, ALA. CODE § 22-8-1 (stating that two or more licensed physicians may “consent” to medical treatment for a patient only if there are no known relatives or a legal guardian and they indicate in writing that such medical services are necessary, and that any attempt to secure consent from the court or locate unknown relatives would result in a delay of treatment that would increase the risk to the patient’s life or health); ALA. CODE § 22-8-3 (allowing medical treatment to be provided to a minor of any age without the consent of a parent or legal guardian if in the physician’s judgment a delay of treatment would increase risk to the minor’s life, health, or mental health).

25 See, *e.g.*, MISS. CODE ANN. § 41-41-9 (setting forth the procedure by which a court, upon the written advice or certificate of a duly licensed physician that there is an “immediate or imminent necessity for medical or surgical treatment or procedures” for an adult of unsound mind or a minor, may consent to and order such treatment or surgery to be performed).

26 See, *e.g.*, ARIZ. REV. STAT. ANN. § 36-2271 (providing an exception to the statute that only a legal guardian or parent of a minor may consent to surgery performed on the minor when a physician determines that it is an emergency and it is necessary to perform the treatment or to save the life of the patient); MISS. CODE ANN. § 41-41-7 (authorizing a duly licensed physician to imply consent to medical or treatment when there is a medical emergency if either of following two circumstances exists: (1) there has been no protest or refusal of consent by a person authorized and empowered to consent, or (2) if so, there has been a subsequent change in the condition of the patient that is material and morbid and there is no one immediately available who is authorized, empowered, willing, and capacitated to consent).

27 See, *e.g.*, GA. CODE ANN. § 31-9-3 (providing for an exception to the consent requirements in cases of an emergency and defining “emergency” as a situation in which “(1) according to competent medical judgment, the proposed surgical or medical treatment or procedures are reasonably necessary and (2) a person authorized to consent under Code Section 31-9-2 is not readily available and any delay in treatment could reasonably be expected to jeopardize the life or health of the person affected or could reasonably result in disfigurement or impaired faculties”).

28 See, *e.g.*, MISS. CODE ANN. § 41-41-7 (providing an example of a definition of emergency based on whether obtaining consent would delay treatment and therefore “jeopardize the life, health or limb of the person affected, or would reasonably result in disfigurement or impairment of faculties”).

decision-makers, and its related application of the HIPAA Privacy Rule provisions pertaining to personal representatives, would be affected in the event of an influenza pandemic?²⁹ Has the organization developed policies and procedures that take into account HIPAA and other relevant patient confidentiality laws and regulations when a patient is incapacitated or otherwise unable to consent and the organization designates a surrogate decision-maker?³⁰

- Does the organization continually educate its physicians, employees and other staff members to enable them to properly implement the emergency informed consent procedures during an influenza pandemic?
- i. Is the organization familiar with the decision tool issued by the DHHS Office for Civil Rights which is designed to assist organizations in determining how to access and use health information for emergency planning consistent with the HIPAA Privacy Rule?³¹
 - j. Has the organization's state enacted patient privacy laws³² that may apply in the organization's state?
 - If so, is the organization familiar with how such laws may also impact an organization's process for choosing and informing surrogate decision-makers?
3. Consent When Transferring Patients

In the event of an influenza pandemic, a healthcare organization may become overwhelmed, and may need to send patients to surge facilities or other facilities with sufficient capacity to accept new patients. The issue of consent arises when either minors or incapacitated adult patients are transferred to these other facilities.

- a. Before transferring any patient to another facility, has proper informed consent been obtained, either by the patient or through a surrogate decision-maker?

- b. Has the organization created policies and procedures to follow when transferring individuals to other facilities that include how medical information about those individuals should be transferred to the receiving facilities?
- c. Has the organization created protocols for sending pertinent medical information with the patient?
 - In what form is the information sent? Is the information transmitted in a summary sheet? Are only portions of the file sent, or will all of the medical records sent?
 - Is any paper information protected either by a sealable plastic bag or by any other means? Is the patient given a wristband with identifying information and key medical information?
- d. What information is sent with a transferred patient?
 - If known, is a brief medical history of the patient sent?
 - If any actions were already taken, is a list of any treatments, screenings, vaccinations, or the like already performed or medications provided by the transferring facility sent with the patient?
 - Is identifying information sent with the patient, such as the name of the patient and the names of the patient's family members or surrogate decision-makers?
- e. Is documentation of consent to treatment transferred with the patient? Is any of the following included (if applicable) in the organization's protocol as information to be transferred with the patient:
 - Consent by the patient;
 - Documentation as to whom has been granted the authority to consent to any medical treatment, screening, vaccination, isolation or quarantine; and/or

²⁹ See www.hhs.gov/ocr/hipaa/guidelines/personalrepresentatives.rtf (last visited Feb. 21, 2008).

³⁰ See 45 C.F.R. § 164.510(b)(3) (2007).

³¹ U.S. Department of Health and Human Services, Office for Civil Rights, *HIPAA Privacy Rule: Disclosures for Emergency Preparedness – A Decision Tool*, www.hhs.gov/ocr/hipaa/decisiontool/ (last visited Feb. 21, 2008) (assisting organizations to apply HIPAA in emergency situations and presenting avenues of information flow that could apply to emergency preparedness activities), which is included in Appendix C.

³² See, e.g., CAL. CIV. CODE §§ 56-56.07; 56.10-56.16 (relating to the disclosure of medical information by providers); 56.17; 56.20-56.245 (relating to the use and disclosure of medical information by employers); 56.25-56.37; TEX. HEALTH & SAFETY CODE ANN. §§ 181.001-181.205 (protecting protected health information but permitting access by the American Red Cross to information necessary to perform its duties to provide biomedical services, disaster relief, disaster communication, or emergency leave verifications for military personnel); MISS. CODE ANN. § 41-41-11 (granting authority to a person empowered to consent to surgical or medical treatment for another to also consent to the disclosure of medical information and the making and delivery of copies of medical or hospital records; however, stating that no authorization of disclosure is needed to furnish information to the State Department of Health in its official duties).

- Documentation of the procedures used to choose the surrogate decision-maker?
- f. Has the organization created protocols that enable families, to the extent practicable, to be transferred together?
 - g. In situations where a minor's parent is incapacitated or otherwise unavailable, has the organization created a procedure for identifying an authorized individual to accompany a transferred minor if practical?
 - h. Does the organization understand what protected health information may be disclosed consistent with the HIPAA Privacy Rule to an individual who asks for the location of a transferred patient, and have a procedure for responding to such inquiries?³³
4. Consent When Receiving Transferred Patients

Facilities that accept patients infected with the influenza virus need to have certain protocols in place to ensure that consent is appropriate and documented.

 - a. Has the organization developed protocols for receiving minors or incapacitated persons in a manner that enables personnel to properly identify who has the authority to consent to treatment, and whether that individual has, in fact, consented?
 - Does the protocol include a method for documenting such information?
 - Does the protocol include a procedure that should be followed if no information is transferred with the patient describing who may consent or whether consent was obtained?
 - Are the organization's staff members and licensed professionals prepared to implement the protocol during an influenza pandemic?
 - b. Has the organization assigned one or more individuals to establish contact with the American Red Cross and other appropriate entities to facilitate reunion and contact with missing family members?³⁴
5. Actions to be Taken After an Influenza Pandemic Outbreak to Minimize Liability and Comply with State Laws

Once the emergent phase of the influenza pandemic has passed, the hospital or healthcare organization should focus on documenting actions taken during the outbreak, and explaining these actions to patients and family members.

 - a. Do the organization's state statutes require documentation of express consent to medical treatment as immediately as possible after treatment is provided during an emergency situation?³⁵
 - b. Does the organization's state law require additional documentation if treatment was provided without express consent during an emergency than it otherwise would require?
 - c. Has the organization implemented policies and procedures for post-pandemic documentation to address treatment that was provided without express consent, and the justification for providing such treatment?
 - d. Has the organization implemented policies and procedures for communicating to patients, parents, and guardians what treatment was provided to the patient during the influenza pandemic outbreak, and the reasons for such treatment?
 - e. Has the organization discussed with court officials and governmental agencies plans for minors orphaned by the pandemic? Are policies and procedures in place for immediate custody and care, as necessary?

33 See 45 CFR 164.510(b)(1)(ii). The HIPAA Privacy Rule permits disclosures as necessary to identify and locate family members, guardians, or anyone else responsible for the individual's care, and notify them of the individual's location, general condition, or death. In an emergency, a healthcare provider may notify the police, the press, or the public at large as appropriate.

34 See 45 CFR 164.510(b)(4). The HIPAA Privacy Rule permits covered healthcare providers to share information with disaster relief organizations that, like the American Red Cross, are authorized by law or by their charters to assist in disaster relief efforts. The healthcare provider is not required to obtain a patient's permission for the disclosure if doing so would interfere with the ability to respond to the emergency circumstances.

35 See, e.g., TEX. HEALTH & SAFETY CODE ANN. § 313.005 (requiring documentation of specific information in the medical record, and the surrogate to either countersign the medical record or sign a consent form as shortly after the treatment as possible under the Texas Consent to Medical Treatment Act).

B. Isolation and Quarantine

Issues regarding consent to treatment may also arise involving mandatory treatment, isolation, or quarantine. Federal and state statutes grant public health authorities the power to isolate or quarantine and, in some cases, order vaccinations, screenings, or treatment for individuals who have contacted or been exposed to the influenza pandemic. The statutes also generally distinguish between imposing mandatory treatments, vaccinations, or screenings from separating individuals by isolation or quarantine.

1. Is the organization familiar with the federal government's isolation and quarantine authority?³⁶ In particular, is the organization aware that the CDC, through its Division of Global Migration and Quarantine, is empowered to detain, medically examine, or conditionally release persons suspected of carrying certain communicable diseases?³⁷
2. Has the organization's state adopted public health laws that provide for mandatory limited screening, testing, and treatment when an individual poses significant public health risks, as provided for in the Turning Point's Model State Public Health Act?³⁸
3. How does the organization's state statute define a medical emergency in which public health officials may require individuals to receive vaccinations, screening, or treatment?³⁹
4. Do the organization's state public health laws provide for the imposition of mandatory isolation or quarantine for certain contagious diseases?⁴⁰
5. Do such state mandatory screening or isolation/quarantine laws permit individuals to refuse treatment for certain reasons?⁴¹
 - a. If so, for what reasons may an individual legally refuse to comply?
 - b. What are the limitations of an individual's ability to refuse to comply?⁴² May the individual

³⁶ "Isolation" and "quarantine" differ with respect to whether a person has already become ill or whether a person has been exposed to an illness. "Isolation" refers to the separation of an individual who has already become ill; "quarantine" refers to the separation of those individuals who have been exposed to an illness but may or may not actually become ill. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, LEGAL AUTHORITIES FOR ISOLATION AND QUARANTINE, *available at* www.cdc.gov/ncidod/dq/pdf/legal_authorities_isolation_quarantine.pdf (last visited Feb. 21, 2008).

³⁷ *Id.* See Public Health Service Act, 42 U.S.C. § 264 (2000, Supp. IV) (granting the Secretary of the Department of Health and Human Services responsibility for preventing the spread of communicable diseases); see also 42 C.F.R. Parts 70 and 71 (2007) (implementing 42 U.S.C. § 264 and empowering the CDC Division of Global Migration and Quarantine to detain, medically examine, or conditionally release any person suspected of carrying a communicable disease); Exec Order No. 13,375, 70 Fed. Reg. 17,299 (Apr. 5, 2005) (amending Exec. Order No. 13,295, 68 Fed. Reg. 17,255 (Apr. 9, 2003)) (pursuant to the President's authority in 42 U.S.C. § 264(b), adding "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic" to the list of communicable diseases for which the CDC is authorized to detain individuals).

³⁸ See PUBLIC HEALTH STATUTE MODERNIZATION NATIONAL EXCELLENCE COLLABORATIVE, TURNING POINT NATIONAL PROGRAM OFFICE AT THE UNIVERSITY OF WASHINGTON, MODEL STATE PUBLIC HEALTH ACT, A TOOL FOR ASSESSING PUBLIC HEALTH LAWS (2003), *available at* www.hss.state.ak.us/dph/improving/turningpoint/MSPHA.htm (last visited Feb. 21, 2008) [hereinafter MODEL STATE PUBLIC HEALTH ACT]. The Turning Point is a result of collaboration with the W.K. Kellogg Foundation and the Robert Wood Johnson Foundation in an effort to improve the public health infrastructure. See also, e.g., FL. STAT. ANN. § 381.00315(1)(b)(4) (granting the Florida State Health Officer the authority to, upon declaration of a public health emergency, take actions such as order an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to the public health).

³⁹ See, e.g., GA. CODE ANN. § 31-12-3(a) (granting the department and all county boards of health the authority to require persons to submit to vaccination against contagious or infectious disease in the case of a declaration of a public health emergency, which may be subject to consideration of the opinion of a person, when either of two standards are met: (1) the location is where the particular disease may occur, whether or not the disease may be an active threat, or (2) to prevent the conveyance of infectious matter from infected persons to other persons as may be "necessary and appropriate"); ARIZ. REV. STAT. ANN. §§ 36-624; 36-787 ("...during a state of emergency or state of war emergency in which there is an occurrence or the imminent threat of smallpox, plague, viral hemorrhagic fevers or a highly contagious and highly fatal disease with transmission characteristics similar to smallpox, the governor, in consultation with the director of the department of health services, may issue orders that ... [m]andate treatment or vaccination of persons who are diagnosed with illness resulting from exposure or who are reasonably believed to have been exposed or who may reasonably be expected to be exposed...").

⁴⁰ See, e.g., GA. CODE ANN. § 31-12-4 (permitting the department and all county boards of health to require the isolation or segregation of persons with communicable diseases or conditions likely to endanger the health of others and to "require quarantine or surveillance of carriers of disease and persons exposed to, or suspected of being infected with, infectious disease until they are found to be free of the infectious agent or disease in question").

⁴¹ See, e.g., ARIZ. REV. STAT. ANN. § 36-114 (stating that "nothing in this title shall authorize the department or any of its officers or representatives to impose on any person against his will any mode of treatment, provided that sanitary or preventive measures and quarantine laws are complied with by the person. Nothing in this title shall authorize the department or any of its officers or representatives to impose on any person contrary to his religious concepts any mode of treatment, provided that sanitary or preventive measures and quarantine laws are complied with by the person.").

⁴² See, e.g., GA. CODE ANN. § 31-12-3(b) (only granting a person the ability to object to immunization in writing if such immunization conflicts with his religious beliefs in the absence of an epidemic or immediate threat thereof).

- refuse treatment, screening, isolation, quarantine,⁴³ or other preventive measures?
- c. Do the reasons for valid refusals vary based on what the individual is refusing?
6. Are the organization's healthcare professionals aware of the federal and state laws regarding mandatory treatment, screening, vaccinations, isolation, or quarantine?⁴⁴
 7. Does the organization have policies and procedures in place for implementing the mandatory treatments, screenings, quarantines, or isolation, as well as for informing individuals or surrogate decision-makers (when possible) of the orders? Does the organization have a process in place for handling those persons to who choose to opt-out?
 8. Are the organization's healthcare professionals prepared to implement these policies and procedures?
 9. Has the organization evaluated the need for additional intake capabilities to receive a large numbers of patients?
 - a. Have alternative ambulance bays been identified?
 - b. Is there a loading/unloading zone that can accommodate a bus load of patients, who may or may not be stretcher patients?
 10. Has the organization prepared secure receiving and storage areas of limited supplies?
 11. Has the organization developed a process for ensuring that critically limited supplies are not diverted?
 12. Has the organization developed a plan for converting from a just-in-time inventory in the event of pandemic?
 13. If the organization re-supplies EMS provider vehicles, has the organization addressed a process for ensuring timely restocking of such vehicles while maintaining adequate supplies for the organization?
 14. Has the organization worked with other providers, including EMS providers, regarding diversion criteria during an influenza pandemic?
 15. Are there policies, procedures, and resources in place to provide adequate staff support during and after an influenza pandemic?
 - a. Does staff support include outreach to employee families (from monitoring status to active support)?
- C. Altered Standards of Care and Avoiding Malpractice Liability**
1. Altered Standards of Care

Preparing adequately for an influenza pandemic may require healthcare organizations to overcome their traditional fears of liability and address altered standards of care that may become necessary in an influenza pandemic situation.

 - a. Has the organization developed modified treatment protocols and treatment/care plans which reflect reasonably anticipated limitations in capability, and are scalable based on the scope of the pandemic?
 - b. Has the organization convened a regional committee to concur on modified treatment protocols and treatment/care plans which reflect reasonably anticipated limitations in capability, and are scalable based on the scope of the pandemic?
 - c. Has the organization's state developed statutes establishing an altered standard of care during emergency situations, such as an influenza pandemic?⁴⁵
 - d. Does the governor of the organization's state have the statutory authority to modify tort standards of care for emergency situations when the governor declares an emergency?
 - e. Does the organization's state have a plan that addresses the potential need for an altered standard of care during an influenza pandemic that may result from a mass casualty and limited resources?⁴⁶

43 See, e.g., FL. STAT. § 381.00315(1)(b)(4) (stating that individuals who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may still be subjected to quarantine, and if there is no practicable method to quarantine the individual, then the State Health Officer may use any means necessary to vaccinate or treat the individual).

44 See, e.g., MODEL STATE PUBLIC HEALTH ACT, *supra* note 159, at §§ 5-107, 5-108; N.Y. PUB. HEALTH LAW § 2120; CAL. HEALTH & SAFETY CODE § 120130; N.H. REV. STAT. ANN. § 141-C:15.

45 Expert commentators are beginning to conclude that there should be a "crisis standard of care" for emergencies such as pandemics where healthcare demands exceed available resources. These commentators also contend that evidence-based research is needed to develop a crisis standard of care. See, e.g., Emile Chang, Howard Backer, Tareg Bey & Kristi Koenig, *Maximizing Medical and Health Outcomes after a Catastrophic Disaster: Defining a New "Crisis Standard of Care,"* JOURNAL OF EMERGENCY MEDICINE, 2008 (abstract); Kristi Koenig, David Cone, Jonathan Burstein and Carlos Camargo, Jr., *Surging to the Right Standard of Care,* ACADEMIC EMERGENCY MEDICINE, 2006, at 195.

- If so, does the state’s plan provide any guidance for healthcare organizations to follow in such a situation?
 - If not, has the organization considered how this may affect the organization’s planning for altered standards of care?
- f. Has the state developed any other planning guide to assist organizations in planning for altered standards of care?⁴⁷
 - g. Given that the state government has the authority to adopt an altered standard of care that would be effective during a public emergency, has the organization considered recommending to the appropriate state governmental body that an altered standard of care be adopted?
 - h. Has the organization considered forming a committee charged with the task of developing a proposed altered standard of care, and communicating appropriately with state officials the need for such an altered standard as well as the committee’s proposals?
 - i. Has the organization (or its designated committee) reviewed various publications regarding altered standards of care, including the Agency for Healthcare Research and Quality’s (AHRQ) report on altered standards of care, the Joint Commission’s report on surge hospitals, and the Homeland Security Council’s report on strategy for an influenza pandemic?⁴⁸
 - j. Has the organization (or its designated committee) taken into consideration the following factors when developing a proposed altered standard of care:
 - The AHRQ’s altered standard of care, which calls for “providing care and allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in contrast to the traditional focus on saving individuals;”⁴⁹
 - The Homeland Security Council’s position that the altered standard of care for a pandemic will be met “if resources are fairly distributed and are utilized to achieve the greatest benefit;”⁵⁰
 - The practicality and feasibility of providing care at the level of the altered standards of care during an influenza pandemic;
 - Potential criminal and civil liability to the healthcare professionals and the organization if an altered standard is adopted; and
 - Ethical implications – and possibly even criminal or civil consequences from alleged detrimental reliance – of *not* operating in a mass-casualty situation under an altered standard of care?
 - k. What policies and procedures has the organization adopted for implementing and integrating an altered standard of care in an emergency?
 - Do policies and procedures accommodate changes as the state develops such a standard?
 - l. What, if anything, should be required to trigger implementation of an altered standard of care during an influenza pandemic? At what point during an emergency should healthcare professionals begin practicing according to the adopted altered standard of care?
 - Does the altered standard rely on the individual judgment of each provider?

46 See, e.g., CALIFORNIA DEPARTMENT OF HEALTH SERVICES, PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN 56 (2006), available at www.dhs.ca.gov/dcdc/izgroup/pdf/pandemic.pdf (last visited Feb. 21, 2008) (recognizing that the traditional standards of care may need to be altered due to a limited amount of healthcare resources and a possible increased demand and, therefore, stating that under a governor’s declaration of an emergency, the California Department of Health Services can “modify healthcare standards to help meet the immediate needs for patient care related to the influenza pandemic”).

47 See, e.g., Steven D. Gravely & Erin S. Whaley, *The Greatest Good for the Greatest Number: Implications of Altered Standards of Care*, HOSPITALS AND HEALTH SYSTEMS RX, Winter 2006, at 10 (explaining how Virginia developed a “Critical Resource Shortage Planning Guide” to help healthcare entities think about “altered” standards of care in advance of an emergency).

48 See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (AHRQ), ALTERED STANDARDS OF CARE IN MASS CASUALTY EVENTS: BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES, AHRQ Pub. No. 0-0043 (2005), available at www.ahrq.gov/research/altstand/altstand.pdf (last visited Feb. 21, 2008); JOINT COMMISSION FOR THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS, SURGE HOSPITALS: PROVIDING SAFE CARE IN EMERGENCIES (2006), available at www.jointcommission.org/PublicPolicy/surge_hospitals.htm (last visited Feb. 21, 2008); HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR INFLUENZA PANDEMIC (2005), available at www.whitehouse.gov/homeland/pandemic-influenza.html (last visited Feb. 21, 2008) [hereinafter NATIONAL STRATEGY]; see also HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR INFLUENZA PANDEMIC: IMPLEMENTATION PLAN (2006), available at www.whitehouse.gov/homeland/pandemic-influenza-implementation.html (last visited Feb. 21, 2008) [hereinafter NATIONAL STRATEGY, IMPLEMENTATION]; HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR INFLUENZA PANDEMIC: IMPLEMENTATION PLAN ONE YEAR SUMMARY (2007), available at www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html (last visited Feb. 21, 2008).

49 AHRQ, *supra* note 56, at Ch. 2.

50 NATIONAL STRATEGY, IMPLEMENTATION, *supra* note 56, at 110.

- Does the altered standard rely on the organization to inform professionals and staff as to when it is appropriate to operate under the altered standard of care? If this is the case, do the organization's procedures require a designated person to signal that healthcare professionals must begin practicing according to the altered standard of care? If so, who is the designated person? Is the designation consistent with the medical staff bylaws? Are successors to the designated person specified by policy?
- m. Are the organization's healthcare professionals (regardless of whether they are contractors or employees) knowledgeable about the proposed altered standard of care? Does the organization have a system in place to educate the professionals about the altered standard of care when it is ultimately adopted by the state?
- Has the organization assisted employees in understanding the need for modified protocols and treatment/care plans, including providing employees with access to ethical and scientific support?
 - How will changes in new patient care practices be communicated and implemented within the organization and at large?
- n. Is the organization's staff knowledgeable about the proposed altered standard of care? Does the organization have a system in place to inform the staff members of the altered standard of care when it is ultimately adopted by the state?
- o. How will temporary healthcare professionals arriving at the organization during an influenza pandemic be made aware of:
- The state's altered standard of care, or any other guidance from the state on applying an altered standard of care;
 - When to practice according to the altered standard; and
 - How to practice under the altered standard of care?
- p. Who has the organization designated to supervise the performance of responsibilities by employees, contractors, and temporary healthcare professionals while they are acting according to an altered standard of care?
- Has the organization considered the use of pre-incident messaging to provide information to the public on the difference in care that may occur during an influenza pandemic and thereby help to manage expectations for both providers and consumers?
 - Has the organization involved all the necessary stakeholders in developing the content of any such messages including providers, government, media and consumers?
 - Has the organization considered using unusual influenza public service announcements as a vehicle for such messages?
- q. Has the organization developed protocols and procedures for transfer of patients from higher levels of care to lower levels of care or to home to accommodate pandemic surge?
- r. Has the community addressed alternative means of transferring early discharge patients to home if caregivers are unable to transport?
2. Liability of Individual Healthcare Providers
- In addition to recognizing altered standards of care, states need to examine their own laws regarding provider liability, and possibly alter those laws to reflect the reality that healthcare organizations will face not only in an influenza pandemic but in other disasters. In order to save the most lives, healthcare providers need to be able to practice under an altered standard of care without fearing traditional civil (and possibly criminal) liability. Healthcare organizations need to know what possible sources of immunity are available, understand the scope of provider liability statutes within their states, and be able to effectively communicate with state officials about liability issues.
- a. In the absence of any grants or waiver of immunity, has the organization considered the potential civil and criminal liability to which healthcare professionals and other personnel would be exposed while responding to an influenza pandemic? What actions will providers have to take that would subject them to civil, or even criminal, liability in the absence of immunity or an altered standard of care recognized by state law?
- b. Has the organization examined applicable state statutes and interstate agreements regarding whether they contain a variety of limiting

- factors as to their scope, which could result in their failure to provide immunity for healthcare professionals responding to an influenza pandemic?⁵¹
- c. If the state’s “Good Samaritan” statute, similar statutes, or its interstate agreements are not adequate to protect healthcare professionals responding to a pandemic from liability, has the organization considered what steps it could take to seek change in the state statutes to address provider liability in an influenza pandemic?
 - d. Has the organization examined applicable grants or waivers of immunity for emergencies with regard to whether they extend to criminal liability?⁵²
 - e. How is “criminal negligence” defined in the organization’s state statutes?⁵³
 - What is the scope of the criminal negligence statute?
 - Is it possible that the actions providers may have to take during an influenza pandemic would constitute criminal negligence unless the definition of this term is statutorily modified?
 - f. Does the organization’s jurisdiction have a “Good Samaritan” statute?⁵⁴

If so:

 - What is its scope? Does it only cover services rendered at the “scene” of an emergency by a non-compensated volunteer? Is the scope of immunity only for civil liability, or only for negligence?
- Does it cover acts taken within a healthcare facility?
 - Given the need for alternative care locations, what will constitute a “healthcare facility” in a pandemic?
 - What professionals or other personnel does it protect from liability?
 - If it includes physicians, are physicians covered if they charge for the services rendered? If the healthcare entity charges for services rendered?
 - Is a declaration of a state of emergency required to trigger the statute?
- g. Has the organization’s jurisdiction adopted the provisions of MSEHPA that grant sovereign immunity to persons who respond to a public health emergency at the request of a state or political subdivision?⁵⁵
 - h. Has the organization considered the possible application in an influenza pandemic of the federal Volunteer Protection Act which provides immunity to, among others, properly licensed personnel who provide services without compensation in a nonprofit setting?⁵⁶
 - i. Has the organization considered the federal law that provides “Good Samaritan” immunity for individuals appointed by the Secretary of DHHS to serve as temporary members of the NDMS because they are considered members of the Public Health Service as long as they act within the scope of their employment?⁵⁷
 - j. Has the organization considered the Public Readiness and Emergency Preparedness Act, a

51 U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMINISTRATION, EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS, (ESAR-VHP) PROGRAM, LEGAL AND REGULATORY ISSUES, 51-62 (2006), *available at* www.hrsa.gov/esarvhp/legregissues/default.htm (last visited Feb. 21, 2008) [hereinafter ESAR-VHP LEGAL AND REGULATORY ISSUES]. *See, e.g.*, 42 U.S.C. § 14503 (2000, Supp. IV) (granting immunity to uncompensated volunteers but not to organizations that employ or supervise the volunteers); OR. REV. STAT. § 30.800 (applying only if the emergency assistance is rendered outside of a location where medical services are readily available and permitting suits when the standard of care is not reasonable under the circumstances of the emergency); S.C. CODE ANN. § 15-1-310 (limiting protection to uncompensated persons and not extending protection when the acts or omissions are the result of gross negligence or willful or wanton misconduct); Emergency Management Assistance Compact, Pub. L. No. 104-321, Art. VI (1996) (granting protection only to “officers or employees” of a state that is a party to the compact).

52 ESAR-VHP LEGAL AND REGULATORY ISSUES, *supra* note 59, at 61 - 62.

53 *See* HEALTH LAWYERS, GULF COAST HURRICANES, *supra* note 25, at 55 (2007) for a discussion comparing DEL. CODE ANN. tit. 11, § 231 (2005), N.Y. PENAL LAW § 15.05 (McKinney 2005), and TENN. CODE ANN. §§ 39-11-106, 39-11, 302 (2005), with GA. CODE ANN. § 16-2-1 (2005).

54 *See, e.g.*, OR. REV. STAT. § 30.800 (2006); S.C. CODE ANN. § 15-1-310 (2006); TENN. CODE ANN. § 63-6-218 (2006); CAL. BUS. & PROF. CODE §§ 2395-2398 (2006); GA. CODE ANN. §§ 31-11-8; 51-1-29 (2006). Although the accuracy of the website has not been confirmed, *see* www.cprinstructor.com/legal.htm (last visited Feb. 21, 2008) for a listing of Good Samaritan laws.

55 *See* MSEHPA, *supra* note 22, at § 804(a).

