

LESSONS LEARNED FROM THE GULF COAST HURRICANES



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1025 Connecticut Avenue, NW, Suite 600
Washington, DC 20036-5405
Telephone: (202) 833-1100
Facsimile: (202) 833-1105
E-mail: info@healthlawyers.org
Website: www.healthlawyers.org

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—from a declaration of the American Bar Association

Lessons Learned from the Gulf Coast Hurricanes is a follow-up publication to the *Emergency Preparedness, Response & Recovery Checklist: Beyond the Emergency Management Plan* in the American Health Lawyers Association's (Health Lawyers) Public Information Series. Health Lawyers hopes that legal counsel will find the frequently asked questions (FAQs) discussed in this title to be a useful supplement to the checklist of key legal and operational issues that was initially developed to facilitate a healthcare provider's emergency preparedness planning in the event of a public health crisis, terrorist threat, environmental disaster, or other emergency situation. In this publication, Health Lawyers draws on experiences from healthcare providers involved in environmental disasters that have implications for providers across the country. Health Lawyers believes that healthcare executives, governing bodies, medical staff, other health professionals, and community leaders will also benefit from the additional insights gained as a result of analyzing these emergency situations and distilling lessons that were learned from the hurricanes that ravaged the Gulf Coast areas during the summer of 2005.

Health Lawyers' Public Information Series is one of a variety of public interest activities that arise from the third element of the Association's mission statement: "...to serve as a public resource on selected health-care legal issues." Health Lawyers recently broadened its public interest role (which previously emphasized activities related to the formulation of health policy) to include activities through which the Association can serve as a public resource on health law issues for certain legal-services agencies and other nonprofit organizations. Many members contribute *pro bono* services in their communities and find that it provides a fulfilling outlet by allowing them to use their professional skills for the betterment of society. Broadening Health Lawyers' initiatives in public resource outreach is consistent with the Association's desire to give back to society from our members' legal expertise. Health Lawyers plans to publish on a periodic basis informational resource guides related to health law topics in the public interest or on *pro bono* matters and to make these complimentary guides available to the public.

The Series is supported in part by generous donations from many Health Lawyers members and their firms and organizations. On behalf of Health Lawyers' Board of Directors, I wish to thank all of the Health Lawyers members who have made a contribution and ask members who may not have contributed in the past to consider doing so.

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If you have suggestions for future publications for 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, J.D., Manager of Public Interest, at (202) 833-0787 or kwone@healthlawyers.org.



Elisabeth Belmont
President, 2007-2008 American Health Lawyers Association
Task Force Leader, *Lessons Learned from the Gulf Coast Hurricanes*
Chair, 2003-2005 Public Interest Committee

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Elisabeth Belmont, Esquire
Jenifer A. Belt, Esquire
Richard G. Cowart, Esquire
Michele M. Garvin, Esquire
Julianna S. Gonen, Esquire
Clinton D. Hermes, Esquire
Melissa L. Markey, Esquire

Anne M. Murphy, Esquire
Dinetia M. Newman, Esquire
Montrece McNeil Ransom, J.D.
Jeffrey M. Sconyers, Esquire
Sarah L. Trautz, Esquire
Colin J. Zick, Esquire

I. Introduction

On December 2, 2004, the American Health Lawyers Association released the inaugural issue of its Public Information Series. *The Emergency Preparedness, Response & Recovery Checklist: Beyond the Emergency Management Plan* identified the key legal and operational issues arising in the event of a public health crisis, terrorist threat, environmental disaster, or other emergency situation to facilitate a healthcare provider's emergency-preparedness planning. When Hurricanes Katrina, Rita, and Wilma hit the U.S. Gulf Coast in 2005, their combined effects became one of the most destructive natural disasters in the nation's history. These natural disasters caused a staggering and unprecedented level of human suffering experienced by Gulf Coast residents who were displaced, injured, or killed. The economic effect of these hurricanes is incalculable, and its aftermath likely will spread throughout the nation for years to come.