56 Volunteer Protection Act of 1997, 42 U.S.C. § 14501 *et. seq.* (2000, Supp. IV).

57 HEALTH LAWYERS, GULF COAST HURRICANES, *supra* note 25, at 54 (2007); *see* 42 U.S.C.A. § 300hh-11(d) (2005). The NDMS is a partnership among several federal agencies that provides healthcare and other services jointly with state, public, and private agencies in the event of an influenza pandemic. Private persons properly appointed under the act receive federal immunity. Members of the Volunteer Medical Reserve Corps, a group of reserve volunteer health professionals and non-health professionals under the direction of an appointed Director of the Corps who are certified and trained to respond in the event of a public health emergency, receive similar immunity.

federal law that grants immunity to individuals who administer or use certain “countermeasures,” which include qualifying drugs or vaccinations, during a pandemic influenza after the Secretary of DHHS declares a public health emergency?⁵⁸ Has the organization considered how this congressional grant of immunity affects the organization’s preparation for an influenza pandemic?

k. Has the organization’s jurisdiction adopted statutory provisions that grant immunity to out-of-state healthcare professionals who respond in the event of a declaration of an emergency?

- What is the trigger for such immunity (*e.g.*, a gubernatorial declaration)?
- Who within the organization has responsibility for assuring that all preconditions for the application of any such immunity have been met?
- Does the immunity apply to non-licensed personnel from other states?

l. Has the organization’s jurisdiction adopted the Model Intrastate Mutual Aid Legislation (MIMAL), or similar statutory provisions thereof, that establish civil liability immunity for volunteer professionals who respond *within* a state by treating them as government employees entitled to immunity?⁵⁹

m. Has the organization evaluated the likelihood that its state will request assistance through EMAC, and that other states will be able to deploy volunteers in response to EMAC in the event of an influenza pandemic?⁶⁰

- Has the organization considered that EMAC states may decline to provide requested resources “to the extent necessary to provide reasonable protection” for that state?

- Has the organization considered that the EMAC provides civil liability immunity only for “officers or employees” of a state who are responding pursuant to the compact?
- Has the state in which the organization is located passed legislation permitting deployment of private individuals under EMAC as state assets?

n. Does the organization’s state or local jurisdiction have any other interstate agreements or legislation granting civil or criminal immunity to actions by healthcare professionals or other employees, contractors, or volunteers when responding to an influenza pandemic?⁶¹

o. Does the organization have MOUs with other healthcare entities that may affect the civil liability for shared employees who respond to an influenza pandemic?⁶²

If so:

- Are the shared employees considered volunteers, or are they paid by the receiving or providing entity?
- Which party has been assigned liability for such shared personnel during the time the personnel are responding to the pandemic?

3. Liability of Healthcare Organizations

Healthcare organizations may be held liable under the theory of corporate negligence for their own actions, or through the theory of vicarious liability as a result of actions by professional providers or staff that are imputed to the entity. Most statutes granting civil immunity to volunteers, professionals, employees of the state, and the like only immunize the *individual providers* of care, and do not also grant immunity to healthcare organizations.

58 Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, 42 U.S.C. § 247d-6d (2006) (preempting related state laws and granting immunity to a manufacturer, distributor, program planner, or “qualified person” (defined to include a licensed health professional or other individual authorized to prescribe, administer, or dispense a qualifying pandemic drug) for all actions caused by the administration or use, design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, or licensing of a qualifying pandemic drug (or other “countermeasure” as defined by 42 U.S.C. § 247d-6d(i)(1), except actions alleging willful misconduct).

59 NATIONAL EMERGENCY MANAGEMENT ASSOCIATION & NATIONAL PUBLIC SAFETY ORGANIZATIONS, MODEL INTRASTATE MUTUAL AID LEGISLATION, Art. X (2004), *available at* www.emacweb.org/?1546 (last visited Feb. 21, 2008); *see, e.g.*, IND. CODE §§ 10-14-3-10.6, 10-14-3-10.7 (2003); OKLA. STAT. tit. 63 §§ 683.2, 683.14 (2004). It is unclear, however, whether non-governmental employees acting under a state or local agency’s control or direction would be considered “officers and employees” of that “participating unit,” and thus not civilly liable. For a discussion regarding similar ambiguous language in EMAC and the Interstate Civil Defense and Disaster Compact (ICDDC), *see* ESAR-VHP LEGAL AND REGULATORY ISSUES, *supra* note 59, at 48-49.

60 Emergency Management Assistance Compact, Pub. L. No. 104-321, Art. VI (1996). For statutes implementing EMAC and granting civil liability immunity for “officers or employees of a party state rendering aid in another state pursuant to [the] compact,” *see* TEX. HEALTH & SAFETY CODE ANN. § 778.001, Art. VI (Vernon 2006); MINN. STAT. § 192.89 (2006).

61 For example, the National Conference of Commissioners on Uniform State Laws adopted in 2007 interim draft model provisions on civil liability for voluntary health professionals which provide comprehensive immunity from civil liability. *See* UEVHPA, *supra* note 24.

62 For model MOU language, *see* AHA & DCHA, *supra* note 20.

- a. Does the jurisdiction provide guidance about whether volunteer responders would be considered employees in an emergency situation, such that the organization would be vicariously liable for the actions of the volunteers?
- b. Has the organization determined its potential liability for the actions of healthcare professionals during an influenza pandemic under the doctrine of vicarious liability? As such, has the organization evaluated the potential benefits of properly training healthcare professionals both on how to respond to an influenza pandemic and on the organization's altered standard of care?
- c. Does the organization's jurisdiction recognize the doctrine of ostensible agency, a doctrine under which healthcare organizations may be liable for physician independent contractors if the organizations hold the physicians out to the public as employees?
 - If so, has the organization considered the impact this doctrine would have on its potential liability during an influenza pandemic?
 - Has the organization considered what steps it could take to minimize its liability under the doctrine of ostensible agency in the event of an influenza pandemic?
- d. Do any state statutes or other emergency response grants of immunity extend to healthcare organizations? If not, has the organization encouraged its state association to seek an amendment?
- e. Has the healthcare organization entered into any MOUs with other organizations for sharing employees? If so, do the MOUs assign liability for shared employees for whom the organizations may be vicariously liable?
- f. Has the organization trained its staff, management and any other personnel utilized on how to respond to an influenza pandemic to minimize the risk of potential malpractice claims, including claims for corporate negligence liability and vicarious liability?
 - Has the organization held candid discussions with its insurance carrier about the potential malpractice risks presented by a pandemic and discussed possible approaches to minimize such claims?
 - Has the organization discussed the potential malpractice risks presented by a pandemic both with its malpractice defense counsel and its emergency preparedness counsel?
- g. Has the organization considered specific actions that can be taken now to provide the highest level of care feasible during a pandemic and thereby minimize the risk of malpractice claims resulting from an influenza pandemic, including the following:
 - Has the organization developed triage protocols to prioritize pandemic cases by level of acuity?
 - Has the organization developed flu algorithms that are similar to, for example, algorithms for myocardial infarctions?
 - Has the organization developed treatment protocols focused on processing large numbers of similar cases in order to make patient care more efficient during an influenza pandemic? For example, has the organization considered a modified history and physical limited to visual inspection, vital signs and cultures?
 - Has the organization developed "short form" documentation requirements for influenza pandemic patients focused solely on influenza issues, including a short form consent to treatment?
 - Has the organization developed policies related to the dispensing of scarce medications, including vaccines and antivirals?
 - Has the organization developed staffing contingency plans, identifying essential staff for an influenza pandemic and other staff for non-pandemic essential services (*e.g.*, trauma, cardiac and obstetrics services)?
 - Has the organization developed plans to cross-train clinical personnel to assist in providing care during a pandemic? Has the organization considered cross-training administrative staff to provide basic nursing services? Has the organization considered training volunteers from the community to help with more menial tasks?
 - Has the organization identified possible sources of temporary personnel in the community for assignment during a pandemic? For example, has the organization considered reaching out to physicians and nurses within the community with special expertise in infectious diseases, pulmonary medicine and critical care medicine or to retired personnel, medical and nursing students, the local Red Cross, and state and federal public health agencies?

- Has the organization developed policies setting forth admission and discharge priorities by patient condition and acuity during an influenza pandemic? Do such policies address triggers for the cancellation of elective procedures, prioritization guidelines for early discharge of current inpatients, and criteria on transfers to other treatment settings?
 - Has the organization developed policies for the restriction of visitors during a pandemic and the development of mechanisms to enforce such restrictions including the use of hospital security services? Has the organization met with local law enforcement officials to determine ways in which they can assist?
 - Has the organization developed criteria for reduction in the routine use of laboratory, radiology and other diagnostic ancillary services?
 - Has the organization stockpiled sufficient quantities of consumable supplies that will be needed in a pandemic (*e.g.*, masks)?
 - Has the organization identified reserve morgue capacity?
 - Has the organization developed “quick study” kits for non-employee personnel that succinctly describe key hospital policies and treatment protocols and that provide contact information (*e.g.*, telephone numbers, pager numbers and e-mail addresses) that are necessary to render care at the organization’s facility?
 - Has the organization developed plans on how to house and feed an out-of-town work force?
 - Has the organization considered discussing with its insurance carriers how insurance coverage may be affected by the use of non-employee personnel including the use of unlicensed professional personnel (*e.g.*, healthcare professionals coming from other jurisdictions)?
 - Has the organization established guidelines for rapidly vaccinating or providing antiviral medications to healthcare personnel including a priority list of essential clinical personnel for scarce vaccines and antivirals?
- Has the organization assessed its potential need for personal protective equipment (PPE) and begun stockpiling sufficient numbers?
 - Has the organization developed policies on cohorting essential clinical personnel such that personnel working in more critical areas do not contaminate less critical areas and vice versa?
4. Altered Standards of Care in Surge Facilities
- An influenza pandemic may require the health-care organization to rapidly expand its facility or take over other nearby buildings, called “surge facilities,” in order to meet a high volume of infected patients. Avoiding potential liability involves adequate planning in advance for the operation of such surge facilities.⁶³
- a. Has the facility considered the potential necessity of surge facilities in an influenza pandemic?
 - b. Has the facility determined its risk for potential liability if surge facilities need to be created, given that there will be a higher volume of patients, additional personnel will be needed, and that the additional personnel will be less familiar operating within a surge facility?
 - c. Has the organization involved nursing, laboratory, infectious disease and plants/facilities personnel to plan in detail how to set up, organize and implement the surge facility?
 - d. Do plans for the alternative care/surge facility address supply lines, medical gas capabilities and adequate infection control measures?
 - e. Do plans for the alternative care/surge facility adequately address security concerns including the ability to secure medications, controlled substances and limited resources?
 - f. Do plans for the alternative care/surge facility provide for:
 - Staff respite;
 - Waiting areas for family/friends of patients;
 - Segregated storage/disposition of bodies;
 - Secure transport/traffic lanes; and
 - Redundant communications, including with EMS and Incident Command?

63 For further discussion regarding expanding surge capacity, see U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, REOPENING SHUTTERED HOSPITALS TO EXPAND SURGE CAPACITY, AHRQ Pub. No. 06-0029 (2006), available at www.ahrq.gov/research/shuttered/shuthosp.htm#Contents (last visited Feb. 21, 2008).

- g. Do the organization’s policies and procedures address whether alternative care/surge facilities will be used for pandemic or non-pandemic care?
 - h. Has the organization considered the use of veterinary hospitals and laboratories as surge facilities? What mechanisms need to be in place to facilitate the use of such facilities?
 - i. Do the organization’s policies and procedures discussing altered standards of care incorporate expanding patient care to surge facilities if necessary?
 - j. Have the organization’s employees and contractors received training on how to implement the procedures to transport patients and services to surge facilities or expansions?
 - k. Do the organization’s plans address alternative means of transporting patients and/or staff between surge facilities and the primary care location?
 - l. Have the organization’s employees and contractors been taught how to care for patients in a surge facility under an altered standard of care?
 - m. Has the organization developed a plan for instructing temporary healthcare professionals who arrive during an influenza pandemic on how to care for patients at the surge facility? Has the organization developed a plan for instructing them on an altered standard of care?
5. Planning on a Community-Wide Basis to Prevent Criminal and Civil Liability
- Because healthcare organizations and individual providers also are part of the community’s healthcare system, organizations should prepare for an influenza pandemic within the context of a community-wide response in addition to operating as an individual entity.
- a. Has the organization recognized a fiduciary duty to its community for establishing broader links with the community as recommended by the American Hospital Association (AHA)?⁶⁴
 - b. Does the organization undergo exercises for emergencies as required by the Joint Commission and other accreditation agencies?⁶⁵
- If so, are any of those exercises directed at an influenza pandemic?
 - Do exercises employ guidelines from the Homeland Security Exercise and Evaluation Program (HSEEP)?⁶⁶
- c. Has the organization worked with other healthcare organizations and those supporting them in the community to establish community-wide exercises to practice for an influenza pandemic?
- If so, do the drills include:
- Outpatient clinics;
 - Private physician offices;
 - Emergency Medical Services (EMS) providers;
 - Home health care agencies;
 - Long term care; and
 - Religious-based care organizations?
- If so, are critical suppliers, vendors and group purchasing organizations included?
- d. Has the organization developed horizontal and vertical relationships between other organizations and governmental entities in the community that could be called upon in the event of an influenza pandemic, as recommended by the AHA?⁶⁷
- Do the relationships include non-healthcare entities?
- e. Have individuals in the organization developed personal working relationships with individuals in other community organizations and governmental entities?
- f. Is the organization part of a daily community-wide communications network? If not, is the organization taking steps to initiate and implement such a network?
- g. Has the organization considered incorporating members of the veterinary medical community in its planning team if the influenza pandemic is of animal origin?

64 See AMERICAN HOSPITAL ASSOCIATION, FINAL REPORT ON HOSPITAL PREPAREDNESS FOR MASS CASUALTIES 20-21 (2000), available at www.aha.org/aha/content/2000/document/disasterpreparedness.doc (last visited Feb. 21, 2008).

65 See JOINT COMMISSION: HOSPITALS MANUAL, *supra* note 14, at EC 4.20.

66 Homeland Security Exercise and Evaluation Program, available at <https://hseep.dhs.gov> (last visited Feb. 21, 2008).

67 AMERICAN HOSPITAL ASSOCIATION, *supra* note 72, at 20.

D. Treating Patients with Chronic Medical Conditions and Availability of Prescription Drugs

Patients who may develop pandemic influenza and who may receive treatment for influenza and related complications – as well as the entire population, who may be at risk for developing pandemic influenza and who may receive some prophylactic treatments (*e.g.*, egg allergies, vaccines, prophylactic therapies) – may also have chronic co-morbid conditions and/or be receiving chronic concomitant therapies, including prescription drug therapies. When focusing on prophylactic measures to avoid influenza or on therapeutic measures to address influenza or its complications, providers will need to continue treatment of these chronic co-morbid conditions; further, they may need to respond to acute complications of the chronic condition that may arise in association with influenza, and will need to consider whether and how influenza, and the treatments for influenza, may affect dosage and administration of chronic concomitant drug therapy. While it is likely that prophylactic and treatment options for pandemic influenza will be quite limited, particularly early in the pandemic, anticipation of the effects of co-morbidities can lead to improved patient outcomes.

1. What types of chronic medical conditions may patients have? Has the organization reviewed the incidence and prevalence of diagnoses treated at its facilities?
2. Will patient suffering from chronic, non-pandemic conditions be treated at primary medical facilities or a surge facilities?
3. Among the chronic medical conditions treated at the institution, which conditions are likely to be worsened or otherwise negatively affected by co-morbid occurrence of an influenza pandemic?
 - a. Has the organization developed treatment protocols intended to minimize or avoid the adverse effects of influenza on chronic medical conditions to the extent practical?
 - b. Has the organization developed educational materials for caregivers and for patients describing the possible problems, recommended interventions and defining symptoms which should trigger immediate care?
 - c. Has the organization evaluated alternative approaches for those tests or treatments that are typically provided at a facility, such as hemodialysis?
4. Among the chronic medical conditions treated at the institution, which conditions are likely to be worsened or otherwise negatively affected by treatments given to patients for influenza, or for prophylaxis against influenza?
 - a. Has the organization developed treatment protocols intended to minimize or avoid the adverse effects to the extent practical?
 - b. Has the organization developed educational materials for caregivers and for patients describing the possible problems, recommended interventions, and defining symptoms which should trigger immediate care?
 - c. Has the organization evaluated whether changes to medication or treatment regimens for the underlying chronic condition will minimize these risks?
5. Since influenza symptoms can be similar to symptoms of other respiratory illnesses, does the organization have protocols to determine whether symptoms are due to influenza or chronic medical conditions? Do protocols address cohorting to decrease the risk of transmission from infected individuals to chronic disease patients during this evaluation?
6. Has the organization identified the pharmacotherapies that patients receive from its facilities and reviewed its utilization of prescription drugs?
7. What pharmacotherapies have been ordered for patients with pandemic influenza or as prophylaxis against influenza?
8. What potential interactions, contraindications, warnings, and precautions among pharmacotherapies ordered can occur for chronic co-morbid conditions from which patients may suffer?
9. What systems are in place to monitor for potential interactions, contraindications, warnings, and precautions among pharmacotherapies generally?
 - a. Do these systems need to be expanded or updated to address potential interactions, contraindications, warnings and precautions among pharmacotherapies used for prophylaxis or treatment of influenza, chronic co-morbid conditions, and/or chronic concomitant medications?
 - b. Has the organization identified maintenance and updating of these systems as a mission-critical component of care which must be maintained during an influenza pandemic?
10. What interventions may be used to avoid adverse events due to interactions, contraindications, warnings and precautions? Does the organization

need to plan to stock additional or different medications to address drug interactions?

11. What systems are in place to determine chronic co-morbid conditions and concomitant medication use when patients are seen in the emergency department or outpatient clinics, or when referred for direct admission by a physician or on transfer from another institution? Do these systems need to be expanded or updated to address potential interactions, contraindications, warnings, and precautions among pharmacotherapies in the setting of pandemic influenza and a resultant anticipated increase in admissions and outpatient visits?
12. What systems are in place to provide appropriate informed consent and other patient education materials about potential interactions, contraindications, warnings, and precautions related to chronic co-morbid conditions, concomitant medications, and therapies used for prophylaxis against or treatment of pandemic influenza?
13. What systems are in place to accept, store, and dispense investigational medications generally? Do these systems need to be updated or expanded to cover investigational therapies that may be used for prophylaxis or treatment of pandemic influenza?
14. Do research-related policies and procedures of the organization address implementation of modified standards for research and the use of investigational drugs in public health emergencies as approved by regulatory agencies?
15. What systems are in place to assess inclusion of new drugs on the institutional formulary? Do these systems need to be updated or expanded to cover new therapies that may be introduced for prophylaxis or treatment of pandemic influenza, recognizing that the risk/benefit calculus may be different in this context than with more-common infectious agents?
16. What systems are in place to control appropriate off-label utilization of drugs and biologicals? Do these systems need to be updated or expanded to address off-label use of drugs and biologicals approved for other uses that may be ordered or prescribed for prophylaxis or treatment of pandemic influenza?

E. Communications Issues

Communications typically is recognized as the most common area of failure in emergency planning and response. By its nature, an emergency typically requires the participation of many different agencies and entities, each of which may have a different goal which drives its particular response. Through careful planning before an emergency, communications challenges can be minimized.

1. Has the organization established multiple lines of communication with other response agencies?
2. Has the organization worked with other response agencies to:
 - a. Clarify the relative roles of the responding agencies;
 - b. Specify the relative priorities of the response effort; and
 - c. Exercise use of different communications methods, given that failures of primary communications realistically will occur?
3. Has the organization established alternative means of communicating with staff in the event of an influenza pandemic, including non-technical means of communication?
4. Has the organization established a website page which is dedicated to providing information regarding emergency response efforts to its community?
5. Has the organization established a location on its intranet which is available to employees and will provide information to employees regarding emergency response efforts during an influenza pandemic?
6. Has the organization worked with other response agencies to identify a Public Information Officer (PIO)?

If so:

 - a. Has the PIO established a strong working relationship with the media?
 - b. Have healthcare providers and administrators been trained to refer all media questions to the PIO?
7. Has the organization established videoconferencing, Carebridge or similar capabilities to permit patients and family to remain in contact without the need for in-person visits?

8. Has the organization prepared guidance regarding release of patient information in the event of an influenza pandemic?
 - a. Has training been provided to caregivers to permit appropriate release of patient information when needed?
 - b. Has educational information been prepared for family and friends of patients?
 - c. Has the organization developed a procedure and designated authorized personnel to provide information regarding patients to family and friends?
 - d. Has the organization consulted with legal counsel to develop a consensus on release of patient information during an influenza pandemic?
9. Has the organization worked with industry groups to develop websites and other resources for “best practices” in pandemic planning and response?
10. Has the organization worked with local leaders, including religious leaders, to develop a communications plan in the event of an influenza pandemic?
 - a. Has the organization facilitated a discussion between public health, ethics and local religious leadership regarding pandemic response?
 - b. Has the organization considered a means of engaging disenfranchised populations in the conversation?
 - c. Has the organization prepared communications capabilities in all major languages represented in the community? Does the organization’s website, telephone service and other means of communication accommodate multiple languages?
11. Does the organization’s communications plan reflect the challenges of accurately communicating complex information to highly stressed audiences?
 - a. Are messages pre-planned, using short, simple sentences?
 - b. Are messages available in the languages present in the community?
 - c. Are messages targeted to the appropriate audience?
 - d. Have messages been prepared based on reasonably anticipated issues?
 - e. Has the organization considered use of a mass notification system?

F. Healthcare Provider’s Relationship with the Emergency Management System and Public Health Authority

An influenza pandemic will have far-reaching consequences for all communities in the United States. From governors and public health authorities (at the state level) to mayors and local law enforcement agencies (at the local level), each state’s emergency management system will be activated to help coordinate the pandemic response. Emergency plans and decisions could directly affect individual providers. For instance, many state pandemic plans call for medical triage centers that will screen individuals before they report to a hospital. Understanding the larger emergency management system will help an organization operate effectively as part of the larger community response during the pandemic.⁶⁸

Under the Pandemic and All-Hazards Preparedness Act,⁶⁹ funding by the Health Resources Services Administration (HRSA) for hospital preparedness is shifted to two new programs, the Hospital Preparedness Program and the Health Care Facility Partnership Program. Organizations should review appropriate steps to request or receive direct grants under these new programs in partnership with hospitals, local healthcare facilities, political subdivisions, and/or states.

1. Declaring Emergencies

Large-scale emergencies⁷⁰ and major disasters⁷¹ are declared by the President of the United States upon request from the governor(s) of the affected state(s), and must “be based on a finding that the [emergency or major] disaster is of such severity and magnitude that effective response is beyond the capabilities of the State

68 See, e.g., CALIFORNIA DEPARTMENT OF HEALTH SERVICES, *supra* note 54, at 93.

69 Pandemic and All-Hazards Preparedness Act, Pub. L. No. 109, 120 Stat. 2831 (2000, Supp. IV) (codified as amended in scattered sections of 42 U.S.C.).

70 An “emergency” for purposes of obtaining federal funding is defined as “any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States.” 42 U.S.C. § 5122(1) (2004).

71 For purposes of obtaining federal funding, a major disaster is defined as “any natural catastrophe (including any hurricane, tornado, storm, high water, wind-driven water, tidal wave, tsunami, earthquake, volcanic eruption, landslide, mudslide, snowstorm, or drought), or, regardless of cause, any fire, flood, or explosion, in any part of the United States, which in the determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance under this chapter to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused thereby.” *Id.* § 5122(2).

and affected local governments and that Federal assistance is necessary.”⁷²

- a. Who has authority to declare a disaster, a state of emergency, or a public health emergency at the state level and at the local level?

If a local agency or legislative body has the authority to declare a disaster, a state of emergency, or a public health emergency, are there limitations on the scope of the declaration?

- b. Do any state or local laws provide a definition of disaster, state of emergency, or public health emergency?

If so, does an influenza pandemic meet that definition?

- If not, does the entity with the authority to declare a disaster, a state of emergency, or a public health emergency consider an influenza pandemic an emergency situation that would trigger a declaration?
- c. Using the stages identified by the WHO and the federal government of an influenza pandemic,⁷³ at what stage during an influenza pandemic will the entity’s state or local authorities declare a disaster, state of emergency, or a public health emergency?
 - d. What is the impact of a declaration of a disaster, state of emergency, or a public health emergency?
 - Is the authority of the governor, mayor, or another government executive enhanced? If so, how could the enhanced authority affect the entity?
 - Is the authority of any state or local agencies enhanced? If so, how could the enhanced authority affect the entity?
 - Does a declaration change the organization’s obligations and/or operations? If so, how?

2. Emergency Plans and Management

Planning is at the heart of sound emergency response, and it is found in all activities engaged in by the organization for its daily operations. Emergency planning weds the knowledge that an emergency will occur with the routine management activities the institution conducts.

- a. Is the emergency operations plan (EOP) for the organization’s state current and available for reference?
- b. Does the organization’s county, township, or municipality have a local EOP?
- c. Does the organization’s state have a mass-casualty or similar response plan?
- d. Does the organization’s county, township, or municipality have a local mass-casualty or similar response plan?
- e. Does the organization’s state have a specific response plan for an influenza pandemic?
- f. Does the organization’s county, township, or municipality have a specific local response plan for an influenza pandemic?
- g. If the organization has an emergency operations plan, is it consistent with the Joint Commission’s new Emergency Management Standards effective January 1, 2008?⁷⁴
- h. Does the organization have an influenza pandemic plan that addresses the following aspects of hospital operations, as recommended by the DHHS Pandemic Influenza Plan, published in November 2005:⁷⁵
 - Disease surveillance;
 - Hospital communications;
 - Education and training;
 - Triage and clinical evaluation;
 - Facility access;
 - Occupational health;
 - Use and administration of vaccines and antiviral drugs;
 - Surge capacity;
 - Supply chain and access to critical inventory needs; and
 - Mortuary issues?
- i. If the organization does not have a response plan for pandemic influenza, has a multidisciplinary planning committee been formed to draft a plan?

⁷² *Id.* §5170.

⁷³ See WORLD HEALTH ORGANIZATION, WHO GLOBAL INFLUENZA PREPAREDNESS PLAN: THE ROLE OF WHO AND RECOMMENDATIONS FOR NATIONAL MEASURES BEFORE AND DURING PANDEMICS (2005), available at www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf (last visited Feb. 21, 2008); NATIONAL STRATEGY, IMPLEMENTATION, *supra* note 56, at Ch. 3.

⁷⁴ JOINT COMMISSION: HOSPITALS MANUAL, *supra* note 14, at EC 4.11 – 4.18.

⁷⁵ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HHS PANDEMIC INFLUENZA PLAN (2005), available at www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf (last visited Feb. 21, 2008).

- j. Does the organization's influenza pandemic plan incorporate the distinct phases of a developing pandemic codified by the WHO?⁷⁶
- k. Does the organization's influenza pandemic plan incorporate the response stages outlined by the Department of Homeland Security?⁷⁷
- l. Does the organization's influenza pandemic plan incorporate the CDC's Pandemic Severity Index (PSI)?⁷⁸
- m. Once a disaster, a state of emergency, or a public health emergency is declared, what agencies are responsible for overall management of the state and local responses?
- Where will each agency conduct its operations? Has a state or local emergency operations center been established?
 - Does the organization have a way to communicate directly with this operations center? Does that method of communication have a back-up?
 - Does the organization (or a group representing it, e.g., a hospital association) have a representative who reports to the emergency operations center?
- n. How is the emergency management system located in the provider's state organized?
- Does it follow the National Response Framework's Emergency Support Function (ESF) structure?⁷⁹
- o. If the applicable state plan follows the National Response Plan's structure, is the health and medical section covered under ESF Annex 8?⁸⁰ If not, under what section is the state's health and medical response covered?
- p. What is the lead agency for the health and medical section of the state-level emergency management system? What is the lead agency at the local level?
- q. Does the applicable state or local EOP require a unified medical command (UMC) system under the health and medical section?
- If the plan requires UMC, who is in charge of the UMC?
 - If the plan does not require UMC, does it call for any other type of state, regional, or local coordination of the delivery of medical care?
 - If a plan requires UMC or coordination of the delivery of medical care, do any applicable laws provide liability protection of a private healthcare provider during the UMC or coordination?
- r. Does the state or local EOP address an increase in the number of deaths that will result (directly and indirectly) from an influenza pandemic?
- If so, does the EOP establish emergency rules governing the death system?
 - If so, does the organization understand how these emergency rules will affect the handling of human remains?
 - Does the organization have a plan to increase its morgue capacity within its facility during an influenza pandemic?
 - If expansion of morgue capacity is not possible within its facility, is the organization working with partners on plans to address increased mortality rates in its facility?
 - If the applicable state or local EOP establishes emergency rules governing the death system, does it provide liability protection for the individuals or organizations following those rules?
- s. Has a state or local agency been established or designated that can order the diversion of patients during a disaster, a state of emergency, or a public health emergency?

76 WORLD HEALTH ORGANIZATION, *supra* note 80.

77 In May 2006, the federal government published the "Implementation Plan of the National Strategy for Pandemic Influenza" and divided its response actions into seven stages (0 – 6). See NATIONAL STRATEGY, IMPLEMENTATION, *supra* note 56. These stages currently are being incorporated into state and local pandemic influenza plans as triggers for different public health responses.

78 In February 2007, the CDC published the "Interim Pre-Pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States." U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, COMMUNITY STRATEGY FOR PANDEMIC INFLUENZA MITIGATION (2007), available at www.pandemicflu.gov/plan/community/commitigation.html (last visited Feb. 21, 2008) [hereinafter CDC COMMUNITY STRATEGY]. This CDC planning document introduced the Pandemic Severity Index (PSI). CDC will use the PSI to help state and local response partners to match the type and intensity of public health interventions to the severity of the pandemic.

79 DEPARTMENT OF HOMELAND SECURITY, NATIONAL RESPONSE FRAMEWORK (2004), available at www.fema.gov/emergency/nrf (last visited Feb. 21, 2008) [hereinafter NATIONAL RESPONSE PLAN].

80 *Id.* at ESF #8.

- Does the applicable state’s emergency preparedness plan or pandemic preparedness plan address the direction or relocation of patients who are to receive medical screening in an alternative location?⁸¹
 - If not, is the organization familiar with how these state plans are amended? Does the organization have the right to request an amendment? If so, what is the procedure for requesting an amendment?
- t. If the state plan follows the National Response Framework’s structure, is the law enforcement section covered under ESF Annex 13?⁸²
- If not, under what sections are state and local law enforcement covered?
- u. What is the lead agency for the law enforcement section of the state-level emergency management system?
- What is the lead agency at the local level?
 - Are the organization’s security officers commissioned by a state or local agency? If so, are they subject to centralized command and control under the state or local emergency operations plan?
- v. Has the organization developed an ICS based on the Hospital Incident Command System (HICS)?⁸³
- Has the organization identified individuals to fill the following ICS roles:
 - Incident Commander;
 - Public Information Officer;
 - Safety Officer;
 - Liaison Officer;
 - Operations Chief;
 - Planning Chief;
 - Logistics Chief; and
 - Finance/Administration Chief?
 - Has the organization shifted, or is it in the process of shifting from the HEICS to HICS?
 - Has the organization identified individuals who might be asked to fill the new HICS position of Medical/Technical Specialist?
 - If individuals have been identified to fill these roles, have they been provided with and trained on the Job Action Sheets for their respective positions? Has training been provided to all individuals who may fill that job?
- w. Does the organization have an evacuation plan?
- Does the organization’s pandemic influenza plan address surge capacity that may require reallocation of hospital department space and resources to address expanded patient care? Does the evacuation plan address both horizontal and vertical evacuations of specific areas of a hospital?
 - Can the horizontal and vertical evacuations sections of the plan be adjusted to allocate space and resources during a pan flu surge?
 - Does the evacuation plan identify temporary staging areas where patients can be held while one area of a hospital is closed and another is prepared for receiving the patients?
 - Does the evacuation plan rely on agencies which may have conflicting demands?
 - Does the evacuation plan contemplate the use of private vehicles?
- If so:
- Has the organization discussed insurance issues with its vehicle insurance carrier?
 - Has the organization addressed provision of care during transport?
 - Has the organization worked with local school administrative districts to discuss conversion of school buses to ambulances and provision of drivers?
- x. Does the organization have a comprehensive security plan for its facility?
- Does the organization have standard operating procedures (SOPs) that outline the triggers for implementation of the security plan?
 - Do the SOPs specify any circumstances of an influenza pandemic that would trigger implementation of the security plan?
 - Does the security plan or SOPs address the following aspects of facility operations:
 - Ingress and egress to the facility as a whole, including procedures and tools to

81 See 42 U.S.C. § 1320b-5(b)(3) (2000, Supp. IV). The Secretary DHHS can waive Emergency Medical Treatment and Labor Act (EMTALA) requirements during an emergency under certain circumstances. See *id.* § 1320b-5(b)(3)(B).

82 NATIONAL RESPONSE FRAMEWORK, *supra* note 86, at ESF #13.

83 The original Hospital Emergency Incident Command System was based on a system developed in California. It has been substantially updated and now is known as Hospital Incident Command System. State of California, Emergency Medical Services Authority, www.emsa.ca.gov/hics/hics.asp (last visited Feb. 21, 2008).

- facilitate redirecting individuals trying to enter the facility for legitimate purposes as well as lockdown protocols or limiting access to one entrance and exit;
- Restricting movement between different departments by way of card key access or other locking mechanisms;
- Securing controlled substances and other pharmaceutical supplies;
- Securing patient isolation and quarantine areas (*e.g.*, negative pressure rooms);
- Securing access to facility grounds and parking lots;
- Providing secure transport from off-site employee parking to the facility;
- Securing tunnels and walkways that connect buildings;
- Securing and establishing alternate locations for ambulance loading and unloading;
- Securing access to air ambulance landing pads; and
- Securing access to public roads serving the facility's campus?

3. Government Authority and Jurisdiction During an Emergency

On the federal level, the Secretary of DHHS has the authority to declare a Public Health Emergency.⁸⁴ The Secretary of DHHS makes a determination that a Public Health Emergency exists after consultation with appropriate public health officials. State law determines who can declare a state public health emergency. Generally, the authority to make such a declaration rests with the governor of state public health officer.

- a. What state or local agency or officer has authority to order an evacuation of an impacted jurisdiction?
 - Is that agency or officer authorized to allow facilities to shelter-in-place during an otherwise mandatory evacuation?
 - If certain facilities are permitted to shelter-in-place, what requirement must be met, and what procedures must be followed?
 - Has the organization considered the impact that an influenza pandemic, and the resulting patient surge, would have on a partial or total evacuation order?
- b. Do any state or local laws authorize government to require healthcare providers, includ-

ing hospitals, to provide healthcare or provide the use of its facilities during a disaster, a state of emergency, or a public health emergency?

- If so, do these or any other laws provide liability protection for the healthcare providers that are required to provide healthcare or provide the use of its facilities?
- c. Do any state or local laws authorize governmental or emergency response officials to require non-healthcare providers to assist during an influenza pandemic, including authority to commandeer equipment and other assets?

If so:

 - Who has this authority?
 - Does that individual/entity have the authority to commandeer or assume command or control over healthcare assets?
 - d. Is the applicable state or local public health authority authorized to order compulsory examination, treatment, or vaccination during a disaster, a state of emergency, or a public health emergency?

- If so, can those examinations, treatments, or vaccinations be ordered to take place at the organization's facilities?
- If the government can order these examinations, treatments, or vaccinations to take place at the organization's facility, will the government agency ordering these activities pay the costs of the procedures or provide the materials and supplies necessary to conduct these activities?
- If the government can order examinations, treatments or vaccinations to take place at the organization's facility, will the examination, treatment or vaccine be provided by a governmental employee or the facility's employee?
- If the organization's employees will be performing the examination, treatment or vaccination, are liability protections available?
- If the organization's employees will be performing the examination, treatment or vaccination, must an organization medical record be completed or merely governmental documentation?
- Will the government provide security during mandatory examination, treatment or vaccination activities?

⁸⁴ 42 U.S.C.A. § 247d.

- If the government can order these examinations, treatments, or vaccinations to take place at the organization's facility, do any restrictions exist regarding the organization's billing for these procedures?
- e. Does a certificate of need or other license limit the facility's bed or patient capacity?
- If so, can such requirements be suspended pursuant to a declaration of emergency?
 - If not, what agency has authority over that certificate of need or license?
 - Does the applicable agency have a process to permit the organization to surge beyond the bed or patient limitation during a disaster, a state of emergency, or a public health emergency?
 - How will the organization request that permission? When is the organization required or allowed to seek permission? Is the organization required to pre-identify the patient surge areas when seeking the permission? If pre-approval of the patient surge locations is required, does the organization then have to notify the regulatory agency before the surge locations are put into use? What are the limits on that permission? Is it required that the surge take place within the four walls of the licensed facility? Will the organization be allowed to use all of the buildings on its campus or under its ownership?
- f. Does a certificate of need, other license, or any state or local law limit the organization's delivery of medical care to a specific campus, certain buildings, or other geographic location?
- If so, what agency has authority over that certificate of need or license?
 - Will this agency allow the organization to move beyond that limitation, and establish an off-site surge or triage facility if it has reached its internal surge capacity?
 - How will the organization request that permission? When is the organization required to seek permission? Are there pre-determined limits on the types of medical services that can be offered at an off-site surge facility? Is the organization required to pre-identify the off-site surge facility when seeking the permission? If pre-approval of the off-site surge facility is required, is the organization required to notify the regulatory agency before the off-site surge facility is put into use?
- g. Does any federal, state, or local agency require certain staffing ratios for the organization's facilities or specific departments within the organization's facilities?
- If so, what agency has authority over those staffing ratios?
 - Will this agency allow the organization to expand the staffing ratios to address the expected surge in patient care during an influenza pandemic?
 - How will the organization request that permission? When is the organization required to seek permission? Are there pre-determined limits on the types of medical services that can be offered under expanded staffing ratios? Is the organization required to pre-identify circumstances that will or might give rise to expanded staffing ratios?
- h. What local law enforcement agencies have jurisdiction over the organization's facilities?
- What local law enforcement agencies have authority to control the public road access to the organization's facilities?
 - If the organization operates a facility campus interspersed with public roads, to what extent can personnel control access to those roads?
 - If control of these roads is prohibited during normal circumstances, would control be allowed if a disaster, a state of emergency, or a public health emergency were declared, or if a local or state EOP was activated?
4. Disease Surveillance
- As a particular strain of influenza evolves into a pandemic strain and moves across the world, the characteristics of the disease will change. Healthcare facilities treating influenza patients will need regular and frequent updates on the status of the influenza pandemic, treatment guidelines, and infection control protocols.
- Once an influenza pandemic starts to move across the world, agencies such as WHO, CDC, and state and local health departments will be developing and modifying case definitions for the disease. As the pandemic moves from WHO Phase 3 into Phases 4 and 5, many state and local pandemic influenza plans call for increased surveillance of influenza-like illness.
- a. Has a state or local public health agency been designated or established from which the organization can receive updates on the

influenza pandemic, including disease transmission and symptom characteristics?

- b. Are surveillance updates immediately provided to EMS providers? Does the EMS agency have a protocol for ensuring road crews are updated? Have clinical screening and treatment protocols been developed and distributed to EMS personnel?
 - c. Has a state or local public health agency been designated or established from which the organization can receive the most recent treatment and infection control guidance from the CDC?
 - d. Is the organization required by state or local law or agreement to participate in a health alert network through which disease updates can be sent?
 - If so, does the organization have formal policies, procedures, or protocols in place to meet this requirement?
 - Do the policies, procedures, or protocols include details about forwarding updated information to front-line medical staff, including paramedics, emergency room nurses and physicians?
 - Even if participation in a health alert network is not required, does the organization have policies in place to receive such information and disseminate it to front-line staff?
 - e. Does the organization have policies or protocols in place to incorporate these case definitions into initial patient screening and evaluation?
 - f. Does the organization have patient-encounter or interview forms that are sufficient to identify possible cases of pandemic influenza?
 - If so, has front-line medical staff been trained on using the form?
 - If not, has the applicable state or local public health agency developed patient-encounter or interview forms that are sufficient to identify possible cases of pandemic influenza?
 - g. Does the organization have plans in place to conduct initial patient screenings outside the facility, and thus separate possible cases of pandemic influenza from other health conditions?
 - Has the organization worked with taxi companies to train drivers on safe transport of patients including plans regarding the use of surge and isolation facilities?
- Has the organization worked with local public transport to arrange for changes in route and schedule which might be necessary during an influenza pandemic for transport of either staff or patients to care sites?
 - h. How will this initial separation be communicated to the public?
 - i. Have protocols been developed for distinguishing between pandemic influenza and other respiratory diseases during initial patient screening?
 - If so, has front-line medical staff been trained on the protocols?
 - j. To which state or local public entities can the organization disclose relevant PHI for surveillance purposes without first obtaining a valid HIPAA Privacy Rule authorization from the patient? Are staff trained regarding which authorities to whom they may disclose PHI for disease surveillance?⁸⁵ See also the HHS Office of Civil Rights Decision Tool for Disclosures for Emergency Preparedness under the HIPAA Privacy Rules, available at www.hhs.gov/ocr/hipaa/decisiontool. This Decision Tool is reproduced in Appendix C.
 - k. What law authorizes this entity to collect or receive PHI for the purpose of preventing or controlling diseases, such as pandemic influenza?
 - What is the scope of information that this law allows the public health authority to obtain?
 - Do any laws expand the scope during a disaster, a state of emergency, or a public health emergency?
 - l. If a patient is identified as a possible case of pandemic influenza, does the organization have protocols in place to collect a sample and send it to a CDC-designated reference laboratory in the Laboratory Response Network that has controlled comparison material of the pandemic influenza strain?⁸⁶
 - m. Is the organization required by state or local law to report cases of influenza-like illness to the state or local public health authority?
 - Is the organization required to submit reports to multiple agencies?

85 45 C.F.R. § 164.512(b) is part of the federal HIPAA privacy rules, and carves out an exception for sharing protected health information with an entity that qualifies as a public health agency.

86 For more information on the Laboratory Response Network, see U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, The Laboratory Response Network Partners in Preparedness, www.bt.cdc.gov/lrn/ (last visited Feb. 19, 2008).

- n. Is the organization required to report the results of rapid influenza tests?
- o. Is the organization required to conduct and report the results of positive influenza cultures?
- If so, does the organization have formal policies, procedures, or protocols in place to meet this requirement?
- p. Does the organization participate in the CDC's United States Influenza Sentinel Provider Surveillance Network (Sentinel ILI Network)?⁸⁷
- q. Because increased absenteeism of healthcare employees could be a first sign of pandemic influenza in a community, does the organization have protocols or systems in place to track employee absenteeism? Do those protocols or symptoms allow for tracking of influenza-like illness?
5. Pandemic Response
- An influenza pandemic will overwhelm most healthcare facilities quickly, and the influx of patients exposed to and infected with the pandemic strain will pose a risk to patients and staff not yet exposed or infected. As the world learned during the Severe Acute Respiratory Syndrome (SARS) outbreak of late 2002 and 2003, healthcare professionals may have higher infection rates than the general population during a severe disease outbreak. The surge also will tax staffing and material resources.
- In a severe influenza pandemic falling within PSI Category 4 or 5, hospitals and other healthcare facilities will be overwhelmed and might have to cancel or limit elective procedures. These procedures contribute more than their share to a hospital's profit margin. To maintain patient and income flow, facilities might need to open alternate or alternative care site (ACS) facilities at on-site or off-site locations so that the facility can serve more patients.
- a. As the disease moves from WHO Phase 3 into Phases 4, 5, and 6, does the organization have plans or procedures in place to modify and enhance its infection-control practices to prevent spread of pandemic influenza to uninfected patients and employees?
- b. Does the organization have procedures or protocols to limit access to its facility by canceling elective procedures, accelerating the discharge of patients, or temporarily close the facility to new admissions or transfers?
- Who at the facility will make those decisions?
 - How will those decisions be coordinated with or communicated to the state or local public health agency?
 - How will the organization communicate these decisions to patients and physicians?
 - Has the organization arranged for transport and alternative care (*e.g.*, home health) for early discharges? Do transport plans acknowledge the likely unavailability of EMS for non-urgent transports?
- c. Does the organization have plans to address the surge in needed medical care?
- d. Have plans been established to initiate a triage assessment, so that personnel and material resources (*e.g.*, ventilators) can be allocated to patient that likely will derive the most benefit from the care?
- e. How will the facility address the increase need for patient care at the same time medical staff become ill and unable to work?
- Are plans in place to cross-train personnel to provide patient care?
 - Has the organization considered the use of nursing, medical and allied health students to provide care?
 - Has the organization considered the use of family members for certain non-skilled care? For skilled care after "just-in-time" training?
- f. How will the facility keep its physical plant operational while maintenance staff become ill and unable to work?
- Are plans in place to cross-train personnel to maintain hospital operations?
 - Has the organization considered seeking community volunteers with plant operations training and experience to supplement staff?
 - Are all plant operations fully documented to permit supplemental staff to perform these duties?

⁸⁷ For more information on the United States Influenza Sentinel Provider Surveillance Network, *see* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Flu Activity & Surveillance, www.cdc.gov/flu/weekly/fluactivity.htm (last visited Feb. 19, 2008).

- g. If the organization provides inpatient services, where will surge of influenza patients be placed within the facility?
- h. Have areas of the facility been identified where different levels of care can be provided to influenza patients?
- i. Will influenza patient care areas be separated from non-influenza patient care areas?
 - How will this separation be communicated to the public?
 - Does the organization have plans for ensuring the security of separated areas?
- j. Does the organization have procedures or protocols to implement worker-safety and health measures to lessen the effects on staff?
- k. Does the organization have policies and procedures to support telecommuting when possible?
 - Does the organization's information technology system have sufficient bandwidth to support increased use of telecommuting?
 - Does the organization have sufficient software licenses to permit a significant increase in remote access to computer systems?
 - Have employees whose jobs would permit telecommuting been trained in remote access procedures?
- l. Has the organization evaluated the possibility of re-locating non-patient care activities, (e.g., biomedical engineering) to an alternate location to minimize exposure of staff to contagion?
 - Do plans address activation and staffing of the alternate location?
 - Do plans address transport of necessary equipment to the alternate location from patient care locations?
- m. Will a working quarantine system be implemented?
- n. How will infection-control measures be implemented? How will compliance be monitored?
- o. Will the organization distribute and administer antiviral drugs to staff as prophylaxis, treatment, or both?
- p. How will the health of front-line staff be monitored? How will ill workers be treated? Will sick workers be directed to stay home? Are leave policies flexible enough to handle such directions or allow telecommuting for administrative support personnel?
- q. Have plans been established to allocate staff according to their disease status, so that workers who have already been ill with pandemic influenza may be called upon to care for new influenza patients?
- r. Have plans been established to house medical and other personnel at the facility to limit the exposure of family members to the pandemic strain?
- s. Does the organization have an ACS plan?
- t. Have any ACS locations been identified?
- u. Do the ACS locations require pre-approval from a state or local agency?
- v. Has the organization identified what medical services will be offered at the ACS?
- w. Has the organization identified how the ACS location will be staffed?
- x. Does the organization have detailed plans on setting up and supplying an ACS? Have those plans ever been tested in an exercise?
- y. Does the organization have any mutual aid agreements with other hospitals or healthcare providers?
 - If so, what has the organization agreed to do under the agreements?
 - If the organization fails to perform a responsibility under the agreements, are any damages or consequences specified?
 - Is there an escape or *force majeure* clause that covers truly catastrophic situations, such as a PSI Category 5 pandemic?
 - Are the mutual aid agreements sponsored or coordinated by a state or local government agency?
- z. Does the organization receive HRSA, CDC, or other federal funds through memoranda of agreements (MOAs)?
 - If so, do any of those MOAs require certain activities during a disaster, a state of emergency, or a public health emergency?
 - If so, are any damages or consequences specified in the event that the organization fails to perform a required service under the MOA?
- aa. Does the organization operate an air ambulance?
 - If so, does the organization need to acquire special permission or an exemption for run-

- ning flights if the federal government grounds flights in the applicable jurisdiction due to limited air control personnel?
- If the Federal Aviation Administration grounds flights during an influenza pandemic, will a general exemption be made for air ambulances?
 - If not, does the organization have to obtain special permission or an individual exemption?
 - If so, what requirements must be met, and what procedures must be followed?
- bb. If the organization is a for-profit organization, does it have a plan to sustain its financial viability during and after an influenza pandemic?
- cc. If the organization is a nonprofit organization, has it met all the requirements to be eligible for reimbursement from the federal government under the Stafford Act?⁸⁸
- Does the organization know what those requirements are?⁸⁹
- Would the organization qualify as a Private Nonprofit Facility?⁹⁰
 - Does the organization provide “Critical Services?”⁹¹
 - Does the organization know what materials and categories of work are eligible for reimbursement?
 - Does the organization know if any of its expenses would be eligible for reimbursement under the Federal Emergency Management Agency’s Disaster Assistance Policy?⁹²
 - Has the organization developed documentation packs that will demonstrate compliance with applicable laws and regulations as well as support reimbursement requests?
- dd. If the organization is not eligible for relief under the Stafford Act, does your client have business interruption insurance that will cover the financial disruption caused by an influenza pandemic?

88 Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. § 5121 *et. seq.* (2000, Supp. IV); *see also* the Federal Emergency Management Agency’s website on Public Assistance, at www.fema.gov/assistance/index.shtml (last visited February 19, 2008).

89 *Id.* § 5172(a)(3).

90 *Id.* § 5172(a).

91 *Id.* § 5172(a)(3).

92 U.S. DEPARTMENT OF HOMELAND SECURITY, FED. EMERGENCY MGMT. AGENCY, EMERGENCY ASSISTANCE FOR HUMAN INFLUENZA EPIDEMIC, DAP 8523.17 (2007), *available at* www.fema.gov/pdf/government/grant/pa/9523_17.pdf (last visited Feb. 21, 2008).

IV. PLANNING (BLUE)

The Planning Chief anticipates the course of events over the relevant time horizon, and oversees the incident planning process. At the initiation of the ICS organization for an incident, the Planning Chief is responsible for monitoring significant events and actions (Situation Status, or SITSTAT), and resources available and assigned to the incident (Resource Status, or RESTAT). In addition, the Planning Section maintains all relevant (or potentially relevant) incident documentation, and is responsible for developing a demobilization plan. Once a longer period becomes the relevant planning horizon, the Planning Chief shifts from a focus on the “next several hours” to an emphasis on “the next several days” as emergency operations commence and stabilize. Eventually, the Planning Chief prepares for the demobilization or “standing down” of the organization from the emergency.

The Planning Section as a whole determines how effectively an organization’s Operations Center functions. Within ICS/HICS, the Planning Section is built around information management: gathering, evaluating, prioritizing and displaying incident information in order to provide decision-making support for Incident Command and the entire response organization.

In a less ICS-specific sense, planning activities go well beyond the activities of a Section Chief or even the ICS organization as a whole. Planning is the heart of good emergency response, and is part of all activities in which the organization engages during its daily operations. Emergency planning weds the knowledge that an emergency will occur with the routine management activities which the institution conducts.

A. Privacy and Security of Protected Health Information

Healthcare providers would be well-served to revisit their HIPAA privacy and security policies and procedures with an influenza pandemic in mind. The protections of the HIPAA Privacy Rule continue to apply during disasters, but many of its requirements, such as the minimum necessary uses and disclosures as well as safeguards incorporate a “reasonable” efforts component.⁹³ The HIPAA Security Rule is concerned not only with the confidentiality of electronic PHI, but also

with the integrity and availability of that information.⁹⁴ This can be critical for patient care and follow-up, particularly for those hospitals whose primary medical record systems are electronic.

It may be possible to convert paper documents into electronic reproductions. Once scanned, an off-site backup copy of important data should be maintained. Under the HIPAA Security Rule, Covered Entities are required to develop and implement effective plans for disaster recovery and business continuity.⁹⁵ Testing of these plans is critical.

Section 1135 of the Social Security Act permits the Secretary of DHHS to temporarily waive or modify the application of requirements of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) programs during an emergency such as a pandemic, including COP, pre-approval requirements, healthcare provider licensure (so long as the provider is licensed in their home state and not excluded from practice in the host state), sanctions related to violations of the Emergency Medical Treatment and Labor Act (EMTALA), and sanctions related to certain violations of the HIPAA Privacy Rule, such as the requirements to honor a request to opt out of the facility directory and to distribute a notice of privacy practices.⁹⁶

1. Do the HIPAA privacy and security policies of the organization address a catastrophic disaster such as an influenza pandemic?
2. Is the organization familiar with, and has it trained its workforce in, the uses and disclosures of protected health information related to emergency circumstances, including a pandemic, that are permitted by the HIPAA Privacy Rule?
3. Does the Notice of Privacy Practices address the exceptions for an emergency, such as an influenza pandemic?⁹⁷
4. Does the employee education emphasize that, while certain provisions of the HIPAA Privacy Rule may be subject to an enforcement waiver, privacy protections and privacy rights continue to be essential to operations? If the organization furnishes health care items or services to Medicare, Medicaid or SCHIP recipients and has instituted a disaster protocol, then has it developed a plan for documenting the 72 hour timeline within which it may use the enforcement waiver?

93 *Id.* See also U.S. Dept. of Health & Human Services Office for Civil Rights, Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situations (Sept. 2, 2005) available at www.hhs.gov/ocr/hipaa/KATRINAAnHIPAA.pdf (last visited May 28, 2008).

94 45 C.F.R. § 164.306 (2007).

95 45 C.F.R. § 164.308(a)(7) (2007).

96 42 U.S.C. § 1320b-5 (2000, Supp. IV).

97 See 45 C.F.R. § 164.520 (2007) (requiring covered entities to notify individuals of the permitted uses and disclosures of protected health information).

5. Does the organization have the capacity to convert to keeping a paper medical record in the event the electronic health record is not available?
6. Does the organization have contingency plans for communication of medical information?
7. Do the plans reasonably protect the privacy of the PHI? Do the plans address disclosures to the Red Cross and other disaster relief organizations and public health authorities as well as disclosures made to locate individuals or their families?

B. Other State Regulatory Issues

States have specific laws that may impact the organization when preparing for pandemic influenza. Some of the areas an organization should review are discussed in the following section.

1. Reporting Obligations

Each state has its own requirements for reporting communicable diseases and conditions to local or state health departments who, in turn, report information to the CDC. Some local jurisdictions also may have communicable-disease reporting requirements. The time and manner of reporting likely will vary among jurisdictions and among diseases. Some state laws on communicable-disease reporting may provide immunity for some individuals making such reports.

- a. Has the organization identified the reporting laws applicable to communicable diseases in local or state jurisdictions?
- b. Has the specific influenza strain been identified by the local public health agency or state agency for reporting purposes?
- c. Has the organization identified the applicable local, regional, state, or national authorities it must contact for reporting purposes?
 - If the influenza pandemic is of animal origin, what communication needs to occur with agriculture and veterinary partners?
- d. Are those responsible for making the reports aware of the timeframes and procedures for reporting pandemic influenza?
- e. Has the organization’s staff been informed of confidentiality requirements whenever law mandates reporting outbreaks of communicable diseases to any government agency?
- f. Has the organization assessed the availability

- of legal immunity for a person making such a report?
- g. Has the organization distributed guidelines to personnel and medical staff describing permissible uses and disclosures of PHI for public health and other reporting purposes under HIPAA?⁹⁸

2. State Pharmacy Issues

- a. A healthcare organization needs to be familiar with legal requirements relating to the dispensing of prescription medications in emergency situations. What state laws and regulations affect the access to medications in an emergency? How, if at all, do the state pharmacy act and regulations address waiver of the refill requirements in the event of an influenza pandemic?
- b. What are the requirements for disposal of drugs for pharmacies in emergency situations?
- c. Does the state provide a mechanism for expanding the ways prescription drugs may be dispensed in an emergency?

3. State Institutional Licensing and Certificate-of-Need (CON) Issues

In planning for an influenza pandemic, a healthcare organization needs to be cognizant of state licensing requirements. Many states have CON laws that may also be relevant.

- a. What are the licensing requirements in the event a licensed healthcare organization (*e.g.*, a hospital or nursing home) needs to close or add beds to accommodate influenza pandemic patients?
- b. Does the state licensing authority have authority to waive, suspend or grant variances or exceptions from state licensure requirements in the event the organization needs to add beds or otherwise increase licensed space during an influenza pandemic?
 - What are the applicable criteria for obtaining any such relief?
 - What is the process for obtaining relief?
 - Is there a time limitation on the relief from licensure requirements?
- c. If the organization is located in California, how will the state’s mobile hospitals (in terms of deployment, operation and management) affect the plans of the organization?

98 Health Insurance Portability and Accountability Act, Privacy and Security Rules, 45 C.F.R. Parts 160 and 164 (2007).

- If the State has a CON law, in what ways does it restrict expansion of facilities for the delivery of healthcare? For example, would it restrict a hospital's use of a nearby building as "surge" capacity?
- Does the state's CON law provide for exceptions, waivers or variances during an influenza pandemic?
- What are the applicable criteria for obtaining any such relief?
- What is the process for obtaining relief?
- Is there a time limitation on the relief from CON requirements?

4. Declaration of a State Public Health Emergency

State law determines who can declare a state public health emergency. Generally, the authority to make such a declaration rests with the governor or state public health officer.

- a. Under what conditions can the governor or state public health officer declare a public health emergency?
- b. What resources are available to the organization once the governor or public health officer has declared an emergency?
- c. What state-level communication process is in place for the identification of the resources?
- d. Who are the state and local officials responsible for developing local disaster plans, and for implementing aspects of those plans?
- e. How is the state distributing the August 2007 funding provided by DHHS?⁹⁹ What has the state done regarding pandemic flu preparedness? How do those plans coordinate with the applicable local and state plans?

C. New Federal and State Rules Requiring Pedigree Tracking for Prescription Drugs

Recent reports have identified the introduction of counterfeit drugs in the U.S. as a serious concern.¹⁰⁰ Counterfeit drugs pose significant health risks to the population, because no assurance can be made that these agents will show efficacy, and they may, in fact, be unsafe. The Prescription Drug Marketing Act required the Food and Drug Administration (FDA) to issue regulations to track the distribution of pharmaceuticals from the manufacturer through every step of the distribution chain (*i.e.*, the drugs' pedigrees).¹⁰¹ The goal behind these regulations is to reduce significantly the risk of having counterfeit drugs reach patients. Several states also have adopted pedigree rules aimed at reducing the likelihood that counterfeit drugs will cause patient harm.¹⁰²

The risk of introducing counterfeit drugs into commercial distribution channels may be increased substantially during a major social crisis (*e.g.*, a pandemic), because the response will involve significant increases in patients, visits, and admissions, as well as in receipt of and dispensing of drugs and biologicals. This may tax institutional systems that ordinarily are aimed at reducing the likelihood of receipt or dispensing of counterfeit drugs.