Lessons Learned from the Gulf Coast Hurricanes reflects experiences of healthcare providers and health professionals involved in these natural disasters and addresses the legal issues that arose in the context of the Gulf Coast hurricanes. It also examines additional insights gained as a result of analyzing the specific healthcare challenges posed by these hurricanes. This publication is organized in a series of Frequently Asked Questions (FAQs) that addresses the following phases of an emergency: (i) preparation; (ii) response; and (iii) recovery.

Following the devastation of the Gulf Coast hurricanes of 2005, many natural disasters have occurred in the United States, including:

- Landslides and mudslides in Hawaii, California, Oregon, Washington, and Pennsylvania (February through June 2006);
- Tornadoes in Tennessee, Missouri, Arkansas, Oklahoma, Virginia, Maryland, Ohio, Illinois, and Kansas (March through July 2006); and
- Flooding in twenty-three states, with the declaration of a Federal Major Disaster on twenty-seven occasions (February to October 2006).

Federal Major Disasters were declared fifty-two times in the United States during 2006.¹ Such disasters are not limited to the United States; landslides in the Philippines in February 2006, an earthquake in Indonesia in May 2006, and floods in Ethiopia in August 2006 were among other natural disasters worldwide. These events illustrate that no part of the world is immune from a natural disaster or other emergency situation. As a result, it is prudent for all healthcare providers to undertake a hazard vulnerability assessment and adopt preparedness measures to address emergency planning, operations during the emergency, and recovery efforts.

¹ See Federal Emergency Management Agency (FEMA), 2006 Federal Disaster Declarations, *available online at* www.fema.gov/news/disasters.fema?year=2006 (last visited April 1, 2008).

The authors advise every healthcare provider to undertake its own hazard vulnerability analysis to identify the particular risks associated with its unique operations and geographic location. Healthcare providers also are encouraged to mitigate those risks most important to its operations. For example, hospitals located in Colorado are at a higher risk of snow- and ice-related disasters. In a hard freeze, fuel will not flow; thus, it may be prudent to locate a fuel-driven emergency power generator on the ground floor of the facility, as opposed to the basement. In contrast, the Gulf Coast region is more susceptible to flood-related disasters, and providers in the region would employ different steps to mitigate potential water damage. Mitigation of potential risks is particularly important because inadequate insurance coverage may be available following a natural disaster or other emergency situation. For instance, in the wake of the Gulf Coast hurricanes, many victims discovered that, although their insurance policies covered damage from the wind, those policies typically did not cover flood damage resulting from a hurricane or wind-driven water damage from storm surges.²

Additionally, little governmental assistance may be available, as illustrated by Fairfax County, VA, where homeowners experienced heavy rains and flooding in late June of 2006. The Federal Emergency Management

Agency (FEMA) denied Virginia's application for emergency aid for residents of Fairfax and Arlington counties and the city of Alexandria whose homes were flooded during these severe storms. In rejecting Fairfax County's request for flood assistance in particular, a FEMA official commented that Fairfax homeowners were not eligible for federal aid because they live in an affluent community that should address its own needs.³

Moreover, the lack of emergency preparedness may subject healthcare providers to criminal liability. The owners of St. Rita's Nursing Home in St. Bernard Parish, LA, were charged with negligent homicide in the deaths of thirty-four people who drowned because they were not evacuated after Hurricane Katrina hit.⁴

A final note: A healthcare provider must take care of its employees both during and after the emergency. Effective crisis response includes recognition and close attention to meeting the needs of affected people—employees as well as members of the larger community—from the immediate aftermath of the disaster and on through the crisis-recovery phase. Ultimately, effective crisis management focuses on adequately addressing the concerns and needs of affected stakeholders.

Both the *Emergency Preparedness, Response & Recovery Checklist: Beyond the Emergency Management Plan* and the *Lessons Learned from the Gulf Coast Hurricanes* are available free of charge through the Association's website.