1. Has the organization identified the pharmacotherapies that patients receive from the institution, including review of the utilization of prescription drugs?
2. Has the organization identified the pharmacotherapies ordered for patients with pandemic influenza or as prophylaxis against pandemic flu?
3. Has the organization determined the current status of federal and state pedigree-tracking requirements for pharmacotherapies that patients receive from the institution?
4. Has the organization determined the current status of pedigree tracking or other tracking requirements for pharmacotherapies ordered for patients with pandemic flu or as prophylaxis against flu? Has the organization identified which

99 On August 30, 2007, DHHS issued a news release announcing \$75 million in supplemental funding (June 28, 2007 - \$430 million was distributed) to states for pandemic flu preparedness. See Press release, U.S. Department of Health and Human Services, HHS Announces \$75 Million in Supplemental Funding to States for Pandemic Flu Preparedness (Aug. 30, 2007), available at www.hhs.gov/news/press/2007pres/08/pr20070830a.html (last visited Feb. 21, 2008).

100 See, *e.g.*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, COMBATING COUNTERFEIT DRUGS: A REPORT OF THE FOOD AND DRUG ADMINISTRATION (2004), available at www.fda.gov/oc/initiatives/counterfeit/report02_04.html (last visited Feb. 21, 2008).

101 21 U.S.C. § 353(e) (2000, Supp. IV). Regulations were promulgated at 21 C.F.R. §§ 203.3(u), 203.50 (2007) and became effective December 1, 2006.

102 See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE (2006), available at www.fda.gov/oc/initiatives/counterfeit/report6_06.html (last visited Feb. 21, 2008).

distributors are authorized distributors of record, or record for each manufacturer of a pharmacotherapy those times as defined under federal pedigree regulations?¹⁰³

5. Has the organization identified systems in place to ensure that pharmacotherapies are received from authorized distributors of record, or that a pedigree is provided from a non-authorized distributor of record? Has the organization identified due-diligence mechanisms in place to confirm status of an authorized distributor or to check drug pedigrees? Has the organization assessed whether these systems need to be updated or expanded to address distribution and receipt of pharmacotherapies used for prophylaxis or treatment of pandemic flu?
6. Has the organization determined whether any pharmacotherapies provided by the institution, or which are ordered for patients with influenza, have been the subject of any special alerts about counterfeit prescription drugs?
7. Does the organization have systems in place to monitor and intervene to remove counterfeit medications? Has the organization assessed whether these systems are likely to be impacted by burdens placed on the institution to manage pandemic flu? Does the institution warehouse or stockpile large supplies of medications to treat pandemic flu? If the institution needs to obtain replenishments, and customary distribution channels cannot provide adequate supplies, is a process in place to ensure that uncommon suppliers comply with applicable federal and state pedigree requirements? How can the institution confirm any assurances it may receive from the suppliers?
8. Has the organization considered how to handle medications which patients may bring from home and which may have been obtained outside the usual supply routes (*i.e.*, Internet-ordered antivirals)?

D. Ethical Considerations in a Pandemic

During a pandemic influenza epidemic, the response provided by government and by healthcare providers will raise myriad ethical issues. If an influenza pandemic were to occur in the U.S., it is estimated that a three- to sevenfold increase in hospitalizations and a four-fold increase in outpatient visits would occur during the outbreak.¹⁰⁴ The human cost of a pandemic could number in tens of thousands of lives. Significant ethical implications will arise due to the potential for this magnitude of loss, the rationed allocation of scarce resources that will be required, and the “application of control measures” that will be undertaken to battle the epidemic.¹⁰⁵ The pandemic response efforts that will be mobilized by various federal, state, and local government actors, as well as by the private sector, will be reviewed critically for ethical as part of an organization’s planning process.

Planning efforts conducted by states and healthcare facilities alike need to include an opportunity for stakeholders to have thoughtful and thorough discussions concerning ethical issues. The policies and procedures ultimately adopted by these actors must incorporate responses to ethical issues for dissemination to all stakeholders and, when appropriate, to the public. By addressing ethical considerations at the planning stages, stakeholders may also achieve greater confidence in stakeholder action by the residents when the plans are implemented.

These principles should guide the planning approach used by the various healthcare actors to address the pandemic, and should be utilized in conjunction with this section of the checklist.

In exploring the ethical dimensions of pandemic planning and response, the following checklist was developed to assist planners to consider additional ethical issues. In an effort to target key actors in pandemic response and planning, the checklist is divided by specific actors: healthcare facilities, healthcare providers, patients, and state and federal government agents.

103 21 C.F.R. §§ 203.3(b), (bb) (2007).

104 Vickie J. Williams, *Fluonomics: Preserving Our Hospital Infrastructure During and After a Pandemic*, 7 YALE J. HEALTH POL’Y, L. & ETHICS 99, 109 (2007).

105 James C. Thomas et al., *Ethics in a Pandemic: A Survey of State Pandemic Influenza Plans*, 97 AM. J. PUB. HEALTH, S1, S26-31 (Supp. 1 2007). The article recommended a multi-faceted approach that healthcare institutions, government actors, and other responsive entities should take: (1) recognize that an ethical dimension to pandemic preparedness exists; (2) identify specific ethical issues; (3) identify guidelines and tools for ethical reasoning; (4) determine who is responsible for making which ethical decisions; (5) require responsible parties to engage in ethical decision-making; (6) implement the plans into action; and (7) evaluate whether the action achieved the intended result.

1. Healthcare Facilities

During a public health emergency, a significant number of Americans potentially will suffer economic losses and have limited access to healthcare. When added to the existing pool of uninsured patients and the possible insolvency of existing insurance plans, ensuring hospital reimbursement for services rendered is a serious concern. Insecurity regarding payment may hinder facilities from implementing emergency plans, and may discourage hospitals from allowing them to be designated as an isolation center.¹⁰⁶ Such decisions, however, will need to be made with an understanding of potential consequences under federal law. EMTLA provides that hospitals are obligated to treat or to screen *all* patients who seek emergency treatment.¹⁰⁷ Furthermore, another provision of the Social Security Act guarantees inpatient hospitalization and other types of post-hospital services be provided for Medicare and Medicaid patients.¹⁰⁸ Finally, the Social Security Act dictates that a hospital's emergency department cannot turn away any patient seeking medical treatment, regardless of that patient's insurance status.¹⁰⁹ By mandating these requirements, Congress recognized that hospitals have a social – and, arguably, an ethical – obligation to provide urgent healthcare to uninsured patients.

- a. Does the hospital have an ethics committee or ethics resource that is familiar with population ethics, public health issues and the unique ethical issues related to an influenza pandemic? Does the facility have an in-house ethicist?
- b. Does the hospital have a plan to access real time ethics advice for decision-making? If so, where will the ethics resource be located during an influenza pandemic (*e.g.*, command center)?
- c. Has the facility developed a triage protocol for all of its services, not simply for the scarce resources such as ventilators and has this protocol been reviewed by ethicists with expertise in a pandemic?
 - Does the facility have a phase-in triage as the pandemic rolls out or does triage take effect only after patient surge?
 - Has the facility's ethics resources examined, critiqued and shared with staff its analysis of

various triage approaches (*e.g.*, first come first served, age priority and maximization of life-span) and explained how the facility will make triage decisions?

- d. Is the hospital (as an individual facility and/or part of a larger organization) part of the community planning process?
- e. What is a hospital's obligation to accept indigent or uninsured patients during a pandemic? In other words, what is the hospital's key mission?
 - To what extent is the mission affected by scarcity of resources (*e.g.*, staffing, supplies, medications)?
 - Does the hospital currently have a plan of sharing medical resources with other facilities in that particular community?
- f. Because Congress may authorize the Secretary of DHHS to waive EMTLA requirements,¹¹⁰ under what circumstances would the hospital consider itself unable to meet the EMTLA requirements?
 - What is the maximum capacity that the facility can manage to triage and admit patients, and does the facility participate in drill exercises?
 - Does the hospital have procedures or protocols relating to waiving EMTLA prior to the declaration of waiving EMTLA by DHHS?
 - Who at the facility will make these decisions?
 - How will these decisions be communicated to the state regulatory entity during the pandemic?
 - What are the potential regulatory and legal implications for waiving EMTALA obligations?
- g. If a hospital chooses to treat all incoming persons, will its triage process inadvertently spread infectious disease, namely by confining incoming patients in a closed area/emergency room?
 - Does the hospital have procedures or protocols relating to the triage process?
 - Who will be involved at the facility to make treatment decisions?

¹⁰⁶ Williams, *supra* note 140, at 110 - 12.

¹⁰⁷ Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C.A §1395dd (West 2007).

¹⁰⁸ Social Security Act, 42 U.S.C.A. § 1395d(a) (West 2007).

¹⁰⁹ EMTALA, 42 U.S.C.A. § 1395dd (West 2007).

¹¹⁰ Bioterrorism Preparedness and Response Act, 42 U.S.C. § 1320b-5 (200), Supp. IV).

- Does the triage protocol distinguish infectious outbreak versus a noninfectious calamity?
 - What are the regulatory consequences when deviating from protocols regarding the standard of care (e.g., when the facility is unable to provide protective respiratory masks or gloves to all incoming patients or to staff when the supply is low or exhausted)?
- h. What are a hospital's ethical obligations to existing patients if it opens its doors to a large volume of patients due to the pandemic?
- How will the facility ensure that existing patients will receive the appropriate resources for their care?
 - What procedures will be taken, including transferring the existing patients out of the facility, to prevent them from contracting the infection?
 - How will the facility develop these procedures to protect the general public while respecting individual patient's wishes?
 - Has the facility prioritized its clinical services such that as resources become more and more limited, particular clinical services can be shut down?
- i. To what extent will staffing shortages affect care to existing patients?
- Are emergency department physicians a part of the hospital staff? If not, will the applicable contractual terms affect the delivery of patient care?
 - How would the facility plan to keep a sustainable workforce during a pandemic, and how would its administrator respond to employees who refuse to work with infectious patients because of their personal reasons or beliefs? What are potential legal implications of these decisions?
 - Does the facility provide prophylaxis medications, transportation, financial incentives, and psychological and/or other social assistance to retain its workforce? In other words, what level of support does the facility feel obligated to provide for its employees?
 - Does the facility have plans to obtain temporary staff if needed, and at what capacity? To what extent will the financial capabilities inform the facility's ability to respond?

- Who will make these decisions in the hospital?
2. Healthcare Providers

Physicians typically address ethical issues that arise from their work with guidance from the Hippocratic Oath, the American Medical Association's professional code of ethics, the ethics policies of the facilities in which they work, and ethical guidelines imposed under state law.¹¹¹ Within the context of these guidelines, physicians generally have relatively broad autonomy in deciding what level of care should be provided to their patients. During a pandemic, physician autonomy will be limited by the scarcity of critical resources, hospital policies regarding public health emergencies, and the state and federal laws affecting the use and distribution of resources. Each of these limitations will create a variety of ethical issues for physicians.

a. The Ethics of Scarce Resources

A physician's ability to render life-sustaining aid to any one patient must be balanced with the need to provide care and resources to other ill patients.

- How will physicians determine to which patients they should allocate resources?
- Do physicians have a standard patient triage plan to address the pandemic situation, rather than use an *ad hoc* determination based on physicians' subjective judgment?
 - If yes, how is this plan created and by whom?
 - Has this plan been adopted or approved for use within the practice?
 - Does the plan decrease the potential of unfair access to care?
 - Is the plan available to the public such that they will understand how and why priorities are set before the emergency?
 - How does this plan affect the physician's ethical obligation to do no harm?
 - How does the plan balance the needs of the individual patient and the public health?
 - What is the principle guiding this assessment? Will the greatest good for the greatest number determine the results? Will the plan prioritize based on the greatest need, the patient's chance of survival, or on the patient's position within the life cycle?

¹¹¹ AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION (2006-2007 ed.).

- Does the physician have guidelines to deal with patients who refuse to consent to treatment or vaccination?
 - Are physicians informed about their authority to perform diagnostic tests, including experimental tests, without full patient consent?
 - Is a policy in place to assist physicians and other providers in managing ethical conflicts associated with quarantining or isolating individuals? Does the policy address quarantine or isolation concerns particular to minors?
 - Is a policy in place to deal with physicians or other care providers who show signs of illness but want to continue to treat patients?
- Does the physician have a standard plan for quarantine and isolation implementation?
 - Are physicians aware of the legal rights and remedies available to those in state-ordered isolation or quarantine?
 - Are physicians prepared to contend with individuals who refuse to comply with isolation and quarantine orders, or other orders?
- To what extent do physicians have legal immunity when rendering aid?
- Has an altered standard of care been considered for public health emergencies?

b. The Ethics of Experimental/Evidence-Based Medicine

Physicians have an ethical obligation to use accepted and proven methods of treatment. During a public health emergency, however, accepted treatment modalities may prove to be ineffective. In addition, providers will have to make decisions regarding the use of new or experimental vaccines that may become available during the course of the emergency.

- When are experimental treatments (*e.g.*, treatments and/or medication not receiving FDA approval) to be used?
- Does an institutional policy promote the review of these treatments by an institutional review board (IRB)? What occurs if the pandemic prevents the IRB from meeting? Can the IRB chair handle these

responsibilities in an expedited fashion? What occurs if the IRB chair is ill or unable to perform duties?

- Has a process been established regarding how informed consent will be handled in situations with an IRB, as well as when the IRB may not be able to meet because of the pandemic and loss of membership?
- If the physician uses experimental treatments, what are potential liability issues that the physician may have from patients and from government regulators of human experimentation?¹¹²
- Do physicians have ethical obligations to share information on treatment, including adverse events data that they have gathered with other practitioners in other facilities?

c. The Ethical Obligation of a Duty to Treat

The physician obligation to “apply [their] knowledge and skills when needed, though doing so may put [physicians] at risk”¹¹³ may require physicians to be at work during a pandemic even when the physician may have ill family members.

- To what extent are physicians immunized from liability when volunteering their services?
- How are physicians (and their families) prioritized in receiving vaccines and prophylactic therapies if they accept a duty to treat during a pandemic?
- Does a plan exist to compensate physicians for extended service during a pandemic?
- To what extent will physicians quarantined in their workplaces have access to basic services and care for their families?

3. Patient-Related Concerns

The general public seems to share a perception that all pandemic influenza patients will receive life-sustaining technology, medications, and services from healthcare care providers. The inevitable scarcity of resources during a public health emergency will raise ethical concerns about the allocation of scarce healthcare resources. During a pandemic, for example, makeshift facilities may be established to house or

112 The Office of Human Research Protections is responsible for overseeing compliance with federal regulations regarding the protection of human subjects. Regulations are located at 45 C.F.R. Part 46.

113 AMERICAN MEDICAL ASSOCIATION, DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE’S SOCIAL CONTRACT WITH HUMANITY (2001), available at www.ama-assn.org/ama/upload/mm/369/decoprofessional.pdf.

to treat patients; however, patients in these facilities may demand to be transferred to hospitals or other buildings that are better equipped or more comfortable.

a. During a pandemic, how are patients' ethical and legal rights to autonomy in treatment affected and how has this been communicated?

- How will patients and families be informed about physician decisions to provide patients with active treatment, as opposed to palliative care?
- How will patients be informed about the scarcity of resources, and the plans to distribute those scarce resources?
- In light of the fact that patients generally have the right to refuse even life-sustaining treatment, what policies have healthcare facilities created to balance this right with obligations to protect the public health? Are physicians informed about the legal rules in the provider's state concerning this issue?
- What is the obligation of the provider to transfer patients to other hospitals or buildings that are better equipped or more comfortable, and to what extent is the patient request accommodated?

b. How will disposition and potential destruction of human remains be addressed during a pandemic and how has this been communicated?

- Does a plan exist to address the ethical and moral treatment of remains prior to destruction or burial?
- Will religious and cultural traditions regarding funeral arrangements and burials be considered?
- How will proper identification of bodies and notification of family be conducted? Who will coordinate this activity? What regulatory implications do these procedures raise?

- How will potential research and data-collection efforts be handled?
- c. How will patients' privacy rights be protected during a pandemic and how has this been communicated?
- How will providers balance the rights of individuals to privacy with the need to alert those who may have been exposed? What is the underlying legal authority for these disclosures?
 - How will healthcare providers be responsive to the privacy concerns of individuals who are isolated or quarantined?

4. State/Government Agents

Confidential Red Cross reports discussing the 1918 Spanish Flu pandemic described public anxiety "akin to the terror of the Middle Ages" caused by the plague.¹¹⁴ A modern pandemic could disrupt basic critical functions, including utilities, public safety, emergency response, production, and supply chains.¹¹⁵ In response, government entities will have to act quickly.¹¹⁶ At a 2006 conference on Public Service and the Law, in which a need was addressed for a rapid government response to a potential influenza outbreak, Jack Schwartz, Maryland's Director of Health Policy Development, was quoted as stating that "Delay is deadly. Delay kills people."¹¹⁷ At the same time, Mr. Schwartz noted, "[We need to] try at least to find an appropriate point of balance between the need to empower government officials to deal with a public health emergency versus the need to preserve basic civil liberties on the other hand."¹¹⁸ Otherwise, "we stand the risk of making many unjust and regrettable decisions."¹¹⁹

Key leadership provided by state and federal actors will achieve better response and a lessened mortality rate as a result of pandemic influenza. Government actors must strive to incorporate and address ethical questions in their planning efforts. Transparency in all efforts will engender community confidence.

114 Illinois Department of Public Health, Pandemic Flu Summit Remarks (Mar. 17, 2006), www.idph.state.il.us/pandemic_flu/remarks.htm (last visited Feb. 21, 2008).

115 *Id.* at 5.

116 Conference, *Public Service & the Law: Federal State Governments Must Cooperate on Potential Flu Pandemic Response*, University of Virginia School of Law (reported by Zak M. Salih, Mar. 22, 2006), www.law.virginia.edu/html/news/2006_spr/birdflu.thm (last visited Feb. 18, 2008).

117 *Id.* (quoting Maryland Director of Health Policy Development Jack Schwartz).

118 *Id.*

119 *Id.*

- a. What is the appropriate balance between efficiency, equity, and accountability¹²⁰ in the government entity's overall pandemic planning?
 - How transparent is the planning process and actual plan?
 - How are communities involved in planning efforts?
 - Do any planning gaps exist due to the uncertainty in the underlying science? If so, to what extent should the government entity inform the public about these gaps?
 - How would state actors ensure transparency during the response efforts and plan implementation?
 - To what extent does the plan and response build in accountability?
- b. What is a government entity's responsibility to detect a pandemic and warn its citizens, or the citizens in neighboring localities?
 - Does the locality have a detection system in place? Does it have a procedure for warning its citizens or neighboring localities?
 - Who makes decisions on how to run the local and state detection systems?
 - Who makes decisions on when to warn its citizens? How is the communication handled to ensure informing the public without causing widespread panic?
 - How will these decisions be communicated to relevant state agencies during a pandemic?
 - What are the implications of false warnings? What are the implications of delaying warnings, or not sharing information with neighboring localities?
- c. How should a government entity enforce compliance with orders for isolation and quarantine, and what are the ethical considerations?
 - To what extent does the state allow an individual to not comply with an order for isolation and/or quarantine? How does the government address due process concerns?
 - What is the role of the judiciary with regard to due process?
 - To what extent should law enforcement use deadly force to respond to a pandemic?
 - Who decides when physical force should be used and to what extent? To what extent do law enforcement officers have legal immunity in attempting to force the public to comply with policies and other governmental mandates?
 - How will "use of force" decisions be communicated to relevant state agencies during a pandemic?
- d. How should a government entity identify and track outbreaks?
 - Who should have access to tracking information?
 - What is the potential impact on ethnic and geographic communities?
 - At what point does the need for name-based information outweigh individual privacy rights? How will the individual privacy rights be protected, and what are the current protections?
 - By whom and by what methods will privacy protections be communicated to the patients/public? How will these protections be communicated by government entities, and how will it be incorporated in planning efforts?
 - Does the scale of the pandemic influenza outbreak affect tracking efforts? If it does, how will it affect the government response and tracking efforts?
- e. What is the responsibility of healthcare providers and state agencies to develop plans to distribute scarce supplies (*e.g.*, ventilators and prophylaxis)?
 - Does the healthcare facility have a plan to address scarcity of resources? Has the state considered a plan to address scarcity of resources from an overall state perspective?
 - How are ethical concerns related to distribution of scarce resources being addressed? How is this plan communicated? How are these ethical considerations incorporated into the planning process? Does the plan require the use of ethicists?

¹²⁰ Elaine Gadd, M.D., identified efficiency, equity, and accountability as the main goals underlying pandemic planning. WORLD HEALTH ORGANIZATION, GLOBAL CONSULTATION ON ADDRESSING ETHICAL ISSUES IN PANDEMIC INFLUENZA PLANNING 3 (2006), available at www.who.int/trade/Ethics_PI_consultation_report_WHO_2006.pdf. (last visited Feb. 21, 2008).

- Who decides which providers will gain access to what supplies, equipment, and prophylaxis? To what extent does the state interest for its citizens supersede those of individual healthcare providers?
 - How will these decisions (at the state and the provider levels alike) be communicated to staffing at healthcare facilities/providers?
 - What role do ethicists play in determining distribution and prioritization?
 - What will be communicated to the public when this distribution plan is put into effect?
 - Who will be given priority? Will the prioritization address those who are ill, versus those exposed to illness?
 - What priority will volunteers and first responders receive?
 - How will equipment (*e.g.*, ventilators) be prioritized and used?
 - Are facilities working with others in their geographical regions to coordinate redistribution of scarce resources?
 - How will the facility demonstrate transparency in its policies, protocols and practices relating to allocation of scarce resources, especially those that result in withdrawal of life support?
- f. What are the ethical concerns if the state or local government actor stockpiles scarce resources?
- How will the state determine what resources to stockpile?
 - How will the state determine distribution of those resources that are stockpiled?
 - What are the ethical considerations involved in determining government stockpiling?
 - How will the stockpiled resources be distributed or allocated?
 - To what extent could stockpiling of medications (for example) contribute to a shortage of drugs for current use, and for use during a pandemic? How will government actors the shortage?

V. LOGISTICS (YELLOW)

The Logistics Chief arranges for the needed support to operations, including delivery of food and other supplies; communication and transportation; assessment and safe use of the facility, if in question (*e.g.*, following an earthquake or explosion); labor pool; staff support and equipping of rooms and alternate-care sites if evacuation or relocation becomes necessary.

A. Protection of Employees and Maintaining Operations

In addition to their role as providers of healthcare services, healthcare institutions are employers. In this context, healthcare institutions must comply with myriad federal and state laws and regulations.¹²¹ In the event of an influenza pandemic, institutional personnel of all varieties will be called upon to perform various functions, both within and outside their typical scope of duties. Preparing for and dealing with the aftermath of a pandemic will involve an array of duties not only to the public and individual patients, but to the institution's employees as well.

Although the laws and regulations discussed in this section apply specifically to the employment relationship between healthcare institutions and their employees, it is important to note that some providers and other personnel work as independent contractors rather than as employees. Institutions should consider the effects of independent-contractor status with respect to the ability to use certain personnel in the event of an emergency, particularly if such individuals have relationships with more than one institution. Moreover, public-sector healthcare institutions also must bear in mind liability issues that might arise under various civil-rights statutes.¹²²

1. General Considerations

On November 1, 2005, the Department of Commerce, DHHS, Homeland Security promulgated a National Strategy for Pandemic Influenza (National Strategy). In part, the National Strategy called upon critical infrastructure entities to assist in the national planning efforts by developing contingency plans to protect employees and maintain operations during a pandemic. The

National Strategy emphasized that entities that provide critical services, such as healthcare, have special responsibilities to maintain delivery of essential goods and services.¹²³ An implementation plan for the National Strategy was announced on May 3, 2006, which included not only more than 300 "actions" for federal, state and local governments, but clear expectations for private sector employees, among others.¹²⁴

Every healthcare employer immediately should take affirmative steps to comply with this strategy, giving specific focus on workforce and employment-related issues to create or supplement emergency preparedness plans that will ensure maintaining the maximum attainable "productivity" and "service" possible under anticipated circumstances should a pandemic become a reality. In developing an influenza pandemic preparedness plan, healthcare providers should consider the following personnel-related issues.

- a. Has the healthcare provider designated an influenza preparedness coordinator who has responsibility for planning and responding to a pandemic from the employment perspective?
- b. Has a formal written influenza preparedness plan been established that addresses workforce and staffing issues during a pandemic?
 - Does the plan address the means to attain and maintain maximum productivity, services, and patient care in the event of a pandemic, including identification of, and delegation to, key personnel in executing the plan?
 - Does the plan recognize the need for staff rest periods while maintaining adequate staff support?
 - Once the plan is developed, will periodic education and training of the line employees, supervisors, administration, and members of the medical staff be conducted?
 - Has the organization's human resources department reviewed (and, if necessary, revised or supplemented) the following employment policies:
 - Americans with Disabilities Act and Special Needs Accommodation;
 - Attendance and tardiness;

¹²¹ For an in-depth discussion of the federal and state laws and regulations affecting workforce management issues, see American Health Lawyers Association, Teleconference Series, *Planning for Pandemonium: Pandemic Flu and Other Disasters*, at Part III (Jan. 23, 2006).

¹²² See generally 42 U.S.C. § 1983 (2000, Supp. IV).

¹²³ See NATIONAL STRATEGY, *supra* note 56, at 11.

¹²⁴ See NATIONAL STRATEGY, IMPLEMENTATION, *supra* note 56.

- Cross-training;
 - Daycare;
 - Employee Assistance Program;
 - Electronic communications;
 - Emergency response;
 - Employee health and hygiene;
 - Employee physicals;
 - Flexing up/down;
 - Fair Labor Standards Act (FLSA) Exempt Status;
 - Family Medical Leave Act (FMLA);
 - HIPAA (as pertains to employees);
 - Hours of work;
 - Leave of absence;
 - Licensure and certification;
 - “Mandatory” vaccinations;
 - Emergent modification or suspension of standard leave policies, including accounting for employees who have minimal accrued leave but cannot or are advised not to report to work;
 - On-call, call-in, and related communications;
 - Overtime;
 - Personal leave and absence;
 - Reduction-in-force and recall;
 - Return to work;
 - Sick leave;
 - Sickness and accidents;
 - Short-term disability and long-term disability coverage;
 - Telecommuting and remote work;
 - Temporary workers;
 - Timekeeping;
 - Transfers and assignments;
 - Uniforms and dress code;
 - Vacation and other paid leave;
 - Wellness program; and
 - Work shifts and shift rotation?
- c. Has the healthcare provider established policies to minimize the opportunities for transmission of the influenza virus through work-related activities (*e.g.*, promoting respiratory hygiene/cough etiquette; prompt exclusion of people with influenza symptoms)?
- Do the policies include guidelines to modify the frequency and type of face-to-face contact (*e.g.*, handshaking; seating in meetings; office layout; shared workstations) among employees, and between employees and customers, consistent with CDC recommendations?¹²⁵
 - Do the policies include department specific guidelines for employees who come in contact with food handlers, cashiers, employees sharing equipment and/or workspaces, and direct care providers?
- d. Has the healthcare provider identified and prioritized essential positions, units, and departments in the event of an influenza pandemic?
- Have minimum staffing requirements on a unit-to-unit basis been identified?
 - Have current staff resources been evaluated?
 - Do minimum staffing plans anticipate changes to job duties required as a result of the influenza pandemic?
 - Do minimum staffing plans reflect anticipated difficulty or time to complete tasks as a result of enhanced infection control procedures?
 - Do minimum staffing plans contemplate just-in-time training to increase capable staff?
 - Has the entity established policies to facilitate increased access to employees critically needed during a pandemic (*e.g.*, telecommuting, staggered shifts)?
 - Has the workforce been evaluated with respect to geographic-specific quarantines and other travel restrictions?
 - Is a plan in place to cross-train and prepare the ancillary workforce on an expedited basis (*e.g.*, independent contractors, temporary agency employees and travelers, employees in other job titles, retirees), and have such costs been budgeted? Do the independent contractors and the temporary and/or traveler agencies know what the healthcare provider’s expectations are with respect to staffing in the event of a pandemic?
 - Has the healthcare provider explored outsourcing to a third party or “partnering” with other similar employers outside of its region in the event that the effect of the pandemic is geographically limited and staffing support is required? If so, has the healthcare provider also considered issues related to the licensing, credentialing, and insuring of staff obtained from out-of-state?
 - In exploring alternative sources of staff, has the healthcare provider considered develop-

¹²⁵ CDC COMMUNITY STRATEGY, *supra* note 85.

ing a relationship with local companies that are likely to need diminished staff during an influenza pandemic?

- e. Has the organization developed multiple methods of communicating with staff regarding call-in to work during an influenza pandemic?
 - Does the plan include a means of communication which does not rely on technology?
 - Does the plan include frequent updates of contact lists?
- f. Has the healthcare provider's employees received materials and training on the development of personal emergency plans for themselves and their families during a pandemic? Do employees' families understand that, in the event of an influenza pandemic, their personal emergency plans may need to be initiated without the employees (or with them only calling into a designated contact), as they may be required to stay at the facility and assist in the facility's response? Do they have enough information about family emergency plans to feel confident that their families will be safe during the pandemic so they can focus on their responsibilities?
- g. Has the healthcare provider made provisions for emergency emotional, spiritual, psychological, and potentially psychiatric support to its employees who are dealing with anxiety caused by the influenza pandemic, as well as the personal effects of the pandemic? Does it have a plan to employ a triage or other mechanism in such a situation?
- h. Does the healthcare provider offer on-site "housing" for employees and contingent staff for prolonged periods?
- i. Can the healthcare provider accommodate and support personnel with child or elder care obligations during a pandemic?
 - Does the healthcare provider currently provide child and/or elder care? If so, is there a contract, and does the contract provide for additional coverage in the event of an emergency?
 - Does the healthcare provider currently pay for child and/or elder care?
 - If the healthcare provider does not provide child or elder care, will the facility assist the employee or have contingencies in place during an influenza pandemic to provide child and elder care for employees?

- j. Has the healthcare provider assessed and reviewed local commuting options and alternatives for employees and medical staff if public transportation becomes unavailable?

- k. Has the healthcare provider established plans for transport pools to assist staff in reporting for work?

- l. Has the healthcare provider coordinated with law enforcement to permit operation of a transport pool in the event local limitations on travel are imposed?

- m. Has the healthcare provider considered the effect of geographic-specific quarantines that can limit employee and medical staff travel, as well as vendor shipments of supplies?

2. Establishing Communication with Displaced Workers

During a disaster, many employees may find themselves in unfamiliar locations without access to communications that might make them inaccessible. The establishment of a communication mechanism for displaced workers is critical.

- a. Has the healthcare provider created active and passive systems that allow employees to make contact and receive information from any location?

- Website (public-access and password-protected);
- Toll-free telephone number with live and recorded information;
- Third-party, out-of-area contact;
- Capability to provide employee information through local media (*e.g.*, screen crawler);
- Default reporting guidelines; and
- Assigned position to track welfare of employees (and their families, if possible) and provide updates?

3. Policies and Procedures for Communicable Illness

Developing sound policies and procedures for dealing with communicable illness is critical to ensuring continued operations and minimizing the spread of disease, as well as protecting employees and medical staff from exposure to communicable illnesses.

- a. Are sound communicable illness policies and procedures in place?

- b. Does the communicable illness policy address the following:

- Definition of what constitutes a communicable illness or disease that is transmitted through work-related activities;
 - Responsibility of the affected employee or member of the medical staff to notify human resources of this condition;
 - Obligation of the healthcare provider to notify the local, state, and/or other appropriate health departments in accordance with applicable law;
 - Reasonable accommodation and leave for an employee or member of the medical staff, if any, based upon the health and physical condition of the employee or medical staff member, as well as the health and safety of the workforce;
 - Return to work when no substantial risk exists of transmitting the communicable illness or disease to others, and when the employee or medical staff member is able to perform the job's essential functions with or without a reasonable accommodation;
 - Permit a leave of absence when public health officials quarantine an employee or medical staff member, or believe that such employee or medical staff member should be absent from work; and
 - Detecting symptomatic employees and medical staff members before they report to duty?
- c. Has the organization developed a process to update the communicable disease policy based upon information from public health officials regarding use of PPE and other infection control procedures?
- How will such changes be communicated to employees and medical staff members?
- d. Does the communicable disease plan clearly state that compliance with work safety-related communicable disease actions is mandatory?
4. Furlough, Paid Leave, Unpaid Leave and Leave of Absence
- The healthcare provider should adopt a leave policy specifically designed for the event of an influenza pandemic to address ongoing employee rights, obligations, and responsibilities before, during, and after the pandemic.
- a. Does the policy permit paid or unpaid leave for employees at high risk of infection?
- b. Does the policy delineate the use of paid or unpaid leave for volunteer efforts?
- c. Does the policy explain the healthcare provider's Employee Assistance Program and the means to contact benefit providers to facilitate the use of such benefits should a pandemic occur?
- d. Does the policy permit donation of unused annual leave to a co-worker who may need the leave?
- e. Does the policy comply with the requirements of the Occupational Safety and Health Administration (OSHA) that an emergency action plan must include evacuation procedures and emergency escape if the employer has ten or more employees?¹²⁶
- f. If the healthcare provider offers paid leave to employees during a pandemic, have the terms of such payments been appropriately communicated to affected employees?
- g. Can the healthcare provider refuse requests from employees to use their accrued vacation and/or other paid leave during a pandemic?
- h. In addition to paid leave, are employees able to use unpaid leave provided by the FMLA¹²⁷ and Uniformed Service Employment and Reemployment Rights Act (USERRA)¹²⁸ for the specific circumstances delineated under the statutes in the outbreak of a pandemic?
- i. Are there policies in place to address the needs of employees without sufficient accrued leave?
5. Vaccination
- Influenza vaccination of employees in the workplace is an effective means of reducing both healthcare costs and productivity losses associated with influenza illness.
- a. Has the healthcare provider prioritized personnel for receipt of vaccine or antiviral prophylaxis?
- b. Does the healthcare provider encourage and track employees to have annual influenza vaccinations?
- c. Has the healthcare provider complied with

126 U.S. Department of Labor, Occupational Health and Safety Administration, E-tools: Develop and Implement an Emergency Action Plan (EAP), www.osha.gov/SLTC/etools/evacuation/implementation.html (last visited Feb. 19, 2008).

127 Family and Medical Leave Act, 29 U.S.C. §§ 2601-54 (2000, Supp. IV).

128 Uniformed Services Employment and Reemployment Rights Act, 38 U.S.C. §4301 *et seq.* (2000, Supp. IV).

Medicare and Medicaid Conditions of Participation (COP) regulations relating to vaccinations, as well as any state law requirements?

- d. Has the healthcare provider determined whether vaccination of employees and medical staff members will be voluntary or mandatory? If vaccination is mandatory, what happens if employees or medical staff members refuse?
 - e. Will employees and medical staff members be charged for influenza vaccinations?
 - f. Is a plan in place to address adverse reactions resulting from vaccinations that result in injury to employees and medical staff members?
 - g. Have human resources department and labor counsel reviewed HIPAA and possible conflict with Equal Employment Opportunity Commission (EEOC) guidelines as to “mandatory” wellness and vaccination programs?¹²⁹
6. Quarantine in the Workplace

In order to minimize the spread of the disease, healthcare organizations may need to consider the quarantine of employees exposed to influenza while performing their job responsibilities. This is particularly important during the gestation period to determine if exposure results in illness.

- a. Can the entity require employees to work in a quarantine area?
- b. If so, is the requirement incorporated into employee job descriptions?
- c. Does the entity include equipment availability (*e.g.*, personal protective equipment), proper vaccination, employee training, and universal precautions practices as part of its infection control program?
- d. What is an employer’s liability for employees harmed as a result of work in a quarantine setting?
- e. Has the entity developed a policy where administrative staff and other nonessential staff may work from home to minimize spreading

influenza (*i.e.*, a quarantine) and preserve access to core administrative functions?

- Does the policy include provisions for time-keeping if the healthcare facility does not have an e-time card system?
- Has the healthcare entity consulted its worker’s compensation carrier to ensure coverage for work-related injuries off-site (*e.g.*, at a home office)?
- Has the entity reviewed its insurance policies to determine if coverage is available for equipment losses in a home-office setting?

7. Statutory and Regulatory Considerations

As part of their influenza pandemic preparedness planning, the human resources department and labor counsel should analyze the implications of the following federal laws and regulations and their state-specific counterparts on certain aspects of the preparedness plan and the consequences of implementing the plan as proposed under such laws.

a. *Occupational Safety and Health Act*¹³⁰

OSHA applies to most private-sector employers. It is enforced by the Occupational Safety and Health Administration (also known as OSHA) within the U.S. Department of Labor (DOL).¹³¹ The act contains a “General Duty Clause” requiring employers to furnish a place of employment free from recognized hazards likely to cause death or serious physical harm.¹³² OSHA sets workplace standards for safety and for various toxic/chemical exposures.¹³³

- Does the emergency present a hazardous working condition triggering OSHA obligations and attendant employee protections? (In some circumstances, employees are permitted to refuse to work in the face of real danger of death or injury.)¹³⁴
- Has the organization considered OSHA’s guidelines for pandemic influenza pre-

129 *See, e.g.*, Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014 (Dec. 13, 2006); EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, ENFORCEMENT GUIDANCE: DISABILITY-RELATED INQUIRIES AND MEDICAL EXAMINATIONS OF EMPLOYEES UNDER THE AMERICANS WITH DISABILITIES ACT (ADA) (2000), available at www.eeoc.gov/policy/docs/guidance-inquiries.html (last visited Feb. 21, 2008).

130 Occupational Health and Safety Act of 1970, 29 U.S.C. § 651 *et seq.* (2000, Supp. IV).

131 For a further discussion of the Occupational Health and Safety Administration, see U.S. Department of Labor, Occupational Health and Safety Administration, U.S. Department of Labor, www.osha.gov (last visited Feb. 19, 2008).

132 29 U.S.C. 654(a) (2000, Supp. IV).

133 *See generally* 29 C.F.R. Part 1910 (2007).

134 *See* 29 C.F.R. § 1977.12(b)(2) (2007).

paredness for healthcare employers?¹³⁵

b. *Family and Medical Leave Act*¹³⁶

The FMLA requires employers with fifty or more employees to allow eligible employees to take up to twelve weeks of unpaid leave in a twelve-month period for a serious health condition (among other reasons).¹³⁷ A “serious health condition” is defined as an illness, injury, impairment, or physical or mental condition that involved inpatient care or continuing treatment by a healthcare provider.¹³⁸

Some states have analogous provisions, some of which are more generous than the federal law.

- Does FMLA cover an employee who is an asymptomatic patient subject to quarantine or isolation?
- Does FMLA cover an employee’s family member who is an asymptomatic patient subject to quarantine or isolation?
- Would a pandemic requiring the participation of all available personnel potentially excuse noncompliance with FMLA, except for those employees with absolute medical needs?

c. *Americans with Disabilities Act*¹³⁹

The ADA creates a variety of duties applicable to employers with regard to disabled employees. It prohibits discrimination against individuals with disabilities who are otherwise qualified for a job, and it limits pre-employment inquiries. A “disability” is defined as “a physical or mental impairment that substantially limits one or more of the major life activities of such individual.”¹⁴⁰ The ADA applies to employers with fifteen or more employees,¹⁴¹ and is enforced by the federal EEOC.¹⁴² Healthcare organizations and others must consider the following issues in an emergency, given the nature of an institution’s physically impaired employ-

ees for whom it might previously have provided an ADA accommodation.

- Do the individuals need any special considerations in ensuring that they:
 - Are located properly at the beginning of a pandemic;
 - Can go to (or be brought to) a staging area for contribution to the response; and
 - Can safely return to their offices (and responsibilities), and/or home, after the response?
- Would it constitute disability discrimination to fire an employee kept out of work due to quarantine or isolation? Does such a decision depend on the employee’s disease condition?
- Do any of the organization’s employees have a disability that will require special assistance in the event of an evacuation? Is the organization’s evacuation plan consistent with the needs and special requirements of each of its employees and medical staff members?
- Could a bona fide emergency convert an accommodation that normally is a reasonable one into an undue hardship?¹⁴³
- What should be the organization’s response where employee absenteeism mounts due to the stress of a particular emergency situation, and employees claim that they are suffering from post-traumatic stress disorder? Can such employees’ essential job functions be accommodated at home?

d. *National Labor Relations Act*¹⁴⁴

The National Labor Relations Act (NLRA) provides legal protection for employees engaging in “protected concerted” activity, and governs the relationship among unions, employees,

135 U.S. DEPARTMENT OF LABOR, OCCUPATIONAL HEALTH AND SAFETY ADMINISTRATION, PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE

GUIDANCE FOR HEALTHCARE WORKERS AND HEALTHCARE EMPLOYERS, OSHA 3328-05 (2007), available at www.osha.gov/Publications/OSHA_pandemic_health.pdf (last visited Feb. 21, 2008) [hereinafter OSHA GUIDANCE].

136 Family Medical Leave Act, 29 U.S.C. §§ 2601-2654 (2000, Supp. IV).

137 *Id.* §§ 2611-2612.

138 *Id.* § 2611.

139 Americans with Disabilities Act, 42 U.S.C. § 12101 *et seq.* (2000, Supp. IV).

140 *Id.* § 12102.

141 *Id.* § 12111.

142 42 U.S.C. § 12117.

143 An employer may reject a job applicant with a disability, or terminate an employee with a disability, for safety reasons if the person poses a direct threat (*i.e.*, a significant risk of substantial harm to self or others) that cannot be eliminated with a reasonable accommodation without violating the ADA. 42 U.S.C. §§ 12111(3), 12113(a), (b). This might cover an adverse employment decision with regard to an employee subject to isolation or quarantine due to exposure and the risk of infection.

144 National Labor Relations Act, 29 U.S.C. §§ 151-169 (2000, Supp. IV).

and employers. The NLRA is enforced by the National Labor Relations Board (NLRB), and governs most private-sector employers.

- Has the organization addressed special emergency circumstances (*e.g.*, overtime, lost wages, work rules, duty to bargain, grievances) ahead of time in existing collective bargaining agreements? If not, will such issues be addressed during the next renewal of collective bargaining agreements?
- What is the role of union stewards in an emergency situation?
- If a union exists within the organization, has the human resources department and labor counsel reviewed the collective bargaining agreement not only for any contract provisions that may be an impediment to planning and/or responding, but also the extent to which an obligation exists to first bargain with the union before implementing changes that could affect wages, hours, benefits, or terms and conditions of employment (or whether a specific waiver exists)? Will union employees be resistant to some of the changes necessary to properly plan to meet the potential demands of a pandemic?

e. *Fair Labor Standards Act*¹⁴⁵

This federal statute established minimum-wage, maximum hour, and overtime requirements. It requires that all non-exempt employees working more than forty hours a week receive overtime pay at a rate of one and one-half times the regular rate.¹⁴⁶ Hospitals and other healthcare institutions are covered employers under the FLSA. The FLSA is enforced by the Wage and Hour Division within the Employment Standards Administration of the DOL.¹⁴⁷

- Does time spent in mandatory quarantine count toward the calculation of compensable hours worked?
- In the event of a major emergency requiring all available personnel to work extended hours, could the good-faith provisions of the Portal to Portal Act¹⁴⁸ excuse noncompliance with economically burdensome overtime requirements (particularly where much of the emergency services provided might well be without any reimbursement or payment)?

¹⁴⁵ Fair Labor Standards Act, 29 U.S.C. § 201 *et seq.* (2000, Supp. IV).

¹⁴⁶ *Id.* § 207(a).

¹⁴⁷ *Id.* § 204.

¹⁴⁸ See 29 U.S.C. § 258 (2000, Supp. IV).

f. *Workers' Compensation*

State workers' compensation laws could be implicated if an employee contracts an illness on the job during the course of a public health emergency. This most likely will occur among first responders, law enforcement, and health-care workers. Emotional distress due to fear of exposure generally is compensable under these rules. During an influenza pandemic, health-care workers may experience injuries while rendering aid during the crisis. Workers' compensation also may be available for such injuries, depending on the activity causing the injury and the worker's job duties during the emergency. Where the injury involves a disease for which a vaccine or medication is available, the application of worker's compensation may depend on whether the person undertakes voluntary vaccinations or medical treatment. Finally, because workers' compensation laws vary significantly among the states, it is necessary to consult the workers' compensations laws of the jurisdiction in question.

- Has the organization reviewed workers' compensation statutes and regulations for the appropriate jurisdiction?
- Has the organization identified the potential liability for injuries, medical expenses, retirement benefits, and disability benefits incurred by the participation of employees and volunteers during an emergency?
- Has the organization determined whether other federal or state benefit programs may apply (or, alternatively, may bar submission of) a claim (*e.g.*, if state laws constitute an exclusive remedy) regarding certain disaster or disaster-preparedness situations?
- Has the applicable jurisdiction(s) established any compensation programs specific for certain activities (*e.g.*, vaccination), and is coverage different for employees as opposed to volunteers?
- Does a "no-fault" compensation program apply?
- Has the organization identified the availability of workers' compensation and/or other forms of financial support for persons unable to return to work because of an isolation/quarantine order?

- How will the organization address any potential legal liability for implementing “working” quarantine policies for essential service personnel?
- If an employee is quarantined, but is asymptomatic, is the employee entitled to compensation for the time spent in quarantine?
- Is the institution prepared for workers’ compensation claims (which may be filed months or years after the actual emergency event) claiming that the event and the even response negatively affected employees’ physical or psychological health?

g. *Other Compensation and Wage/Hour Issues*

Similar to other employers, healthcare institutions are subject to federal regulations that pertain to employee compensation and hours. In addition, organizations must comply with specific labor, compensation, and general employment laws relating to healthcare workers. For example, some states have enacted measures banning mandatory overtime for nurses and other healthcare professionals.¹⁴⁹

Meeting these obligations could present a significant challenge in the face of a major public health emergency, involving a redefinition of the work day, work week, and/or overtime. Some states currently are considering mandating the continuation of wages if employees are kept from work due to isolation or quarantine (policies that might be considered akin to jury duty). Such measures might enhance compliance by reducing individuals’ fears of lost income, and also afford protection for the rest of the workforce.

- Would discharging an employee who is absent because she is subject to quarantine be deemed illegal as a public-policy violation?
- What is the outcome if extended hours required of healthcare workers run up against legal limits on the hours that physicians and nurses can work consecutively, thereby limiting overtime or requiring minimum staffing ratios?

- Will payment be provided for temporary lodging, meals, or other incidental expenses?

B. Temporary Licensing and Credentialing of Healthcare Workers

1. Credentialing Professionals from Other Healthcare Entities

Because healthcare organizations credential and, for independent practitioners, grant privileges to all healthcare professionals who practice in their institutions, healthcare organizations need to have procedures in place for verifying credentials and granting privileges during and after an influenza pandemic.

- Has the organization adopted procedures for issuing disaster privileges to healthcare professionals in the event of an influenza pandemic?
 - Do the policies and procedures implementing the HIPAA Privacy Rule address the training of temporary healthcare professionals as well as their use and disclosure of protected health information consistent with the requirements of the Rule?
- Is the organization familiar with the applicable standards of the Joint Commission for Accreditation of Healthcare Operations (Joint Commission) for issuing disaster privileges to independent healthcare practitioners?¹⁵⁰
 - Has the organization adopted its own procedures in accordance with such accreditation standards?
 - If not, is an amendment to the medical staff bylaws contemplated and/or needed?
- Who has been designated in writing as the person responsible for activating the procedures for issuing disaster privileges to healthcare professionals?
 - Does the chief executive officer (CEO), medical staff president, or another official have the responsibility for activating disaster privileges?
 - Is this position identified in the emergency management plan and/or otherwise accessible to the emergency preparedness director (or other person responsible for the

149 See Ann E. Rogers et al., *The Working Hours of Hospital Staff Nurses and Patient Safety*, 23 HEALTH AFF. 202, 203 (2004); ME. REV. STAT. ANN. tit. 26 § 603(5) (2003) (stating that any nurse “who is mandated to work more than 12 consecutive hours” in the event of an unforeseen emergent circumstance “must be allowed at least 10 consecutive hours of off-duty time immediately following the worked overtime”); see also OR. REV. STAT. § 441.166 (2003); N.J. STAT. ANN. § 34:11-56a34 (2004).

150 JOINT COMMISSION FOR THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JOINT COMMISSION), COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK MS 4.110 (January 2008) [hereinafter JOINT COMMISSION, HOSPITALS MANUAL].

- facility's response to an emergency) in an influenza pandemic or other emergency?
- Has the responsibility for actual grant of privileges been delegated to individuals who are unlikely to be first-line command staff?
- d. What disaster conditions trigger the designated person's authority to activate the procedure for issuing disaster privileges?
- Are there different triggers for internal (single-facility only) and external (community-wide or regional) events?
 - Do the procedures require that the organization first have activated its emergency management plan?
 - Are the triggers based on resource levels (*e.g.*, staffing levels or bed availability), clinical (*e.g.*, actual or potential degradation in patient care which may be an outcome of resource constraints), or other criteria?
 - Does the emergency management plan permit activation in anticipation of a pandemic surge?
- e. Who decides how many temporary staff is needed and what types of professionals are needed?
- f. Who decides what compensation, if any, will be paid to the temporary healthcare professionals who respond to an influenza pandemic?
- Is the compensation set in advance?
 - Has the organization taken into consideration what effect compensating temporary healthcare professionals will have on state and federal professional liability and immunity from liability?
 - If compensation will be provided, has the organization considered how providing such compensation will comply with the Stark,¹⁵¹ anti-kickback,¹⁵² and other applicable laws and regulations?
- g. Who has been designated in writing as the person responsible for granting emergency privileges to healthcare professionals?
- Does the CEO, medical staff president, or another official have the option to grant emergency privileges pursuant to the Joint Commission standards?¹⁵³
 - Does the emergency management plan contemplate more than one individual granting privileges?
- h. Are the organization's emergency-credentialing processes consistent with the processes established under the organization's medical staff bylaws? If not, is an amendment to the medical staff bylaws contemplated and/or needed?
- i. Do the organization's policies and procedures for its employees also apply to the temporary healthcare professionals while they are working for the organization in response to an influenza pandemic? Does the employee handbook, or sections therein, apply to the temporary healthcare professionals?
- j. Has the organization considered how federal and state employment laws apply to the temporary healthcare professionals? Does compensation of the temporary healthcare professionals affect the analysis?
- k. Has the organization's respective state developed a state-based Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) for registering volunteer health professionals into a database, and credentialing the volunteers within the database in advance of an emergency, so that healthcare organizations experiencing an emergency can readily identify volunteers from the database?¹⁵⁴

151 42 U.S.C. § 1395nn (2000, Supp. IV); 42 C.F.R. §§ 411.350 – 411.389 (2007).

152 42 U.S.C. § 1320a-7b (2000, Supp. IV); 42 C.F.R. § 1001007.

153 JOINT COMMISSION, HOSPITALS MANUAL, *supra* note 14, at MS 4.110(2).

154 See Public Health Security and Bioterrorism Response Act of 2002 § 107, 42 U.S.C. § 247d-7b (2000, Supp. IV); see also U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Emergency System for Advance Registration of Volunteer Health Professionals, www.hrsa.gov/esarvhp/ (last visited Feb. 21, 2008); U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HRSA, EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS, (ESAR-VHP) PROGRAM, INTERIM TECHNICAL AND POLICY GUIDELINES, STANDARDS AND DEFINITIONS 55-57 (2005), available at www.hrsa.gov/esarvhp/guidelines/default.htm (last visited Feb. 21, 2008) [hereinafter ESAR-VHP GUIDELINES]. The federal government is awarding grants to an organization in each state that is responsible for implementing the respective state ESAR-VHP. The Health Resources and Services Administration has drafted the interim guidelines for implementing the state-wide ESAR-VHPs, which is referenced in this publication, but as of September 15, 2007, had not yet developed and implemented *ESAR-VHP Technical and Policy Guidelines, Standards and Definitions*. The interim guidelines address physician, behavioral health, and registered nurse volunteers, and the next set of guidelines will apply to other health professional volunteers. The Health Resources and Services Administration plans also to provide supplemental funding and technical guidance to help each state develop an ESAR-VHP.

- l. If the state does not yet have an ESAR-VHP, who has been designated to monitor the progress of the state's implementation of an ESAR-VHP and inform the organization of such progress?
 - m. How does the organization's respective state's ESAR-VHP work?¹⁵⁵
 - What are the details of the program?
 - What processes are in place?
 - n. Does the organization's process for granting emergency privileges incorporate the state ESAR-VHP, including a mechanism and process for contacting volunteers registered on the ESAR-VHP and bringing them to the organization in the event of an influenza pandemic?
 - o. Does the organization have a process in place for registering its own employees as volunteer health professionals in the ESAR-VHP?
 - If so, has the organization actively recruited its own employees to register as volunteers?
 - Does the organization's volunteer policy address the preference for employer-assigned duties if mobilized?
 - Has the organization implemented a mechanism for updating its employees' credentials who have registered in the ESAR-VHP?
 - Does the organization have a procedure for extending its employees as volunteers to other facilities? Does the organization have a process for recalling them if necessary?
 - p. Has the organization entered into Memoranda of Understanding (MOUs) with other healthcare entities within the state, whereby the organizations agree to share employees and equipment or transfer patients in the event of an emergency, such as an influenza pandemic?¹⁵⁶ If so, what are the procedures for credentialing and granting privileges to such shared employees through the MOUs?
 - q. Does the medical staff have an expedited process for verifying the volunteers' credentials and privileges as stated in the Joint Commission standards? Do the procedures provide for initiation of the verification process within seventy-two hours of receiving the volunteers or as soon as the immediate situation is under control, as required by the Joint Commission standards?¹⁵⁷
 - r. What procedures has the organization codified for supervising the activities of healthcare volunteer professionals who receive disaster privileges?
 - s. Who is designated as the person responsible for supervising the volunteer healthcare professionals?
 - Has the designated person received appropriate training on how to supervise healthcare volunteer professionals in an emergency situation?
2. Integrating Retired Healthcare Workers, Students and Others into the Workforce
 - a. Has the organization considered providing refresher training to permit retired healthcare workers to supplement existing staff in a pandemic?

If so:

 - Has the organization contacted retiree groups, retired staff and other sources of retirees to organize a retiree corps?
 - Has the organization developed training materials for the retirees with identification to permit immediate activation of the retirees when needed?
 - Has the organization established policies and procedures which will permit rapid activation of access for the retirees to electronic health record and other systems when the Emergency Management Plan is activated?
 - b. Has the organization considered the use of nursing, medical and allied health students, trainees and others to supplement existing staff in an influenza pandemic?

If so:

 - Has the organization addressed the ability to call upon student and trainees in the education affiliation agreements?
 - Has the organization integrated into student orientation materials information on disaster response and emergency call-in?

¹⁵⁵ For an example of a state's ESAR-VHP, see Connecticut Department of Public Health, State of Connecticut Emergency Credentialing Program for Healthcare Professionals, www.ct-esar-vhp.org/ (last visited Feb. 21, 2008).

¹⁵⁶ For model MOU language, see AMERICAN HOSPITAL ASSOCIATION (AHA) & DISTRICT OF COLUMBIA HOSPITAL ASSOCIATION (DCHA), MODEL HOSPITAL MUTUAL AID MEMORANDUM OF UNDERSTANDING (MOU) (2002), available at www.aha.org/aha/content/2002/pdf/ModelHospitalMou.pdf (last visited Feb. 21, 2008).

¹⁵⁷ JOINT COMMISSION, HOSPITALS MANUAL, *supra* note 14, at MS 4.110(6).

- Has the organization established policies and procedures which will permit rapid activation of access for the students and trainees to electronic health record and other systems when the emergency management plan is activated?
- c. Has the organization evaluated the possibility of using non-traditional caregivers to supplement staff in an influenza pandemic?
- If so:
- Has the organization worked with the state regulators to fully understand the scope of training required for non-traditional caregivers?
 - Has the organization developed plans for the use of:
 - Emergency Medical Technicians;
 - Paramedics;
 - Ski Patrollers; and
 - Lifeguards, professional guides and others?
- d. Has the organization developed policies and procedures that can be activated quickly to permit the use of non-traditional providers?
3. Use of Licensed Personnel from Other States
- When using licensed professionals from other states to assist in responding to an influenza pandemic, healthcare organizations need to address licensing issues that arise from accepting out-of-state healthcare volunteers or employees, because healthcare professionals are licensed by the individual states.
- a. Has the organization considered the potential liability to out-of-state healthcare professionals who respond to an influenza pandemic within the organization's facility and who do not hold a license in the organization's state?
- b. Has the organization considered the potential liability to the organization created by accepting unlicensed out-of-state healthcare professionals in response to an influenza pandemic?
- c. Has the organization's state adopted the provisions of the Model State Emergency Health Powers Act (MSEHPA),¹⁵⁸ or similar provisions authorizing a gubernatorial declaration of a "public health emergency" in the organization's state to suspend out-of-state licensure requirements for medical professionals and personnel?¹⁵⁹ What other powers or protections for healthcare professionals are incident to a gubernatorial declaration of a "public health emergency"?
- d. Has the organization's state adopted the Uniform Emergency Volunteer Health Practitioners Act,¹⁶⁰ which provides for reciprocal licensure for healthcare professionals among adopting states?
- e. Has the organization considered that the Secretary of DHHS may need to waive federal healthcare program physician licensure requirements to enable out-of-state physicians to provide care to Medicare enrollees?¹⁶¹ Has the organization considered the limitations on such a waiver considering that professional licensure is otherwise a state function?
- f. Have open lines of communication been established between the healthcare organization and the proper state agency responsible for communicating with healthcare organizations regarding public health emergencies? Can those lines of communication be utilized quickly and efficiently by the organization to notify the state of an influenza pandemic, so that the state can declare an emergency?
- g. Is the organization familiar with the Emergency Management Assistance Compact (EMAC) that grants license reciprocity to state-

158 MODEL STATE EMERGENCY HEALTH POWERS ACT (MSEHPA), A DRAFT FOR DISCUSSION § 804(a) (2001), *available at* www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf (last visited Feb. 21, 2008).

159 After Hurricane Katrina, Governor Kathleen Blanco declared a public health emergency to suspend out-of-state licensure for medical professionals and personnel. *See* La. Exec. Order No. KBB 2005-26, Declaration of Public Health Emergency to Suspend Out-of-State Licensure for Medical Professionals and Personnel (Sept. 2, 2005), *available at* www.doa.state.la.us/osr/other/kbb05-26.htm (last visited Feb. 21, 2008).