To download the **Checklist**, go to www.healthlawyers.org/checklist
To download **Lessons Learned**, go to www.healthlawyers.org/lessonslearned

2 See, e.g., *Leonard v. Nationwide Mutual Ins. Co.*, 2006 WL 2353961 (S.D. Miss. Aug. 15, 2006).

3 See Lisa Rein and Bill Turque, *FEMA Denies Aid to Homeowners, Tells Fairfax to Help Its Own More*, WASHINGTON POST, Aug. 2, 2006, at B03, available online at www.washingtonpost.com/wp-dyn/content/article/2006/08/01/AR2006080101407.html (last visited April 1, 2008).

4 See *Nursing home owners face charges: couple charged with 34 counts of negligent homicide*, CNN, Sept. 13, 2005, available online at www.cnn.com/2005/US/09/13/katrina.impact (last visited April 1, 2008).

II. Declaration of an Emergency

A. What is a “declaration” of an Emergency or Major Disaster?

A declaration of a disaster or emergency is a public announcement—a statement or declaration by which the government recognizes that an emergency situation exists. A declaration is a legal determination made by an authorized official, in accordance with criteria specified by law, which has the particular effect specified in the governing law. A declaration may trigger special emergency powers, e.g., allowing the expenditure of emergency funds in advance of appropriation or in lieu of appropriation, and waiving or modifying normal legal requirements.

B. What are the three key types of federal declarations available?

There are many types of Emergency and Disaster declarations, each with different purposes, uses, and procedures. The three key types of declarations are general “Emergency,” “Public Health Emergency,” or “Major Disaster.” They are defined as follows.

1. Emergency

An Emergency is an 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.⁵

2. Public Health Emergency

A Public Health Emergency exists when the Secretary of the Department of Health and Human Services (DHHS) determines that “(1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.”⁶ For purposes of this discussion, the term “Emergency” will include Public Health Emergencies.

3. Major Disaster

A “Major Disaster” is 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 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.⁷

C. Who has the authority to declare an Emergency?

On the federal level, the Secretary of DHHS has the authority to declare a Public Health Emergency.⁸ The Secretary of DHHS makes a determination that a public Health Emergency exists after consultation with appropriate public health officials. Such a declaration lasts for ninety days, unless terminated or extended by the DHHS Secretary. After consultation with such public health officials as may be necessary, the DHHS Secretary may take such action as may be appropriate. Such action may include making grants; providing awards or reimbursement for expenses; entering into contracts; conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder; mobilizing the Public Health Service (PHS) Corps; allowing emergency approvals of medical products; waiving requirements for Medicare, Medicaid, or other DHHS programs; and allowing waiver of any deadlines for submission of any data or reports required under any law administered by the DHHS Secretary.

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.

⁵ 42 U.S.C. § 5122(1).

⁶ 42 U.S.C. § 247d.

⁷ 42 U.S.C. § 5122(2). On August 31, 2005, Hurricane Katrina became the first event to be declared an “Incident of National Significance.” This declaration triggered the new National Response Plan, which names the Department of Homeland Security as the lead in coordinating federal response and recovery efforts.

⁸ 42 U.S.C.A. § 247d.

Under federal law, Emergencies and Major Disasters alike must be declared as such by the President of the United States. A request for such a declaration must be made by the governor of the affected state(s), and it must be based on a finding that the emergency or disaster is of such severity and magnitude that effective response is beyond the capabilities of the state and local governments, and that federal assistance is needed.⁹

As part of the governor's request to make a federal declaration, the governor must take appropriate responsive action as defined by state law, direct execution of the state's emergency plan, and authorize the deployment and use of personnel, including mobilization of the National Guard. In addition, the governor must furnish information about the nature and amount of state and local resources that have been or will be committed to the emergency/disaster, and must certify that state and local cost-sharing requirements will be met.¹⁰

In certain emergencies, the President may determine that the primary responsibility for response rests with the United States due to the fact that the emergency involves an area for which, under the Constitution or laws of the United States, the United States exercises exclusive or preeminent responsibility or authority. In determining the existence of an emergency of this nature, the President should consult with the governor(s) of the affected state(s), if practical; nevertheless, the President can make an emergency declaration absent the request and certifications from the governor outlined earlier.¹¹

D. What are the potential results of declaring a federal Emergency?

Under a declaration of a Public Health Emergency, the DHHS Secretary "may take such action as may be appropriate to respond to the public health emergency."¹² Such action may include the following.

1. Social Security Act waivers – The Secretary of DHHS may waive requirements of the Social Security Act during a declared

Emergency if necessary to ensure that items and services are available to recipients of Social Security, Medicare, and Medicaid patients. DHHS also may ensure that providers can be reimbursed even if providers cannot comply with all requirements due to the emergency.¹³

2. Authorization for medical products for use in Emergencies – The declaration of an Emergency allows the Secretary of DHHS to authorize the use of medical products prior to approval by the Food and Drug Administration (FDA) during the emergency period.¹⁴
3. Enhanced control of dangerous biological agents and toxins – In an Emergency, the requirements for control of dangerous toxins can be waived by DHHS if necessary to allow workers to address the crisis.¹⁵

E. What federal resources may be available without declaring a federal Emergency?

The National Disaster Medical System and/or the Strategic National Stockpile can be deployed without a declaration of a Public Health Emergency. Federal law indicates that they can be deployed to respond to the needs of a Public Health Emergency, regardless of whether one is so declared.¹⁶

Note: With the declaration of an Emergency, funding for activities may be more substantial, given that the Secretary of DHHS may use the Public Health Emergency Fund (assuming there is a current appropriation to this fund; in many years, this fund does not receive specific appropriation).¹⁷

F. What are some important questions to consider in relation to the declaration of an Emergency or Major Disaster?

The following list presents some important questions to consider when an emergency occurs.

1. Has the President of the United States declared an Emergency or Major Disaster that triggers federal response mechanisms (including Small Business Administration [SBA] and Federal Emergency Management Agency [FEMA])?

9 42 U.S.C. §§ 5170, 5191(a); 44 C.F.R. § 206.48.

10 42 U.S.C. §§ 5170, 5191(a); 44 C.F.R. §§ 206.31 – 206.40.

11 42 U.S.C. § 5191(b).

12 42 U.S.C. § 247d(a).

13 42 U.S.C. § 1320b-5.

14 42 U.S.C. § 360bbb-3.

15 42 U.S.C. § 262a.

16 42 U.S.C. § 300hh-11.

17 42 U.S.C. § 247d(b).

DECLARATION OF AN EMERGENCY

2. Has the SBA declared a disaster, triggering the SBA disaster-loan program?¹⁸
3. Is the affected organization located in the declared emergency or disaster area?
4. If yes, is it located in a declared county or an adjacent county? (Location may affect the type of SBA loan for which the business is eligible.)
5. What type of assistance does the business need? (Short-term assistance, which is coordinated through FEMA, may include supplies, personnel, debris removal, technical assistance, and the like. Long-term assistance may include loans, which are coordinated through the SBA.)
6. Is the business considered a “large” or “small” business by federal standards? (Large businesses are eligible for SBA Physical Disaster Business Loans, but not Economic Injury Disaster Loans or Pre-Disaster Mitigation Loans. Small businesses are eligible for all three types of loans.)
7. Is the business eligible for loans from other sources that may be used for disaster assistance? (If so, the business may not be eligible for SBA disaster assistance loans.)

¹⁸ For more information on SBA assistance, see section 11, *supra*.

I. Licensing and Credentialing Issues: Temporary Licensing and Credentialing of Healthcare Workers

The regulatory structure for licensing healthcare workers is done on a state-by-state basis. Accordingly, the actions of state government to determine which healthcare workers require licensing, and which licensing is suspended due to natural disasters or other states of emergency, is the important point of the demarcation. Credentialing is performed on an institutional basis, with certain licensure and accreditation requirements built into the institutional processes. Both are discussed briefly in this section.