160 NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS, UNIFORM EMERGENCY VOLUNTEER HEALTHCARE PRACTITIONERS ACT (UEVHPA), 2007 INTERIM DRAFT (2007), *available at* www.law.upenn.edu/bll/archives/ulc/uihsa/2006annualmeeting_approvedtext.pdf (last visited Feb. 21, 2008).

161 AMERICAN HEALTH LAWYERS ASS'N, LESSONS LEARNED FROM THE GULF COAST HURRICANES 8 (2007) [hereinafter HEALTH LAWYERS, GULF COAST HURRICANES]. *See* Press Release, Secretary of Health and Human Services, HHS Declares Public Health Emergency for Hurricane Katrina, Waiver Under Section 1135 of the Social Security Act (Sept. 4, 2005), *available at* www.hhs.gov/katrina/ssawaiver.html (last visited Feb. 21, 2008).

- employed healthcare professionals responding to a request from a member state in response to an emergency declaration?¹⁶²
- h. Has the organization determined whether the state is prepared to request that other states send healthcare professionals to assist in the response to a pandemic pursuant to the EMAC?
 - i. Has the organization's state adopted the Interstate Civil Defense and Disaster Compact (ICDDC)?¹⁶³ Has the organization's state adopted other compacts among other states (*e.g.*, regional compacts) that grant license reciprocity?
 - If so, what types of healthcare professional licenses are granted reciprocity? Has the organization considered that such compacts are, as a general rule, limited to the sharing of state personnel, and thus typically do not provide a mechanism for sharing private personnel?
 - What process does the organization have for notifying the state of an influenza pandemic and the necessity for the state to make requests of other states pursuant to the EMAC, ICDDC, or any other compacts?
 - Given the likelihood that an influenza pandemic will affect multiple jurisdictions simultaneously, has the organization and/or the jurisdiction ascertained whether it is likely that other states will be able to donate providers through EMAC, ICDDC or other agreements?
 - j. Does the organization have a procedure for receiving these out-of-state healthcare professionals? Is the procedure integrated with the organization's procedures for credentialing and granting emergency privileges to the in-state healthcare professionals?
 - k. Is the organization familiar with the National Disaster Medical System (NDMS), a partnership among several federal agencies that provides healthcare and other services jointly with state, public, and private agencies in the event of an influenza pandemic or other emergencies?¹⁶⁴
 - l. Do any of the agreements into which the organization's state has entered include license reciprocity for healthcare professionals other than physicians? Has the applicable state adopted the Nurse Licensure Compact (NLC), which appears as Chapter 16 of the Model Nursing Practice Act (MNPA), which grants license reciprocity for nurses?¹⁶⁵
 - m. In addition to the various interstate compacts and partnerships already discussed, has the organization's state adopted statutes or regulations that waive licensure requirements for physicians during emergencies? If so, does the waiver include other healthcare professionals?
 - n. Is the organization familiar with statutes and regulations applicable to license waivers? Has the organization implemented a process for obtaining a waiver of the licensure requirements for physicians and other healthcare professionals according to the statutes and regulations?
 - o. Are licensed medical personnel employed by federal agencies permitted to assist during an emergency in the organization's state?
 - If so, is their ability to practice in an emergency contingent upon the state's licensure requirements?
 - p. Has the organization considered whether out-of-state healthcare professionals who are not licensed in the organization's state and who respond in an emergency may be held civilly or even criminally liable for their actions?

162 The Emergency Management Assistance Compact (EMAC) is a state-to-state agreement pursuant to which states have agreed to provide resources to support emergency/disaster response. Resources are available after a gubernatorial declaration of emergency and request for assistance. Because this is a state-level agreement, it cannot accommodate individual volunteers -- all individuals must be deployed through the state's emergency management function. A healthcare provider may receive minimal benefit from EMAC since the region in which a particular organization is located likely would be affected by an influenza pandemic such that the healthcare provider would need to look outside its customary contacts for parties who could lend assistance. *See* Emergency Management Assistance Compact (EMAC), Article V; *see, e.g.*, MINN. STAT. § 192.89 (2006); TEX. HEALTH & SAFETY CODE ANN. § 778.001 (Vernon 2006); VT. STAT. ANN. tit. 20 §§ 101-112 (2006).

163 *See* CAL. GOV'T CODE § 177-178.5 (2006); DEL. CODE ANN. tit. 20 § 3301 (2006).

164 HEALTH LAWYERS, GULF COAST HURRICANES, *supra* note 25, at 54 (2007); *see* 42 U.S.C.A. § 300hh-11 (2005).

165 *See* NATIONAL COUNCIL OF STATE BOARDS OF NURSING, MODEL NURSING ACT AND RULES (2006), *available at* www.ncsbn.org/312.htm (last visited Feb. 21, 2008). For state statutes adopting provisions of the MNPA relating to license reciprocity, *see* MINN. STAT. § 148.271 (2004); WIS. STAT. § 441.115 (2003); MO. REV. STAT. § 335.081 (2003). For a listing of states that have enacted the NLC, *see* Nurse Licensure Compact Administrator and National Council of State Boards of Nursing, Participating States in the NLC, www.ncsbn.org/158.htm (last visited Feb. 21, 2008).

- q. Has the organization considered whether the organization itself may be held liable for the actions of the out-of-state healthcare professionals?
- If so, what is the scope of the organization's liability?
- r. Do the temporary healthcare professionals' employers retain any potential liability for the healthcare professionals' actions while the professionals are responding to an influenza pandemic within the organization?
4. Healthcare Providers Acting Outside the Scope of their Licenses and Privileges
- An extreme influx of patients into a healthcare entity during an influenza pandemic may require healthcare professionals to act beyond the scope of their licenses and privileges in order to meet patient demands, at least until additional licensed healthcare professionals arrive. State laws vary regarding the scope of practice and professional liability in an emergency situation.
- a. Does the organization's jurisdiction permit healthcare professionals responding to a health emergency (*e.g.*, an influenza pandemic) to act outside of the scope of their licenses?
- If so,
- Which health professionals? Must they be volunteers, or can they also include employees?
 - Do statutes or regulations grant civil immunity for claims resulting from such actions?
 - Do statutes or regulations grant criminal immunity for claims resulting from such actions?
 - Has the organization reviewed job descriptions to identify common or similar skill sets to facilitate expansion of the scope of practice for its healthcare professionals?
- Has the organization worked with the state licensing agencies to identify types of healthcare professional licenses which have common or similar skill sets to facilitate expansion of the scope of practice?
 - Have "just-in-time" training materials been developed that build on similar skills to expand the scope of practice for healthcare professionals?
 - Has the organization or the jurisdiction evaluated the ability to use non-traditional licensed personnel in the facility?
- b. Does the organization's state have a "Good Samaritan" statute or a similar volunteer protection act?¹⁶⁶
- Does either statute protect or immunize volunteers or employees acting outside the scope of their licenses during a public health emergency, such as an influenza pandemic?¹⁶⁷
 - Has the jurisdiction developed a process for granting an expanded scope of practice to healthcare professionals?
- c. Has the organization considered the protection granted by the federal Volunteer Protection Act¹⁶⁸ which provides immunity for, among others, licensed personnel who volunteer without compensation at a nonprofit facility?
- d. What guidance, if any, does the state's ESAR-VHP program provide on the issue of professionals acting outside the scope of their licenses?¹⁶⁹
- e. If authorized in the applicable state, what is the scope of a gubernatorial waiver of requirements for healthcare-professional licensure in

166 *See, e.g.*, OR. REV. STAT. § 30.800 (2006); S.C. CODE ANN. § 15-1-310 (2006); TENN. CODE ANN. § 63-6-218 (2006); CAL. BUS. & PROF. CODE §§ 2395-2398 (2006); GA. CODE ANN. §§ 31-11-8; 51-1-29 (2006). Although the accuracy of the website has not been confirmed, *see* www.cprinstructor.com/legal.htm (last visited Feb. 21, 2008) for a listing of Good Samaritan laws.

167 The State of Georgia recently passed the Corporate Good Samaritan Act which provides additional liability protection to businesses and nonprofit organizations when they perform "Good Samaritan" acts in times of emergency or crisis. The Act provides that any natural person, association, organization, or private entity (directors, employees, and agents of such organization) working in coordination with and under the direction of an appropriate state agency who, voluntarily without the expectation or receipt of compensation, provides services or goods to another to prevent or minimize harm resulting from an emergency or disaster for which an emergency is declared by the Governor or federal agency, shall not be civilly liable to any natural person receiving such assistance as a result of a good faith act or omission unless the damage was caused by willful wanton negligence or misconduct of such natural person, association, organization, or entity. *See* Ga. Code Ann. § 51-1-29.2 (2008).

168 Volunteer Protection Act of 1997, 42 U.S.C. § 14501 *et seq.* (2000, Supp. IV).

169 For state guidance documents that have discussed the issue of licensed professionals acting beyond the scope of their licenses in an emergency, *see* Connecticut Department of Public Health, State of Connecticut Emergency Credentialing Program for Healthcare Professionals, Frequently Asked Questions, www.ct-esar-vhp.org/FAQ.asp (last visited Feb. 18, 2008); Virginia Department of Health, Medical Reserve Corps of Virginia, Frequently Asked Questions, www.vdh.virginia.gov/MRC/faq.asp (last visited Feb. 18, 2008).

the event of an influenza pandemic? Does such a waiver permit healthcare professionals to act outside the scope of their licenses, or does the waiver only enable out-of-state professionals to come into the applicable state and practice within the scope of their out-of-state licenses?¹⁷⁰

- f. Does the organization’s jurisdiction permit healthcare professionals to act beyond the scope of their licenses in a public health emergency, such as an influenza pandemic, and does the jurisdiction grant civil and/or criminal immunity for such actions?

If so:

- Must the professionals first obtain permission? If so, from whom? Is there a procedure in place for obtaining such permission?
- What events, if any, are required in order to trigger the procedures for professionals acting beyond the scope of their licenses?

If not:

- Has the organization considered the possibility that it may become necessary for professionals to act outside their licenses?
- Has the organization created a committee to evaluate this issue, along with its legal and ethical implications?
- Has the organization developed internal policies and procedures for such situations based on such a committee’s evaluation and recommendations? If so, what are the policies and procedures?
- What reasoning underlies the organization’s decisions? What defenses may it raise?

- g. What procedures are in place to ensure that healthcare professionals received by the organization from other healthcare entities in an influenza pandemic know the proper procedures for acting in situations that may necessitate acting beyond the scope of their licenses?

C. Supplementing Non-Caregiver Personnel

- 1. Does the organization’s emergency management plan address the need to supplement non-caregiver staff, such as maintenance, food services, information technology and biomedical engineering?

If so:

- a. Has the organization reviewed agreements with outside vendors who provide such services to evaluate contractual issues?
 - b. Has the organization worked with its outside vendors to ensure adequate staffing in the event of an influenza pandemic?
 - c. Has the organization considered community resources which might be used to supplement non-caregiver staff or other assets, such as use of church kitchens?
- 2. Has the organization worked with community resources to identify individuals who can supplement non-caregiver staff in the event of an influenza pandemic?
 - a. Has the organization worked with the local Community Emergency Response Team (“CERT”), Metropolitan Medical Response Team and other organized response organizations?
 - b. Has the organization considered the use of teachers, child care providers and others to address child care needs of staff and the child-life needs of pediatric patients?
 - c. Has the organization developed a list of community members who would like to volunteer in response efforts?

If so:

- Has the organization determined whether such volunteers wish to work only in roles that do not include exposure to patients?
- Has the organization provided advance training to volunteers regarding infection control and volunteer duties?
- Has the organization worked with state and local officials to consider and address means of obtaining prepared meals, groceries, medications and other requirements to individuals who are working at home or are quarantined at home?

D. Ensuring Adequate Supplies and Relationships with Vendors

During an influenza pandemic, healthcare organizations likely will find it difficult to maintain stable supply lines and adequate supplies of necessary resources. To ensure the availability of essential services, healthcare institutions should enter into agreements with utility companies, telecommunications providers and

¹⁷⁰ See, e.g., La. Exec. Order No. KBB 2005-26, *supra* note 23.

other critical suppliers to negotiate priority in repair and provision of services during a disaster.

1. Has the organization identified its critical supply vendors including:
 - a. Power sources;
 - b. Water;
 - c. Waste water disposal;
 - d. Air handling and indoor air quality;
 - e. Solid waste transport and disposal;
 - f. Fuels;
 - g. Electricity;
 - h. Patient care items;
 - h. Communications (including computer and Internet services);
 - i. Transportation vendors;
 - j. Laundry;
 - k. Food delivery and preparation services;
 - l. Janitorial supplies;
 - m. Vehicles parts and labor;
 - n. Mortuary services; and
 - o. Temporary staffing agencies?
2. Has the organization reviewed contracts with mission-critical vendors and suppliers to evaluate the possible impact of *force majeure* clauses on the ability of the organization to respond to an influenza pandemic?
3. Has the organization required suppliers to have and practice continuity of operations (COOP) and disaster recovery plans?
 - a. If so, does the COOP plan for mission-critical suppliers include a depth of authority of at least five qualified individuals for each critical role?
4. Has the organization prepared purchase orders and taken other actions necessary to ensure suppliers are prepared to immediately ship required supplies?
5. Has the organization evaluated other possible sources of mission-critical supplies?
6. Has the organization worked with its suppliers and community resources to ensure the ability to supply response teams in the community?
7. Has the organization discussed with suppliers the ability to return or receive a credit for pre-stocked influenza pandemic supplies that expire prior to use?

VI. FINANCE/ADMINISTRATION (GREEN)

The Finance/Administration Section Chief makes arrangements to ensure the organization’s continued financial health. This includes measures from recording the cost of emergency response to arranging credit for needed supplies and coordinating financial arrangements for emergency operations, such as costs associated with relocating patients from an evacuated building.

A. Provider Issues

Healthcare providers should review third-party payer agreements, as well as examine what other funding sources may exist to cover treatment rendered to patients during an influenza pandemic.

1. Do private health-insurance policies provide for coverage for treatment mandated by public health authorities (e.g., in the case of isolation)?
 - a. Is such treatment covered by a private payer, Medicaid, Medicare, or the Federal Employees Health Benefits Program (FEHBP)?
 - b. Can a determination of medical necessity by a public health authority trump a determination to the contrary by a private payer?
 - c. Are prior authorization/pre-certification requirements waived in the event of a major disaster or emergency?
 - d. Do payer agreements contain a *force majeure* clause that references epidemics or other public health emergencies as excluded events?
 - e. Are Medicare Disproportionate Share (DSH) payments¹⁷¹ or other similar funds available to cover the costs of this treatment if private-payer coverage falls short?
 - f. Can institutions address these issues in provider agreements with health plans?
2. What other funding sources are available to the institution?
 - a. Is business-interruption insurance available?
 - b. Does the county or state have funds to compensate an institution if private coverage is insufficient?

- c. Are federal funds available for any of the following:
 - Bioterrorism preparedness appropriations (and, if received, can the organization set aside these funds for cash-flow interruption in an emergency);
 - New CMS funds appropriated in the Medicare Modernization Act for hospitals to aid hospitals providing uncompensated care; and/or
 - Post-event appropriations?
- d. Can the institution create a new funding stream through patient surcharges or other mechanisms?
- e. Are Red Cross funds available?
- f. If the institution is designated as an isolation or quarantine facility, are there plans (on a federal and/or state level) to provide compensation to facilities if revenues are adversely affected?

B. Health Plan Issues

An influenza pandemic will affect payers as well as providers. Each payer will need to operate within the broader healthcare system to support access to care, protect the well-being and productivity of its own employees, continue business services (e.g., coverage, claims processing and payment, care management, nurse hotline, call center) and maintain the financial viability of our healthcare infrastructure. Many of the issues overlap with those faced by providers; many issues are unique. The following discussion is centered on private health plans.¹⁷²

1. General Readiness and Workforce Management

A failure to train and prepare for a pandemic could be a source of business and legal exposure to health plans in the event that the lack of preparedness is the cause of an inability to provide service during a pandemic.

 - a. Has the organization established an influenza pandemic response team, including representatives from the following operational departments:
 - Clinical services;

¹⁷¹ 48 See 42 C.F.R. §§ 412.106, 447.272(c) (2) (2004).

¹⁷² The CDC has published a valuable “Health Insurer Pandemic Influenza Planning Checklist.” U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, HEALTH INSURER PANDEMIC INFLUENZA PLANNING CHECKLIST, www.pandemicflu.gov/plan/workplaceplanning/healthinsurer.pdf (last visited Feb. 18, 2008).

- Human resources;
 - Legal;
 - Business continuity;
 - Information technology;
 - Corporate communications;
 - Security;
 - Claims;
 - Provider services; and
 - Member services?
- b. Does the organization's risk mitigation planning and training include the following elements:
- Development of pandemic response plan and attendant documentation;
 - Pandemic surveillance;
 - Employee education and awareness programs;
 - Acquisition of pandemic-related supplies;
 - Creation of a mechanism (automated or otherwise) for reporting of personnel work status;
 - Preparation and establishment of alternative work locations (home or otherwise) during a pandemic;
 - Training on social distancing practices;
 - Training and implementation on increased hygiene practices and work space cleaning;
 - Review of human resources and clinical policies for application in a pandemic;
 - Enhanced protocols regarding fitness for duty;
 - Communications planning (involving employees, members, providers, employers, and brokers);
 - Coordination with external stakeholders including providers, employers, public health agencies, and regulators;
 - Identification of vendor interdependencies and coordination with vendors; and
 - Simulation exercises?

2. Access to Care

The essence of managed care health plans is the agreement by the plan to make medical care available to members in return for a pre-paid premium.

- a. What steps has the payer taken to provide for an adequate network of providers in the event of a pandemic (during which demand for medical services will be extreme, and providers themselves may suffer from the illness)?
- b. Do "Act of God" or other contract exceptions protect the payer from this obligation in the event of a pandemic?
- c. Absent such an exception from the contractual obligation, what are the theories of liability (*e.g.*, breach of contract, consumer protection, unfair insurance practices, fraud) that might be asserted against payers where medical services are unavailable but the insurer collected pre-paid premium?
- d. Can access be increased by waiving the standard that care is only covered if received from network providers?
 - If so, how is compensation level determined (*e.g.*, average contracted rates; usual and customary rates in relevant market)?
 - Do existing provider contracts preclude such a network expansion (*i.e.*, are any exclusive or limited network provisions implicated)? If so, what is the exposure from a violation?
 - Does/can state law mandate a waiver of the network requirement in event of pandemic emergency? Does such law set the rates to be paid?
 - What are the implications for contracts with self-insured groups?
 - How does the plan maintain quality of service in absence of credentialing for non-contracted providers?
- e. Can access be increased by precluding coverage for elective services during the emergency?
 - Would provider, group, and member contracts allow such an emergency measure?
 - Must payers generally pay for "medically necessary" care under contracts?

- Is “medically necessary” a relative term? That is, does the standard change in an emergency? Does the provider need to look at definitions in relevant contract documents and applicable state laws?
 - Who decides what is elective? How is “elective” defined within the context of an emergency such as a pandemic?
 - Can/does state law mandate a halt to elective procedures pending such an emergency?
- f. Can access be increased by waiving or relaxing plan administrative requirements (*e.g.*, utilization review, prior authorization, pre-registration, referral requirements, medical management coordination, time limits for filing claims) during the emergency?
- Would group contracts allow for such an emergency measure? What happens to performance guarantees in group contracts tied to medical management programs?
 - Can/does state law effectively amend group contracts by mandating a waiver of such requirements?
 - If these requirements are waived, what happens to performance guarantees given by subcontractors to the plans with respect to savings to be achieved from the programs?
 - If these requirements are not waived, how does the plan ensure its ability to process claims appeals in a timely fashion during the emergency?
 - To the extent prior authorization requirements are not waived but an altered standard of care exists in a pandemic emergency, are plan medical directors and other personnel trained in the application of the adjusted standard of care?
 - What possible statutory and/or regulatory relief from network and administrative requirements may be available during an emergency? What possible statutory/regulatory preclusions of elective services apply during an emergency?
 - What triggers application of the law? Does the governor or other official declare an emergency?
- How is emergency defined in terms of geographic scope and duration?
 - Could a law be crafted to immunize plans from liability for access problems to the extent they comply with the law?
 - Would such laws be preempted by the Employee Retirement Income Security Act (ERISA) to the extent they impact coverage under group benefit plans?¹⁷³ Or are they saved as relating to insurance at least as to fully insured (as opposed to self-insured) groups?
- g. Can access be increased by making plan medical personnel (*e.g.*, medical directors, nurse case managers) available to provide health services?
- Are licensures and institutional credentialing up to date and appropriate in scope? Does ESAR-VHP apply?
 - Are medical personnel providing services within plan’s network? If so, are they properly credentialed by the plan?
 - Would plan liability exist for any failure of these individuals to meet the applicable standard of care?
 - Are they providing services as plan employees?
 - Can these services be structured to allow the individuals time off from their jobs so they can, as they may or may not choose, provide services as volunteers and not as employees?
 - If the service providers are seeking compensation during this time, who is responsible for payment, and how is it structured? Does continued compensation by the health plan increase its exposure?
 - Even if the medical personnel are not employees in providing care, are there circumstances in which the plan could still be liable under an ostensible agency theory? Can the plan protect against this exposure by precluding reference to itself by the service providers?
 - Does any altered standard of care apply (*e.g.*, Good Samaritan laws or laws tailored to pandemic emergency), particularly if these individuals are serving without compensation? Would any such

¹⁷³ See 29 U.S.C. § 1144(a) (2000, Supp. IV).

- immunity apply to a deemed employer/principal of the individual service provider?
- Would the organization face any liability for failure to properly train the personnel to provide care in the pandemic?
 - Does the plan have any supervisory obligation over the service providers, regardless of any attempts to disassociate the services from plan activities?
- h. Can/should access be increased by ensuring continuity of coverage for non-renewed groups and for groups in payment default, absent affirmative evidence of intent not to renew?
- Has it been determined that failure to renew or to pay may be a result of a lack of resources during the emergency due to group personnel shortages?
 - Are any waivers applied consistently across groups, without discrimination based on claims experience or health status?
 - Are contractual or other mechanisms in place to ensure that continuing coverage in these circumstances is not a waiver of obligation to pay the premium?
 - Are collection mechanisms in place for ultimate recovery of premiums owed?
 - Do state emergency laws call for such continuity of coverage and, if so, are they drafted so as to protect the payer from ultimate default on premium payments (*e.g.*, through a statutory lien in on assets)? Would such laws be preempted by ERISA?
- i. Is the health plan coordinating with any state Influenza Specialty Care Units (ISCUs) established to find care for patients unable to access services through their usual providers?¹⁷⁴ Does the plan's network include such ISCUs?
- j. Are other flexible benefit designs available in the event of a pandemic emergency (*e.g.*, increased mental health coverage; emergency room co-pay waivers; allowing accumulation of an increased supply of maintenance medications in advance of a pandemic; increased coverage for vaccines and antiviral drugs)?

3. Business Continuity

Failure to continue providing any of a plan's obligated services presents legal, in addition to business, exposure. That exposure could arise in contract, tort, or statutory/regulatory actions. The list of such obligations is expansive, and will differ among plans. The earlier discussion about access to care is, in effect, one aspect of business continuity. The following additional specific issues are illustrative and common, but do not necessarily cover the entire spectrum of business-continuity concerns.

- a. In light of the expected high volume of claims and workforce shortages, will the health plan be in a position to make timely and accurate payment on claims?
- Do laws governing a declared emergency provide relief from prompt payment obligations?
 - Do any such laws governing a declared emergency provide for a continued cash flow from payers to providers (*e.g.*, at average rates over a prior measured period), subject to reconciliation after the emergency?
 - Is contractual relief available? Do "Act of God" limitations apply?
- b. Does the plan face exposure from inability to meet reporting obligations (including reports on claims and financial experience and performance metrics) to employer groups, at-risk provider groups, and regulators?
- c. Does the plan face exposure due to an inability to meet performance guarantees (*e.g.*, member service call-response times; accuracy in claim processing) made to employer groups?
- d. Does the plan face exposure from an inability to meet all regulatory filing requirements, including keeping licensures up to date, during the emergency?¹⁷⁵
- Do laws governing declared emergency provide relief from such regulatory requirements during the emergency?
- e. Does the plan have exposure from inability to provide care management? Would such liability include exposure for bad medical outcomes?

¹⁷⁴ For an example of a state implementing Influenza Specialty Care Units, see Commonwealth of Massachusetts, Executive Office of Health and Human Services, Pandemic Planning / Hospital Influenza Specialty Care Units (July 13, 2006), available at www.mass.gov/Eeohhs2/docs/dph/quality/hcq_circular_letters/hospital_flu_unit_pandemic_planning.pdf (last visited Feb. 21, 2008).

¹⁷⁵ This may be a particular concern where the health plan's place of business is impacted by the emergency but the regulatory requirements apply in states where the emergency has not presented itself.

- f. Has the plan addressed ongoing needs for the following:
- Credentialing;
 - Quality metrics;
 - Web-based information;
 - Personal Health Records provided for members;
 - Member and provider services;
 - Appeals and claims dispute resolution;
 - Prompt resolution of administrative requirements to the extent they are not waived during the emergency (*e.g.*, utilization review; pre-registration);
 - Group and member renewals; and
 - Increased demand on computer and communication systems?
- g. Are reserves and cash on hand sufficient to cover increased claims volume and decreased revenue during the emergency?
- h. Is the plan in compliance with HIPAA security standards governing emergency readiness?¹⁷⁶
- Has the plan established and implemented procedures “to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode?”¹⁷⁷
 - Has the plan established and implemented procedures that allow facility access in support of restoration of lost data in the event of an emergency?¹⁷⁸
 - Has the organization tested its technology disaster recovery plan?
 - Does the organization occasionally require reversion to manual procedures to test disaster capabilities?
- i. In addition to self-evaluations, has the plan assessed its subcontractors, vendors, and suppliers with respect to these exposures?

VII. CONCLUSION

In acute and long term care settings alike, healthcare providers play a critical role in community pan-flu preparedness, and planning for such an event needs to occur immediately. As critical members of the community, healthcare providers also must be fully integrated into preparedness planning from the federal level down to the local level to ensure continued operations prior to, during, and after a pandemic.

¹⁷⁶ 45 C.F.R. §§ 164.308(a)(7), 164.310(a)(2)(i) (2007).

¹⁷⁷ 45 C.F.R. § 164.308(a)(7)(ii)(C) (2007).

¹⁷⁸ 45 C.F.R. § 164.310(a)(2)(i) (2007).

SPECIAL CONSIDERATIONS FOR PRE-HOSPITAL PROVIDERS

I. System Preparedness and Mitigation

- A. Are pre-hospital providers part of system-wide pandemic planning?
 - 1. Are emergency medical services (EMS) providers linked to public health planning?
 - 2. Are EMS providers linked to hospital planning?
 - 3. Is the full EMS system represented, including:
 - a. First response and transport;
 - b. Public and private providers
 - c. Fire-based, law-enforcement-based, hospital-based, and third service;
 - d. Paid and volunteer;
 - e. Medical director, clinical staff, and support staff; and
 - f. Public Safety Answering Point (PSAP) dispatch providers?
- B. Have the EMS providers taken all available mitigation measures?
 - 1. Are staff immunized against co-morbid diseases, including
 - a. Seasonal influenza; and
 - b. Pneumococcal disease?
 - 2. Are staff current on standard immunizations?
 - 3. Is an effective infection control program in place that includes:
 - a. Training on disease types and characteristics, routes of transmission, and preventive measures;
 - b. Personal protective equipment, including fit-testing, training on use and maintenance; and
 - c. Exposure reporting procedures?
- C. Are EMS providers prepared for an extended period of non-routine operations?
 - 1. Have individual employees established effective personal and family preparedness, including:
 - a. Emergency supplies;
 - b. Emergency communication plan between family members;
 - c. Extended absence by one or more family members who are critical staff; and
 - d. Extended school closures?
 - 2. Has the EMS organization expanded its capacity for extended operations, including:
 - a. Critical operational supplies (*e.g.*, clinical, hygienic, mechanical);
 - b. Daily-need supplies (*e.g.*, food, water, hygienic, mechanical); and
 - c. Other policies and procedures?
- D. Have EMS roles and responsibilities for influenza pandemics been identified and communicated?
 - 1. Have new/different roles for EMS been defined?
 - 2. Have all necessary capabilities been identified and incorporated into influenza pandemic planning?
 - 3. Has specialized equipment and/or additional amounts of routine equipment been identified and acquired?
 - 4. Has specialized training been identified and provided?
 - 5. For systems in which local fire departments are not primary EMS responders (either transport or first response), have expanded roles for local fire/hazmat responders been considered?
- E. Have the applicable plans, protocols, equipment, and training been evaluated?
 - 1. Have drills and exercises been conducted on all levels, from individual through system, and from task performance to strategic management?
 - 2. Have corrective action plans been developed to address critical needs?
 - 3. Have partner agencies been included (*e.g.* for systems in which local fire departments are not primary EMS responders, either transport or first response, have local fire/hazmat responders been included)?

II. Trigger Points and Notification

- A. Are pre-determined thresholds, system indicators, or other criteria in place for activating emergency plans and/or implementing special protocols?
1. Do these thresholds/indicators include EMS?
 2. Have thresholds/indicators been communicated to EMS?
 3. Have thresholds/indicators been tied to specific considerations or actions?
- B. Is an established notification process in place?
1. How is notification accomplished for the healthcare system as a whole? Within EMS and public safety, will notification include all constituents? (Large numbers, and a wide range, of providers are common to many systems.)
 2. Who is notified within each agency/institution? Are they tracked/listed by title and position, or as named individuals? Do these lists include information regarding the delegation of authority to be used if the persons listed cannot be reached in an emergency?

III. Information Flow and Decision-Making

- A. Are involved agencies aware of how information flows within their respective organizations (*i.e.*, horizontal vs. vertical) and throughout the system as a whole (*i.e.*, internal for each vs. inter-agency reporting)?
- B. What actions/decisions will be communicated? Do they include:
1. Activation/escalation;
 2. Decisions involving other agencies/levels of government;
 3. Special procedures/equipment; and/or Altered standards?
- C. Who makes critical decisions? Will these decisions be made individually for each group, or on a system-wide basis? Is the delegation of authority included on such communications?
- D. How are decisions communicated within a facility, throughout an agency, and within the system (through consistent application across all elements)? How will these decisions be communicated to the public?

- E. What decision-making support exists? Does this support include:

1. Incident Command System;
2. Emergency, Agency, and Department Operations Centers; and
3. Training and exercises?

IV. Response

- A. Within EMS, does a mechanism exist to confirm implementation of new procedures, assess performance quality (“correctness” of performance), and assess efficacy (to determine whether new procedures are effective, even if done correctly)?
- B. Is there an effective way to monitor EMS and public safety system status (internally and system-wide alike), providing a common operating picture?
- C. Is a system in place to seek, capture, and disseminate surveillance information from EMS and other public safety providers? Does that system take into consideration:
1. Syndromic changes;
 2. Effectiveness of disease control measures;
 3. Effectiveness of public information/risk communication measures; and
 4. Effectiveness of personal protective equipment, infection control procedures, and any chemoprophylaxis provided for EMS personnel?
- D. Can surveillance information be effectively gathered and processed, in a timely manner, with non-routine reporting mechanisms? Will they take into account:
1. Modification to existing patient-care record (PCR) systems; and
 2. Substitution of paper PCRs for electronic PCRs, due either to internal or system-wide breakdown of electronic system?
- E. Is a mechanism in place for providing “just-in-time” training for new procedures, equipment, or other adaptations that may become necessary?

V. Recovery

- A. Will EMS providers have counseling available to them to help address potential trauma associated with pandemic response? Will that counseling be prepared to address trauma associated with:
1. Extended operations;
 2. Illness and death of colleagues and family;
 3. Prolonged fear of contracting disease; and
 4. Potential “shunning” by others who fear contracting disease?
- B. Will EMS providers have resources available to them to help address potential financial issues associated with pandemic response, including:
1. Potential loss of income/benefits due to illness;
 2. Potential long-term disability related to response; and
 3. Potential tort involvement related to altered standards;
- C. Does the EMS system have sustainable funding that could survive short- or long-term loss of revenue? (Exact issues will vary widely, depending on type(s) of providers, local severity of an

influenza pandemic, and local resiliency of community structure.) Is that funding arranged in a way that will address losses due to changes in:

1. Taxes (*e.g.*, decrease in property-tax valuation, death of property owners, decrease in income- and sales-tax revenue);
 2. Billing (*e.g.*, reduction in insurance reimbursement, suspension of billing);
 3. Subscription fees (*e.g.*, decreased subscriber totals and/or inability to pay);
 4. User reluctance (*e.g.*, continued association of EMS with illness, fear of contracting illness from EMS provider or ambulance);
 5. Supply-chain disruptions; and
 6. Procedures to maximize recovery from federal disaster grant programs (*e.g.*, Public Assistance through the Stafford Act)?
- D. Is a mechanism in place for capturing and memorializing essential lessons from the response, addressing identified needs, and incorporating lessons into future practice internally, across the healthcare system as a whole, and for the community as a whole?

SPECIAL CONSIDERATIONS FOR PANDEMIC INFLUENZA PLANNING IN LONG TERM CARE FACILITIES

I. INTRODUCTION

Long-term care encompasses care provided at skilled nursing facilities, nursing facilities, assisted living facilities and intermediate care facilities for individuals with mental retardation. These facilities vary in size, resources, corporate structure and organization. Accordingly, not every long-term care facility will have the capacity to address all of the issues discussed in this Appendix. These issues are offered as suggested considerations that long-term care facilities should take into account in planning for an influenza pandemic and adapt their practices to their individual circumstances accordingly. The intent is that these considerations be scaleable.

The considerations in this Appendix also do not mandate specific processes, procedures or mechanisms to accomplish preparedness for an outbreak of an influenza pandemic. These will necessarily vary with facility capability and capacity as well as local community resources. The Appendix is intended to raise issues and provide suggestions to stimulate individual planning.

In an actual influenza pandemic, long-term care facilities may find that, as a practical matter, their needs for supplies and human resources are not adequately addressed by the public health emergency system or private vendors, which may favor primary and acute care providers.¹ This means that long-term care providers in the pre-pandemic period need to encourage their trade associations to work with public health authorities and lawmakers to take steps to protect their interests when an influenza pandemic ultimately occurs. They also need to recognize and appreciate the “inconvenient truth” that they may have no choice but to fend for themselves during an influenza pandemic. This reality underscores the importance of serious and realistic planning during the pre-pandemic period.

II. PLANNING PROCESS

Positioning a long term care facility to cope with an outbreak of pandemic influenza requires establishment of internal infrastructure in order to effectively engage in the planning process, and to effectively respond to an actual outbreak.²

- A. Does the facility have a planning committee to address pandemic influenza issues?
- B. Is the membership of the planning committee interdisciplinary, consisting of representatives of all stakeholders who will be affected by or involved in responding to an outbreak of pandemic influenza? Membership should optimally include the following disciplines, as applicable to the facility:
 1. Executive management (facility-specific and corporate);
 2. Financial management;
 3. Medical director and key attending physicians, including their nurse practitioners or physician assistants;
 4. Nursing management (Director of Nursing [DON] and/or Assistant Director of Nursing [ADON]);
 5. Pharmacist;
 6. Infection control management;
 7. Human resources management;
 8. Materials management;
 9. Physical plant management and housekeeping;
 10. Admissions coordinators;
 11. Building security;
 12. Union representatives;
 13. Chaplains or pastoral care;
 14. Behavioral health professionals;
 15. Activities coordinators;
 16. Public relations;
 17. Information technology/management; and
 18. Educators/trainers.
- C. Does the planning committee have a clear charge from the facility’s governing body regarding its mission and function? Is the charge, and the committee’s operational structure and functioning, documented in writing?
- D. Is the planning committee integrated with the facility’s existing emergency preparedness committee and process, in order to capitalize upon existing work product regarding responses

¹ The experience of long-term care facilities during hurricanes Katrina and Rita in 2005 demonstrate how attention is not often focused upon long-term care facilities during times of disaster.

² U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, LONG-TERM CARE AND OTHER RESIDENTIAL FACILITIES PANDEMIC INFLUENZA PLANNING CHECKLIST, www.pandemicflu.gov/plan/pdf/longtermcare.pdf (last visited Feb. 21, 2008).

common to disease-based emergencies and other disasters?

- E. Does the planning committee have access to informational resources regarding pandemic influenza sufficient for it to understand the projected nature of the situation for which it is planning? Is the committee familiar with the U.S. Department of Health and Human Services' planning assumptions regarding pandemic influenza?³
- F. Does the planning committee have a mechanism to obtain support from the facility's governing body if its planning recommendations involve the expenditure of the facility's funds, establishment or modification of contractual relationships, or modifications in the facility's operations?
- G. Has the planning committee designated an Incident Commander to oversee the process of planning for pandemic influenza, execution of drills and other training exercises regarding the plan, and execution of the facility's response to an actual outbreak of influenza? Is the committee's choice someone whom the facility's staff will respect and obey?
- H. Has the facility's governing body approved the designation of Incident Commander, and granted her the necessary authority to carry out the responsibilities assigned to her?
- I. Has the planning committee designated lines of succession for the Incident Commander to address the contingency of the Incident Commander's incapacity due to personal illness or other factors? Has the facility's governing body approved these lines of succession, and granted the successors appropriate contingent authority?
- J. Is a mechanism in place to activate the authority of a successor, including determination of the principal's incapacity and notification to appropriate individuals of the change in command?
- K. Has the planning committee designated a core team of officials to support the Incident Commander in the execution of an appropriate response to an actual outbreak of pandemic influenza? The core team should optimally consist of individuals with expertise in each of the following areas of importance to the facility's response:
1. Disease surveillance;
 2. Internal and external communications;
 3. Education and training;
 4. Utilization of facility beds and physical-plant resources;
 5. Clinical and medical management of infected residents, including infection control techniques and use of vaccines and antiviral medications;
 6. Staffing and occupational health issues; and
 7. Materials management and surge capacity.
- L. Has the facility's governing body approved these designations, and granted appropriate authority to the designated individuals to accomplish their assigned responsibilities?
- M. Has the planning committee prepared an organizational chart delineating the chain of command, including successors, for an emergency response? Has this chart been distributed to staff, and is it available in accessible location(s) throughout the facility for easy access during an actual emergency?
- N. Does the pandemic influenza response plan build in flexibility to address current unknowns about the characteristics of a pandemic virus?
- O. Has the planning committee considered and articulated the facility's core ethical values to serve as a "bottom line" for response to an actual outbreak of pandemic influenza, in the event that unforeseen circumstances prevent implementation of the response plan as originally envisioned?

³ U.S. Department of Health and Human Services, Pandemic Planning Assumptions, www.pandemicflu.gov/plan/pandplan.html (last visited Feb. 21, 2008).

III. DISEASE SURVEILLANCE

As part of the healthcare continuum, long term care facilities (particularly skilled nursing facilities) are key components of the public health effort to monitor for disease outbreak, peak, and resolution. The facility must understand and implement national, state, and local disease surveillance protocols.

A. Is information available to the facility's clinical team about the signs and symptoms of pandemic influenza (particularly symptoms anticipated from the H5N1 virus) in order to recognize suspected cases in its resident population and/or staff?⁴ Symptoms include:

1. Fever;
2. Cough;
3. Headache;
4. Sore throat;
5. Myalgia;
6. Prostration;
7. Coryza; and
8. Respiratory difficulty.

B. Is information available to the facility's clinical team about atypical disease presentation in the elderly, individuals in long term care facilities, and individuals with chronic underlying disease?

C. Because certified nurse aides (CNAs), personal care attendants, and direct support staff in intermediate care and mental retardation facilities have the most daily direct contact with residents, have they been trained and tasked with monitoring residents for signs/symptoms of possible pandemic influenza, documenting them, and reporting them to appropriate supervisory staff? Have licensed practical nurses (LPNs) and registered nurses (RNs) been trained in appropriate assessment for possible pandemic influenza in individual residents, and the factors that likely distinguish it from seasonal influenza? Have the facility's housekeeping and dining staff who also have frequent contact with residents been

educated to report apparent changes in resident condition?

D. Is a mechanism in place to involve resident families in disease surveillance by having them report signs/symptoms of possible pandemic influenza infection to appropriate staff?

E. Have appropriate worksheets been developed or modified to facilitate consistent surveillance documentation by CNAs, personal care attendants, direct support staff, LPNs and RNs?

F. Have LPNs and RNs been instructed that suspicion of pandemic influenza, particularly in the pandemic alert period, constitutes a significant change in a resident's condition warranting immediate physician notification?⁵

G. Is information available to physicians attending residents at the facility regarding the situations in which the U.S. Centers for Disease Control and Prevention (CDC) recommends laboratory confirmation of a suspected case of pandemic influenza, particularly during the pandemic alert period?⁶

H. Does the facility have a protocol for timely collection of appropriate specimens and their timely transport for laboratory examination? Does this protocol include adequate precautions to prevent inadvertent contamination of the facility's nursing staff during collection, temporary storage, and transit, as well as of laboratory workers during receipt of the specimen?

I. Does the facility's arrangement with the laboratory include a requirement that the laboratory report on an immediate (*i.e.*, STAT) basis to the organization any results confirming pandemic influenza infection to the extent of the facility's ability to negotiate such contractual advantages? Have the facility's LPNs and RNs been trained that positive lab results for influenza infection constitute a significant change in a resident's condition warranting immediate physician notification⁷ and that they present a serious hazard of infection control warranting immediate notification of the facility's infection control staff?

4 U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan Supplement 5 Clinical Guidelines, www.hhs.gov/pandemicflu/plan/sup5.html (last visited Feb. 21, 2008); WORLD HEALTH ORGANIZATION, CLINICAL MANAGEMENT OF HUMAN INFECTIONS WITH AVIAN INFLUENZA A (H5N1) VIRUS, *available at* www.who.int/csr/disease/avian_influenza/guidelines/clinicalmanage07/en/index.html (last visited Feb. 21, 2008).

5 42 C.F.R. § 483.10(b)(11) (2007).

6 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Pandemic Influenza Preparedness Tools for Professionals, www.cdc.gov/flu/pandemic/preparednesstools.htm (last visited Feb. 21, 2008); U.S. Department of Health and Human Services, National Institute on Allergies, Testing for H5N1 in Humans, www.pandemicflu.gov/vaccine/humantests.html (last visited Feb. 21, 2008).

7 42 C.F.R. § 483.10(b)(11) (2007).

- J. Does the facility have a mechanism for its clinical management and its attending physicians to stay abreast of the specific surveillance data elements required to be reported to local public health authorities during the pandemic alert period and the pandemic period? If the facility lacks access to the Internet where many such resources exist, does that mechanism include telephone communication with its local public health authority for periodic updates? Does the facility have a mechanism to facilitate timely and accurate capture and reporting of all required data elements?
- K. Does the facility have a mechanism for its clinical management to keep abreast of CDC, state, and local public health authorities' assessments of the outbreak, spread, peak, resolution, and re-emergence of an influenza pandemic in its geographic locality? Does this mechanism include consultation with the facility's local public health authority in the pre-pandemic period to learn how such information will be shared during an influenza pandemic, and take steps to prepare itself to receive such communications?

IV. EDUCATION AND TRAINING

Timely and effective implementation of the facility's response plan to pandemic influenza will depend upon a knowledgeable workforce.

- A. Does the facility have a mechanism to educate and train appropriate groups regarding pandemic influenza and the facility's response plan, including:
1. The medical director and attending physicians;
 2. Nursing staff;
 3. Residents and resident surrogates; and
 4. Resident families?
- B. Has information been made available to physicians about clinical workshops, online training, and literature regarding the medical management of pandemic influenza? Will the medical director and/or attending physicians participate in training on this subject?
- C. How will the facility track nursing participation in internal and/or outside education and training? What will the consequences be if nursing management does not participate in the requisite amount of educational programs?
- D. If the facility opts to offer in-person in-service clinical education for attending physicians and nursing staff, has it identified appropriately qualified individuals to conduct the in-services?
- E. How will the facility educate residents, and their surrogate decision-makers about pandemic influenza? Educational options may include:
1. Posters and signs (DHHS has developed some useful items);⁸
 2. Written brochures;
 3. Small group instruction; and
 4. Individual instruction.
- F. What will such resident/surrogate education consist of? Pertinent topics may include:
1. Symptom recognition;
 2. Basic infection control measures;
 3. Policy and procedure changes that will occur in the facility once the pandemic influenza response plan is implemented, and how these will affect resident care and daily activities; and
 4. Anticipated psychosocial implications of an outbreak of pandemic influenza, and coping strategies that the facility plans to employ for the benefit of residents.
- G. How will the facility address education of cognitively impaired residents, or residents whose primary language is not English? Is the facility prepared to tailor the message and the method of presentation to the capabilities of cognitively impaired residents and those at the end of life who may lack interest in education?
- H. How will the facility provide education to resident families? Once an outbreak of pandemic influenza is identified at the location where their residents are living, families will want and need to know at least the following information:
1. How will families obtain timely information as to their resident's health status?
 2. Will visiting hours be eliminated or curtailed?

⁸ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Cover Your Cough, www.cdc.gov/flu/protect/covercough.htm (last visited Feb. 21, 2008) [hereinafter CDC, Cover Your Cough].

3. Will permitted visitors (if any) be required to take any special precautions upon entering the premises?
 4. Will medical management of ill residents occur at the facility or at a local hospital? If at the facility, what provisions will be made for acutely ill residents?
 5. Will special precautions be established that a permitted visitor should take to avoid spreading pandemic influenza (*e.g.*, to other family members in the household) outside of the facility upon departure?
 6. Will family members be needed to assist staff in basic care-giving if staff absenteeism escalates? If so, how will family members be notified and trained for their responsibilities?
- I. How will the facility train staff about the content of its response plan for pandemic influenza, and how will the facility practice implementation of it?
1. Has the facility developed in-service programs specific to the pandemic influenza response plan so that staff understand:
 - a. Who will command the response effort;
 - b. What their roles in the response effort will be;
 - c. How they will be notified of the implementation of the response plan; and
 - d. What action steps they will need to take in order to fulfill their roles in implementing the response?
 2. Has the facility participated in “table top” exercises with DHHS and local public health departments to simulate an outbreak of pandemic influenza, which provide an opportunity for drills and practice in plan implementation as well as an opportunity to identify and correct gaps in the public health response respecting long-term care facilities?⁹
- V. COMMUNICATION
- During an outbreak of pandemic influenza, clear internal and external communication will be essential to an effective response.
- A. Has the facility designated a communications officer to perform or oversee the facility’s internal and external communications needs? If appropriate or necessary, have additional individuals been designated to support or assist the communications officer with communication tasks requiring specialized knowledge or expertise, such as communications regarding clinical issues? Have reporting lines been established?
 - B. Does the facility have a mechanism to obtain up-to-date information from outside sources¹⁰ about:
 1. The current World Health Organization (WHO) pandemic phase;
 2. Identification of a human-to-human transmissible strain of the H5N1 virus anywhere in the world;
 3. Characteristics of the human-to-human transmissible strain of the H5N1 virus, including virulence, susceptible populations, susceptibility to anti-viral medications, paths of transmission, symptoms and complications;
 4. Requirements for surveillance reporting to public health authorities;
 5. Mandatory community containment measures, such as school and event closures, mass transportation closures, quarantine, or isolation;
 6. Public health authority distribution plans for antiviral medications and vaccines, as available;
 7. Public health authority prioritization for use of antiviral medications and vaccines prior to widespread availability;
 8. Local availability of in-patient beds and/or ventilator support for infected individuals with acute respiratory distress; and
 9. Local availability of manpower and supplements to usual suppliers as the health-care system reaches surge capacity?
 - C. Has the facility gathered current contact information for appropriate outside information resources? Does this contact information

9 U.S. Department of Health and Human Services, Office of Public Health Emergency Preparedness, Tabletop Exercises for Pandemic Influenza Preparedness in Local Public Health Agencies, TR-319-DHHS (2006), *available at* www.pandemicflu.gov/plan/states/tr319.html (last visited Feb. 21, 2008).

10 For a comprehensive resource, *see* the U.S. Government’s “one stop” information source about pandemic flu managed by the U.S. Department of Health and Human Services, at www.pandemicflu.gov/ (last visited Feb. 21, 2008).

include alternative means of contact such as land phone lines, cell phones, beepers, email addresses, and internet addresses?

D. Does the facility have a mechanism to notify off-duty staff about scheduling, work assignment, or other staffing changes necessitated by an outbreak of pandemic influenza? Communication options might include:

1. Phone trees;
2. Blast or computer-generated recorded messages; and/or
3. Web pages or Internet-based bulletin boards?

E. Does the facility have a mechanism for off-duty staff to notify the facility of upcoming absence due to an outbreak of influenza (*e.g.*, dedicated telephone line(s) to accommodate increased absenteeism as the pandemic progresses)?

F. Does the facility have a mechanism to provide resident families with information about the health of the resident, and about implementation of any special visitation policies because of an outbreak of influenza? Communication options may include:

1. Public media announcements;
2. Web page(s);
3. Dedicated phone line(s); and/or
4. Dedicated email address(es)?

G. Does the facility have a mechanism to obtain up-to-date information regarding availability of hospital beds, and to advise hospitals of its own overflow capacity? This communication capacity should not be limited to hospitals with which a skilled nursing facility already has a Medicare transfer agreement.

H. Does the facility have a mechanism to notify supply vendors (*e.g.*, food service, pharmacy, durable medical equipment, or clinical consultants such as wound care professionals, psychiatrists, and psychologists) of its service, equipment, and supply needs, particularly as the healthcare system approaches surge capacity? Do contracts with these vendors need to be modified to require increased support from the vendors as circumstances require (*e.g.*, exceptions to the *force majeure* clause, or commitments for increased service)?

I. Does the facility have a mechanism for on-duty staff to obtain information about the health and care needs of their family in a way that does not impede resident care operations (*e.g.*, establishing exceptions to “no cell phone” or “no use of resident phone” policies)?

J. Does the facility have a mechanism to notify the general public about changes to the facility’s visitation policies, infection control measures, and ways to obtain information about residents?

K. Has the facility devised efficient and effective lines of communication between the Incident Commander and others internally responsible for implementation of the response plan? Does this include methods to communicate with leaders who may be off-site or personally incapacitated?

VI. FACILITY UTILIZATION

During an influenza outbreak, long term care facilities (particularly skilled nursing facilities) may be called upon to care for acutely ill individuals, whether this is their preference or not. This can happen for two main reasons. No hospital in-patient beds may be available to care for the facility’s own residents as the healthcare system reaches surge capacity. Alternatively, hospitals may be transferring non-influenza patients to skilled nursing facilities in order to free up their own beds for the most seriously ill influenza patients. Either of these circumstances will be problematic for long term care facilities, which generally do not have the resources or training to care for acutely ill individuals. Nonetheless, in light of the anticipated practical realities of an actual influenza outbreak, long term care facilities must prepare themselves as best they can to care for higher-acuity individuals, especially their own residents that cannot be transferred to a hospital setting due to bed shortages.

A. Will the facility be able to obtain sufficient quantities of respiratory support equipment to care for residents with acute respiratory distress secondary to pandemic influenza (*e.g.*, ventilators)? Should the facility purchase used or older model ventilators during the pre-pandemic period, if resources permit, for its residents’ use during an influenza outbreak? Has the facility discussed with local public health authorities whether it will have the ability to tap into federal and/or state government stockpiles of medical equipment during an influenza outbreak?

B. Has the facility discussed with local public health authorities a practical mechanism for it

to obtain and properly store sufficient quantities and types of antibiotics to care for residents with acute respiratory distress secondary to an influenza pandemic including the facility's ability to tap into federal and state government stockpiles of medications?

- C. Has the facility considered training clinical staff during the pre-pandemic period to provide acute care, including operation of ventilators, tracheotomy care, suctioning, use of nebulizers, and use of oxygen? Should this acute care training be done through in-service education or by using community educational resources such as local colleges? Should the facility begin contingency recruiting of more skilled staff (employed or volunteer) to address the anticipated high acuity level of its residents during an actual outbreak including twenty-four-hour physician presence at the facility to direct resident care as the resident acuity level increases?
- D. Does the facility have a mechanism to create cohort rooms, wards, or units, as well as to relocate infected residents to the cohort area?¹¹ Is a mechanism in place to give the resident or family the Medicare/Medicaid required advance notice of relocation to a cohort room or ward?¹² If the relocation moves residents from a certified distinct part to a non-certified area or between certified distinct parts, the facility may be required to comply with the Medicare/Medicaid rules applicable to involuntary transfers.¹³
- E. If the facility chooses to accept acutely ill individuals discharged from hospitals, does the building have space to put up temporary additional beds to accommodate them? Does this space have sufficient electrical outlets and plumbing to accommodate essential medical equipment? How will resident privacy be maintained in temporary space? How will basic fire protection be maintained in the temporary space? Can the temporary space be allocated between infected and non-infected individuals, and can infection control measures be maintained in it? Where will temporary beds come from?
- F. Have the facilities addressed the following issues with appropriate government agencies in anticipation of the use of facility space for acutely ill individuals?
1. How will the facility comply with state certificate of need, facility licensing, or physical plant laws as a prerequisite to operating temporary beds? Will the state waive or modify these requirements during an outbreak of pandemic influenza, and how will the facility's staff be made aware of and take advantage of any such waivers?
 2. Will the facility be able to bill for acute care services that it renders to either its existing residents or newly admitted residents? What mechanism will the facility have for capturing data necessary to bill for these services?
 3. At what point will the facility violate the terms of its own licensure (or unlicensed status) by caring for high-acuity residents? Will state licensing authorities waive licensure requirements during a confirmed outbreak of pandemic influenza? How will the facility apply for or otherwise take advantage of such a waiver?
- G. How will the facility obtain sufficient clinical staff to manage an influx of new residents, if the facility chooses to accept acutely ill individuals discharged from hospitals? Will the facility need to forego traditional long term care clinical services (*e.g.*, physical, occupational, and speech therapy) in order to re-deploy staff to accommodate the clinical needs of a more acute population? What effect will this have on resident progress toward personal goal achievement, and how can the facility mitigate any loss in goal attainment?
- H. How will the facility conduct resident assessments and complete minimum data sets, as required by the Centers for Medicare & Medicaid Services (CMS), and prepare care plans for new residents if staff are absorbed in care delivery?¹⁴
- I. At what point will the facility be unable to accept any new residents, despite requests from area hospitals or public health authorities to do so? How will this decision be communicated to area hospitals? How can the facility avoid tarnishing valued referral patterns from these hospitals once the influenza pandemic has subsided?
 - J. How will the facility prepare for and handle deaths of acutely ill residents? Will the facility

11 U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan Supplement 4 Infection Control, www.hhs.gov/pandemicflu/plan/sup4.html (last visited Feb. 21, 2008) [hereinafter DHHS, Supplement 4].

12 42 C.F.R. § 483.15(e) (2007).

13 42 C.F.R. § 483.12(a) (2007).

14 42 C.F.R. § 483.20 (2007).

need a temporary morgue? How will the facility train staff to handle deceased residents?

VII. INFECTION CONTROL

Once pandemic influenza is identified in the facility's geographic location, the facility will need to implement strict infection control measures to help contain illness, particularly given the anticipated limited availability of virus-specific vaccine and antiviral medications at the beginning of an outbreak of pandemic influenza.

- A. Has the facility familiarized itself with current CDC, WHO, and DHHS infection control guidelines for pandemic influenza?¹⁵
- B. Has the facility considered the following strategies to prevent the virus from entering the residential facility:
 1. Limit visitors to those essential for resident welfare;
 2. Actively screen all permitted visitors upon entry for signs/symptoms of pandemic influenza, and turn away any with suspected infection;
 3. Require permitted visitors to use appropriate barrier precautions, cough etiquette, and respiratory hygiene;
 4. Mobilize security staff or local police as needed to enforce visitation restrictions;
 5. Require vendors to leave deliveries at the loading dock rather than entering the building;
 6. Eliminate person-to-person sales calls;
 7. Screen attending physicians, employees, and contract staff upon entry into the building for signs/symptoms of pandemic influenza, and turn away any with suspected pandemic influenza;
 8. Cancel planned resident group outings;
 9. Cancel community group social or religious activities at the facility (*e.g.*, scout troops, school choirs, church groups);
 10. Cancel all resident non-therapeutic personal leaves unless the resident will not return to the facility; and

11. Screen all residents returning from a hospital visit or outpatient care for signs/symptoms of pandemic influenza, immediately isolate any resident with suspected pandemic influenza, and commence medical management?
- C. How will the facility isolate residents who contract pandemic influenza, despite efforts to prevent its entrance into the facility? Options include the following:
 1. Providing a private room (will third-party payers cover the extra cost as "medically necessary?");
 2. Establishing a cohort with exposed or infected roommate in rooms disbursed throughout facility (this is less disruptive to residents than the following option, but is likely a less effective containment measure); or
 3. Establishing a cohort with exposed or infected roommate in segregated wing or floor.
- D. If an infected resident refuses to remain in isolation, may the facility use physical restraints without violating Medicare/Medicaid Requirements for Participation?¹⁶
- E. How will the facility implement social distancing as an infection control technique? Has the facility considered adopting one or more of the following strategies?
 1. Is the facility appropriately staffed to cancel meal service in the dining room and provide meals in resident rooms? How will the facility adequately supervise residents requiring eating assistance? Will mealtimes have to be staggered to accommodate tray delivery, setup, and supervision needs?
 2. Is the facility appropriately staffed to cancel group activities (*e.g.*, exercise classes, bingo, religious observances), and focus upon solo activities for residents that provide equivalent physical and intellectual stimulation? Does the facility have sufficient recreational supplies and staff to accomplish this? Will it be able to provide adequate assistance to residents on a one-on-one basis, as needed

15 DHHS, Supplement 4, *supra* note-10; U.S. Department of Health and Human Services, Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings During an Influenza Pandemic (Oct. 2006), www.pandemicflu.gov/plan/healthcare/maskguidancehc.html (last visited Feb. 21, 2008); U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Pandemic Influenza Information for Health Professionals, www.cdc.gov/flu/pandemic/healthprofessional.htm (last visited Feb. 21, 2008).

16 42 C.F.R. § 483.13(a) (2007).

- for the resident to pursue individual activities?
3. Can the facility limit its usual social activities and the corresponding use of lounges for such scheduled or other informal resident gatherings (*e.g.*, card games, watching TV in small groups, discussion of current events)?
 4. Can the facility safely limit the areas that residents may stroll through in the facility, even if alone?
 5. When residents must gather together or gather with staff, does the facility have sufficient space in its common and dining areas to seat people at least three feet apart from each other? If not, can alternate measures, such as staggering the gatherings, be used to maintain proper physical distance? Can face masks be used to avoid interpersonal contamination if sufficient space is not available even with program modification?
 6. Does the facility have the necessary equipment and Internet connectivity to conduct resident care conferences, staff meetings, and in-service educational programs by audio and/or video conference, even if all participants are in the same building or floor?
 7. Is there a mechanism for the facility to initially respond to call lights without entering resident rooms (*e.g.*, intercom contact with resident room, robot technology) to avoid multiple resident-to-staff exposures for a single resident need?
 8. How will the facility provide the special supervision necessary for cognitively impaired residents to adhere to social distancing measures?
 9. How will the facility plan for the change in resident routine and services involved when social distancing is implemented, and how will it address the psychosocial consequences of this measure?¹⁷
 10. Has the facility discussed with CMS and/or its trade associations whether CMS will waive compliance with those of its certification requirements that implementation of social distancing will violate? How will the facility implement respiratory hygiene, including cough etiquette for staff, residents, and visitors? Cough etiquette requires that a coughing individual cover her mouth when coughing or wear a mask; dispose of used tissues in a specified container; and perform hand hygiene after each coughing incident.
 11. Will the facility utilize posters and brochures available from public health authorities for facilities to remind staff, residents, and visitors about cough etiquette?¹⁸
 12. How will the facility implement the special supervision that cognitively impaired residents will need to adhere to cough etiquette procedures?
- F. Does the facility have sufficient PPE for staff to use when caring for infected or exposed residents? Has the facility considered stockpiling such equipment if resources permit, and discussing supply chain issues with local public health authorities in order to take advantage of state and national stockpiles?
- G. Does the facility's clinical staff know when and how to use personal protective equipment?¹⁹
- H. Does the facility have a mechanism to plan for residents' psychosocial needs occasioned by the barriers interposed by PPE?
- I. Recommended PPE includes:
1. Disposable gloves for one-time use for every contact;
 2. Disposable surgical or procedure masks for one-time use per contact;
 3. N95 respirators for tasks that may aerosolize small-particle droplets from an infected resident (*e.g.*, performing nebulizer treatments or suctioning secretions);
 4. Disposable or washable gowns for contacts or procedures that involve direct contact with a resident's bodily fluids or secretions;
 5. Hand hygiene products (*e.g.*, soap; water- or alcohol-based hand rubs);
 6. Facial tissues;
 7. Disposable and sealable plastic bags; and
 8. Bleach or other environmental cleanser.

17 42 C.F.R. §§ 483.20, 483.25(f) (2007).

18 CDC, Cover Your Cough, *supra* note 8.

19 U.S. Occupational Safety and Health Administration, *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers*, OSHA 3328-05 2007, available on OSHA homepage www.osha.gov (last visited Feb. 21, 2008).

- J. Does the facility have a plan for addressing the maintenance of appropriate infection control measures if shortages occur in the stock of personal protective equipment and supplies when the healthcare system reaches surge capacity? In the absence of PPE, has the considered alternative infection control strategies such as increased emphasis upon social distancing, isolation and quarantine and environmental sanitation?
- K. Will permitted visitors be provided personal protective equipment through the facility, or will they be responsible for providing their own as a condition to entry into the facility?

VIII. ANTIVIRAL MEDICATIONS AND VACCINES

These key medical management tools may not be sufficiently available when pandemic influenza enters the facility's geographic locality. The facility needs a plan to obtain its share, and to use them wisely, until they become generally available again to the healthcare community.

- A. Does the facility have a mechanism to obtain up-to-date information on at least the following points:²⁰
 - 1. Availability of vaccines developed through government grants to protect against pre-pandemic strains of the H5N1 virus;
 - 2. Status of the development and manufacture of vaccines effective against the pandemic strain of the H5N1 virus;
 - 3. Distribution plans for the new vaccine;
 - 4. Current prioritization of recipients of a new vaccine;²¹
 - 5. Dosage recommendations for the new vaccine, and mechanisms to provide second doses to recipients in order to confer maximum immunity;
 - 6. Susceptibility of the pandemic strain of the H5N1 virus to existing and available antivirals;
- 7. Availability of sufficient quantities of effective antivirals to make a difference in clinical outcome, either through prophylactic or therapeutic use;
- 8. Distribution plans for effective antivirals; and
- 9. Priority of residents and staff to receive antivirals during shortage periods?²²
- B. If long term care workers subsequently become eligible for initial receipt of the new vaccine, what policies and procedures will the facility follow in administering the vaccine?
 - 1. Will the facility require the workers to take the vaccine if not medically contraindicated?
 - 2. What mechanism will the facility use to accomplish worker vaccination (*e.g.*, time off work to attend public health clinic, temporary vaccination clinic on-site, administration by the facility's own personnel)?
 - 3. How will the facility monitor for and address adverse vaccine reactions?
 - 4. Will the facility make vaccine available to volunteer healthcare workers recruited to assist during periods of surge capacity?

IX. OCCUPATIONAL HEALTH

Effective healthcare for the residents of long term care facilities depends upon a healthy workforce. The facility will need to take extra steps to protect its staff from exposure to and the effects of an influenza pandemic.

- A. How will the facility's sick leave policies affect the behavior of symptomatic staff? (Sick leave policies should encourage staff to stay home if they are symptomatic in order to avoid spreading illness to residents and other staff.) If a symptomatic staff member has already used up all available sick leave days before the outbreak of a pandemic, how will such leave be treated? Will the same policy apply to asymptomatic staff who have been exposed to pandemic influenza, or to asymptomatic staff who have child- or elder-care responsibilities at home?

20 U.S. Department of Health and Human Services, Pandemic Flu Planning Update IV, www.pandemicflu.gov/plan/panflureport4.html (last visited Feb. 21, 2008). See also U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan Supplement 6 Vaccine Distribution and Use, www.hhs.gov/pandemicflu/plan/sup6.html (last visited Feb 21, 2008); U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan Supplement 7 Antiviral Drug Distribution and Use, www.hhs.gov/pandemicflu/plan/sup7.html (last visited Feb. 21, 2008).

21 At present, residents of long term care facilities are not thought to be a "top tier" priority for receipt of a new vaccine when it becomes available. Some healthcare workers will be in the top tier, but it is unclear whether workers at long term care facilities will be included in this group. Government officials are presently considering the prioritization of individuals during the period of vaccine shortage.

22 At present, residents of long term care facilities are thought to be in the top tier to receive antiviral medications, but government officials are presently considering prioritization schemes.

- B. How will the facility screen staff upon entry into the building for signs/symptoms of pandemic influenza? How will the facility handle staff who become symptomatic at work (*e.g.*, isolation, send home early)? Will the facility supply transportation if the symptomatic worker's usual transportation is not available at the time that the worker needs to leave?
- C. How will staff be assigned to care of infected residents? (Once selected for this assignment, staff should be cohorted to avoid workforce-wide exposure to the virus.) How will the facility respond if staff refuses to care for infected residents? At what point is such a refusal the protected exercise of an employee's rights under the Occupational Safety and Health Act to refuse to work in unsafe environments?²³
- D. How will the facility protect staff at especially high risk of contracting pandemic influenza, or of severe complications or death from the illness (*e.g.*, pregnant women or immunocompromised individuals)? Will the facility mandatorily reassign them to job responsibilities that do not involve resident care or contact? Will the facility place them on mandatory administrative leave? How will the facility respond to workers who refuse job reassignment or leave, despite their heightened personal risk?
- E. How will the facility assist staff who encounter fear or discrimination in the community or in their family because they may be carriers of the virus as a result of their potential occupational exposure?
- F. Will the facility provide personal-care accommodations to staff who are asked to work extended hours due to increased resident census or increased resident acuity? Will overnight accommodations be available to staff who could benefit from it? How much personal-care time will be subject to overtime pay requirements?
- G. How will the facility assist staff with the psychosocial consequences of:²⁴
1. Workplace stress as the number and acuity of residents increases and job duties become more demanding;
 2. Fear of working in an environment in which occupational exposure is likely;
 3. Worry over the safety and health of their families;
 4. Grief over resident deaths;
 5. Physical exhaustion from overtime; and
 6. Isolation secondary to social distancing and barrier precautions?
- H. As possible psychosocial supports to staff, will the facility offer:
1. Services of mental health professionals;
 2. Services of faith-based counselors; and/or
 3. Rest and recreation opportunities?
- I. To what extent will the facility be required to negotiate with labor unions in order to implement occupational health strategies that involve use of expanded work hours, change in work conditions, sick leave, job reassignment, or administrative leave?

X. SURGE CAPACITY

If an outbreak of pandemic influenza occurs, it is anticipated that the healthcare continuum as a whole will quickly become overwhelmed with the care needs of infected individuals. Long term care facilities may have few options but to continue caring for their residents despite dwindling staff and supplies, because many residents will have no other housing or care alternatives. Strategies must be devised to address anticipated shortages.

- A. For those residents who have known and available family, will the facility attempt to discharge the resident to the care of family when the facility hits surge capacity? How will the facility ensure that the family is properly trained to address the resident's care needs, both related to pandemic influenza and related to the resident's general care plan? Would the facility have a legal obligation to ensure that the family is able to provide—and is, in fact, providing—around-the-clock care to the resident?
- B. For those residents who cannot be discharged to family, can family nonetheless assist the facility in providing care at the facility building itself in the event that the facility experiences severe staff absenteeism? What tasks could family members provide without violating applicable licensure laws or Medicare/Medicaid requirements? How will the facility incorporate family involvement into the resident's care plan?

²³ See 29 C.F.R. § 1977.12(b)(2) (2007).

²⁴ U.S. Department of Health and Human Services, HHS Pandemic Influenza Plan Supplement 11 Workforce Support: Psychosocial Considerations and Information Needs, www.hhs.gov/pandemicflu/plan/supp11.html (last visited Feb. 21, 2008).

C. Does the facility have a strategy to obtain additional staff during periods of severe staff absenteeism? Options to consider include:

1. Increasing working hours of existing staff;
2. Increasing the workload of existing staff during their regular work hours;
3. Using clinical managerial staff to provide resident care, or assigning administrative staff to clinical tasks with appropriate “just in time” training and appropriate supervision;
4. Eliminate non-essential clinical services (*e.g.*, activities, medical social work, therapy) and reassigning staff from those service areas to cover essential services;
5. Borrowing staff from other states, to the extent that the pandemic is not simultaneously affecting multiple states;
6. Recruiting community volunteers, regardless of whether they are licensed;
7. Recruiting health professional retirees; and
8. Consolidating certain operations with neighboring facilities in order to share remaining staff (this may be most helpful for “back office” operations, *e.g.*, laundry, billing).

D. How will the facility credential supplemental staff in a timely manner? States are developing lists of licensure-verified volunteer healthcare practitioners that may assist in basic credentialing.

E. How will the facility continue fall prevention protocols, wander monitoring, assistance with activities of daily living, eating supervision, and other essential accident prevention functions with a severely reduced staff?²⁵ Can additional technology or automation be an appropriate solution?

F. Does the facility have a strategy for procuring additional equipment and supplies as current stocks become depleted?²⁶ Has the facility considered stockpiling certain essential products in anticipation of shortages?

G. Does the facility have a mechanism to approach residents’ families with requests for assistance with common supplies or equipment that may be in short supply in a surge-capacity situation? To what extent could this constitute an impermissible Medicaid supplementation?

XI. ETHICAL POLICY CONSIDERATIONS

During an influenza outbreak, long term care facilities will be faced with many ethical and policy questions.

A. Does the facility have access to a medical ethicist to assist in the resolution of difficult ethical and policy issues?

B. Will the facility’s population be discriminated against in community triage, funding, and resource allocation because it is perceived as “worthless” due to age and/or disability? What is the appropriate role of the long term care community to champion the social cause of its population?

C. Is it ever appropriate for the facility to force staff, on pain of termination, to work with infected or exposed residents if the staff member is fearful?

D. Is it appropriate for facilities to continue to compensate staff who are asymptomatic but quarantined at home? What sector of society should shoulder the financial burden of a quarantine?

E. Will racial and cultural minority groups be disadvantaged during an influenza pandemic, as their general difficulty accessing high quality care likely will be exacerbated when the health-care continuum reaches surge capacity?

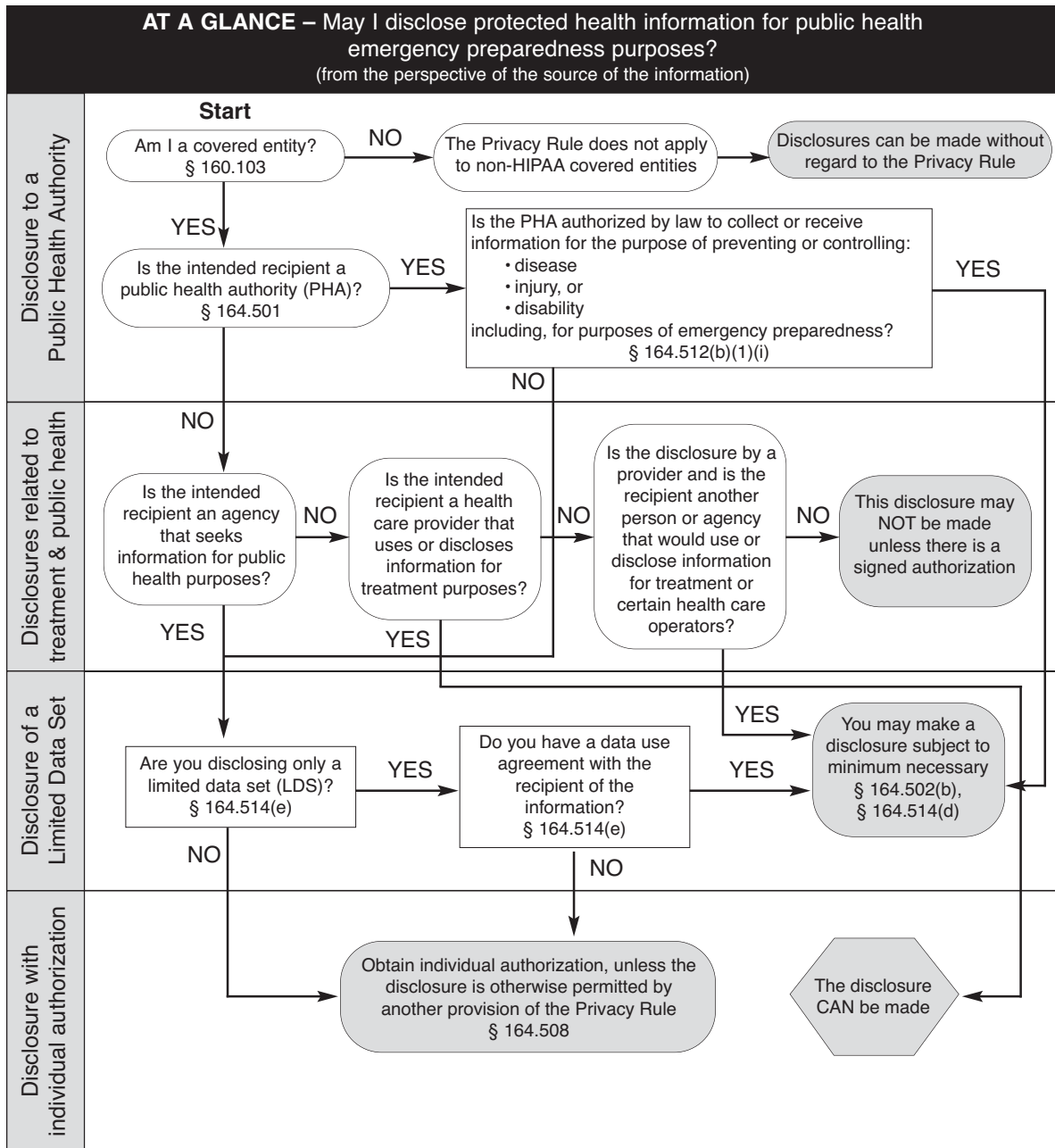
²⁵ 42 C.F.R. §483.25(h) (2007).

²⁶ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Flu Surge 2.0*, www.cdc.gov/flu/tools/flusurge/ (last visited Feb. 21, 2008).

DHHS OFFICE FOR CIVIL RIGHTS – DECISION TOOL FOR DISCLOSURES FOR EMERGENCY PREPAREDNESS UNDER THE HIPAA PRIVACY RULE

The HHS web-based interactive tool helps emergency preparedness and recovery planners deter-

mine how to access and use health information consistent with the HIPAA Privacy Rule by asking the user a series of questions regarding how the Rule applies to a particular disclosure. The intended audiences are covered entities and emergency preparedness and recovery planners.¹



¹ See the DHHS Office for Civil Rights Tool for Disclosures for Emergency Preparedness Under the HIPAA Privacy Rule available at www.hhs.gov/ocr/hipaa/decisiontool/ (last visited May 28, 2008).

SELECTED ONLINE RESOURCES

- Influenza Pandemic Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination** (October 2007) GAO Report
www.gao.gov/new.items/d0836.pdf
- Trust for America's Health, Ready or Not? Protecting the Public's Health from Diseases, Disasters and Bioterrorism**
healthyamericans.org/reports/bioterror07/
- Homeland Security Presidential Directive/HSPD-21, Public Health and Medical Preparedness** (October 18, 2007)
www.whitehouse.gov/news/releases/2007/10/20071018-10.html
- OIG Memorandum Report – Laboratory Preparedness for Pandemic Influenza, OEI-04-07-00670** (October 24, 2007)
oig.hhs.gov/oei/reports/oei-04-07-00670.pdf
- Department of Health and Human Services Pandemic Influenza Plan**
www.hhs.gov/pandemicflu/plan/
- Currently Available State Plans**
www.cste.org/specialprojects/Influenzaplans/StateMap.asp
- The Official U.S. Government Web Site for Information on Pandemic Flu and Avian Influenza**
pandemicflu.gov/
- State and Local Pandemic Influenza Planning Checklist**
pandemicflu.gov/plan/statelocalchecklist.html
- Business Pandemic Influenza Planning Checklist**
pandemicflu.gov/plan/businesschecklist.html
- CDC Interim Guidance & Recommendations for Protection of Persons Involved in U.S. Avian Influenza Outbreak Disease Control and Eradication Activities**
www.cdc.gov/flu/avian/professional/protect-guid.htm
- US Department of Labor – OSHA: Guidance for Protecting Workers Against Avian Flu**
www.osha.gov/dsg/guidance/avian-flu.html
- Center for Infectious Disease Research & Policy (CIDRAP), University of Minnesota**
www.cidrap.umn.edu/
- Promising Practices: Pandemic Preparedness Tools**
www.pandemicpractices.org/
- Respiratory Hygiene/Cough Etiquette in Healthcare Settings**
www.cdc.gov/flu/professionals/infectioncontrol/resphgiene.htm#
- U.S. Department of Health & Human Services – Agency for Healthcare Research and Quality, Public Health Emergency Preparedness** (includes multiple resources on surge preparedness)
www.ahrq.gov/prep/
- US Department of Labor – OSHA: Best Practices for Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances** (January 2005)
www.osha.gov/dts/osta/bestpractices/firstreceivers_hospital.html
- World Health Organization, “Avian Influenza: Assessing the Pandemic Threat,”** (January 2005)
www.who.int/csr/disease/influenza/H5N1-9reduit.pdf
- World Health Organization, “Global Influenza Preparedness Plan,” Geneva (2005); World Health Organization, “WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment,”** (March 17, 2006)
www.who.int/csr/disease/avian_influenza/guidelines/fluprotocol_17.03.pdf
- Hospital Preparedness website**
www.tvfr.com/dept/em/em_hospitals.html
- American Hospital Association Emergency Readiness** (The third link relates to AHA's Hospital Preparedness for Mass Casualties publication in conjunction with the Office of Emergency Preparedness & DHHS)
www.aha.org/aha_app/issues/Emergency-Readiness/index.jsp
www.aha.org/aha/issues/Emergency-Readiness/resources.html
www.aha.org/aha/content/2000/pdf/2000forumreport.pdf

- **AHA Emergency Preparedness: Guidance for Individuals**
www.aha.org/aha/issues/Emergency-Readiness/individuals.html
- **DHHS Disasters & Emergencies**
www.hhs.gov/emergency/index.shtml#emergency
- **Bioterrorism & Epidemic Outbreak Response Model**
www.aha.org/aha/issues/Emergency-Readiness/berm.html
- **Hospital Incident Command System**
www.emsa.ca.gov/hics/hics.asp
- **Recommendations of the Working Group on Emergency Mass Critical Care**
www.sccm.org/professional_resources/disaster_resources/Documents/Rubinson_Online.pdf
- **Definitive Care for the Critically Ill During a Disaster** (special supplement to *Chest Journal*, addressing critical-care surge capacity during pandemics and other disasters)
www.chestjournal.org/content/vol133/5_suppl/
- **Homeland Security Exercise and Evaluation Program (HSEEP)**
<https://hseep.dhs.gov>
- **Medical and Health Incident Management (MaHIM) System: A Comprehensive Functional System Description for Mass Casualty Medical and Health Incident Management** (December 2002)
www.gwu.edu/~icdrm/publications/MaHIM%20V2%20final%20report%20sec%202.pdf
- **Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza** (May 12, 2008)
www.osha.gov/dsg/guidance/stockpiling-facemasks-respirators.html

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JOANNE R. LAX, ESQUIRE, is a 1978 *magna cum laude* graduate of the University of Michigan Law School, and has been practicing healthcare law at Dykema Gossett PLLC in Michigan since then. Ms. Lax focuses her practice on acute and long term care at health systems, hospitals, nursing homes, homes for the aged, assisted living facilities, home health agencies, and hospices. Her practice includes counseling on state

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Melissa L. Markey, Esquire is a shareholder with Hall, Render, Killian, Heath and Lyman, one of the nation's top health law firms, in the Troy, Michigan office, and is licensed to practice as an attorney in Texas and Michigan. Melissa leads the Life Sciences team at Hall Render, and she has a particular interest in emergency preparedness, human subject research, and technology law, including electronic health records, health information exchange, software licensing, data rights management and e-commerce issues, as well as patient care issues, and compliance. She is a member of the State Bar of Michigan, Health Care Law, Computer Law, and Intellectual Property Sections, the American Bar Association, and the American Health Lawyers Association, for which she is the Chair of the Teaching Hospitals and Academic Medical Centers practice group. She is also a member of the Health Information and Technology practice group and the Emergency Medical Services/Medical Transportation affinity group. Ms. Markey has presented and authored publications both within Michigan and nationally, including articles on clinical research and human subject protection research misconduct, emergency preparedness and response law, electronic medical records, HIPAA Privacy and Security, and the clinical-technology interface. Ms. Markey graduated *summa cum laude* from St. Louis University School of Law and is a Michigan licensed and Nationally Registered Emergency Medical Technician-Paramedic with many years of field experience.

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RICHARD L. SHACKELFORD, ESQUIRE, is a partner in King & Spalding's Atlanta, Georgia, office, and is a member of the firm's Healthcare Practice and Business Litigation groups. Mr. Shackelford represents health systems, health plans, home health agencies, long term care facilities, physician organizations, pharmaceutical and medical device companies, and managed care organizations in a wide variety of litigation and regulatory matters. He has been involved in many complex commercial litigation matters for healthcare clients, including consumer class actions against health plans and provider entities. He regularly represents healthcare clients in the defense of False Claims Act actions and government investigations. He also regularly advises healthcare clients on federal and state regulatory issues, including compliance, fraud and abuse, reimbursement and certificate of need. Mr. Shackelford also represents providers, health plans, and other managed care entities with regard to ERISA, insurance regulatory matters, and managed care disputes. He is a frequent lecturer and writer on healthcare regulatory, fraud and abuse, and health-

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MARILYN THOMAS, ESQUIRE, serves as the Chief Legal Counsel and Ethics Officer at the Illinois Department of Public Health (DPH). The DPH is a state agency that is the lead regulatory body over all health care facilities in the state and has a lead role in providing emergency response. She has held this position since October 2005. Prior to this time, Ms. Thomas was the Deputy Chief Legal Counsel and the lead attorney for the Office of Preparedness and Response. As Chief Counsel, Ms. Thomas is involved in a variety of complex legal issues related to regulatory issues of facilities (including hospitals, long term care facilities, and ambulatory and surgical treatment centers); contractual agreements; drafting and review of all DPH regulations and statutes; managing all internal and outside litigation; addressing issues related to employee relations issues and labor relations; leading efforts related to HIPAA, confidentiality, and electronic health records; and addressing human subjects research issues. Ms. Thomas serves as the ethics officer for the Illinois Regenerative Medicine Institute (Illinois' stem-cell research program), and is the Chair of the Department's Legal Workgroup for the HISPC project, an effort to develop and promote an Illinois health information exchange. Her responsibilities as in-house counsel are to oversee and manage all legal matters, and to advise the director and provide effective legal counsel and administration in all substantive areas of law affecting the agency. As Chief Counsel, she is responsible for all legal affairs affecting the DPH, and also serves as the ethics and privacy officer for the agency. She also represents and counsels the agency on many boards and advisory panels, and oversees all agency rulemaking. In the past year, she has been substantially involved in the development of agency regulations relating to emergency powers legislation, and specifically with developing comprehensive regulations on disease investigation, isolation, and quarantine. Ms. Thomas has worked to encourage preparedness activities and to promote educational efforts at the local level for state's attorneys and local health departments. She developed training for attorneys and local health departments, and hosted a sepa-

rate multi-agency meeting with other state agencies to review legal issues and to prepare for state-wide exercises. More recently, she has worked on implementing efforts for preparedness efforts in healthcare settings and with the private sector, and is currently working to develop a legal training for the judiciary. She has extensive civil and criminal litigation experience, and has served as an Assistant Attorney General and defended state agencies and state employees in state and federal court in central and southern Illinois. She also is a former prosecutor, having worked in the State's Attorney office for several years on criminal matters. She completed her post-graduate work at New York Law School and received her Juris Doctorate in 1993.

AUGUST J. VALENTI, M.D., is a graduate of Cornell University Medical College. He completed his internship and residency in internal Medicine at New York-Presbyterian Hospital and the Memorial Sloan-Kettering Institute for Cancer and Allied Diseases before completing a fellowship in infectious diseases at Yale University. Dr. Valenti is Director of Epidemiology and Infection Prevention at Maine Medical Center, and is Co-chair of Maine's Infectious Diseases Working Group, which meets regularly to bring people in the public and private sector together to work on matters related to communicable diseases. A nationally recognized authority in infectious diseases and healthcare epidemiology, Dr. Valenti has served the Society for Healthcare Epidemiology of America on its board and as a member of the annual scientific meeting's planning committee. He has authored a number of chapters for medical texts, and is a regular contributor to peer-reviewed scientific journals as an author, reviewer, and editor. Dr. Valenti is Clinical Professor of Medicine at the University Of Vermont College Of Medicine, a Fellow of the American College of Physicians, a Fellow of the Infectious Diseases Society of America, and a Fellow of the Society for Healthcare Epidemiology of America. For three decades, he has worked closely with experts in Maine and around the country to raise public awareness of infectious diseases, including pandemic influenza, biological disasters, emerging infectious diseases, and drug-resistant organisms. In addition to pandemic influenza and biological terrorism, Dr. Valenti's present interest is in the control of multidrug-resistant organisms in the healthcare setting and *Clostridium difficile*-associated disease. He is a member of the Centers for Disease Control and Prevention's *Clostridium difficile* Investigation Team, which is working on the current spread of a more virulent strain of this serious healthcare-associated infection. Maine has been preparing for pandemic

influenza as a model for biological disasters for more than ten years. Dr. Valenti has been involved in all levels of planning in his home state. He acts as an advisor to the Southern Maine Regional Resource Center, which is responsible for aiding communities in planning for biological disasters. He has participated in the development of pandemic influenza plans for healthcare institutions, businesses, and communities through educational outreach and writing or reviewing plans.

LISA DIEHL VANDECAVEYE, ESQUIRE, currently is serving as the Corporate Vice President of Legal Affairs with Botsford Health Care in Farmington Hills, Michigan. She graduated from the University of Toledo College of Law, earning a Juris Doctorate, with a Master of Business Administration Degree, specialization in Health Care Administration. Ms. Vandecaveye is Fellow of the American College of Healthcare Executives (FACHE). She completed the University of Chicago/MMI Companies' Healthcare Risk Management Certificate Program (HRM). As a member of the Senior Management Team at Botsford, Ms. Vandecaveye is responsible for the coordination of all legal services, including risk management, insurance, corporate compliance/ privacy, and security for a fully integrated healthcare system. She is a member of the Michigan Society of Healthcare Risk Management (past Board Member), the Michigan Society of Healthcare Attorneys (past President), the Michigan Bar Association (Health Law Section), and the American Health Lawyers Association (Board Member, Chair and Past Vice Chair, Teaching Hospitals & Academic Medical Centers Practice Group, 2001 Nominating Committee, 2006/2007/2008 Program Co-Chair for the In-House Counsel Program). In 2006, she was named Outstanding Alumnae from the University of Toledo College of Business Administration. She has presented on multiple healthcare topics, and authored many publications both within Michigan and nationally. She is currently Adjunct Faculty for Health Care Law, University of Toledo College of Law.

The American Health Lawyers Association, the U.S. Centers for Disease Control and Prevention, and the Office of Inspector General of the U.S. Department of Health & Human Services greatly appreciate the participation of the following individuals in AHLA's Public Interest Dialogue Session on Community Pan Flu Preparedness, Pandemic and H5N1 Flu: A Prescription for Preparedness.

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