Each state has a process in which the governor can declare a state of emergency based on imminent threat or major disaster. Gubernatorial authority also extends to the declaration of Public Health Emergencies. Depending on state law, such declarations also may suspend out-of-state licensure requirements for medical professionals and personnel. Some states also may extend the benefit of state sovereign immunity, or provide protection under state tort claims acts to medical professionals and other personnel providing disaster-response services.¹⁹

On a federal level, DHHS Secretary Michael O. Leavitt waived certain requirements under the Social Security Act on September 1, 2005, to ensure that sufficient healthcare items and services were available to meet the needs of Medicare enrollees affected by Hurricane Katrina.²⁰ Among other requirements, this action waived the requirement that physicians hold licenses in the state in which they provide services. It is important to note that, although this federal action

was helpful, only state action (as described in the preceding paragraph) actually conferred the authority to practice medicine or another licensed profession during the emergency.

A. What temporary licensing measures are available for displaced professionals who have relocated to other states during the Emergency and during the pendency of recovery efforts?

The Gulf Coast hurricanes displaced a significant number of healthcare professionals and personnel, who were then in the position of seeking employment in the aftermath of the hurricane. A number of states issued gubernatorial executive orders suspending licensure requirements for medical professionals and personnel for a brief period after the hurricanes. These orders are generally within the authority of state governors, and in any event depend on the provisions of state (not federal) law.²¹

B. What licensing requirements are applicable to healthcare facilities who closed during an Emergency?

Many hospitals were forced to close as a result of the hurricane. State licensing statutes and regulations came into play with those closures and subsequent re-openings. With Louisiana Executive Order No. KBB 1005-37,²² Governor Blanco instituted the following emergency suspension of certain provisions regarding temporarily inoperable hospitals and simplified the reopening process.

1. LA. ADMIN. CODE tit. 48, § 9305 (2003), which voids a hospital license once a hospital ceases to operate, was suspended to the

19 For example, in the case of Hurricane Katrina, Kathleen Blanco, governor of Louisiana, declared a state of emergency based on the imminent threat of Hurricane Katrina on August 26, 2005. See Declaration of State Emergency, Proclamation No. 48KBB2005-40, Kathleen Blanco, Governor of Louisiana, August 26, 2005, available online at www.gov.state.la.us/assets/docs/Proclamations/48pro2005-Emergency-HurricaneKatrina.pdf (last visited April 1, 2008). After the hurricane, Governor Blanco declared a public health emergency to suspend out-of-state licensure for medical professionals and personnel. See Executive Order No. KBB2005-33, Kathleen Blanco, Governor of Louisiana, September 12, 2005, available online at www.gov.state.la.us/assets/docs/26PublicHealthEmergencyDeclaration.pdf (last visited April 1, 2008). In addition to declaring that the Louisiana state-licensure laws, rules, and regulations for medical professionals and personnel were suspended for those professionals and personnel from other states offering services to Louisiana, the governor also declared that all such out-of-state medical professionals and personnel shall be covered under the Louisiana Tort Claims Act. Similar declarations were issued by the governors of Mississippi and Alabama.

20 As originally executed, this waiver applied only to the affected states of Louisiana, Mississippi, Florida, and Alabama. Concerns arose that Texas was not included in the DHHS initial waiver, despite the fact that Texas healthcare providers were, in large part, responding to the emergency needs of evacuees. In response, over the Labor Day weekend, the DHHS Secretary amended the waiver to include providers in Texas. This amended waiver, effective September 6, 2005, is retroactive to August 24, 2005, for Florida; August 29, 2005, for Alabama, Louisiana, and Mississippi; and September 2, 2005, for Texas. See www.cms.gov (last visited April 1, 2008).

21 For example, Phil Bredesen, governor of Tennessee, issued an executive order allowing displaced medical professional and personnel to practice in Tennessee for 100 days without a license while the scope of the disaster and recovery plans were developed. See Executive Orders Nos. 27, 29 and 32, Phil Bredesen, Governor of Tennessee, dated respectively September 3, September 29, and October 31, 2005, available online at tennessee.gov/sos/pub/execorders/ (last visited April 1, 2008).

22 La. Exec. Order No. KBB 2005-37, Emergency Suspension of Certain Provisions Regarding Temporarily Inoperable Hospitals, Sept. 19, 2005, available online at www.gov.state.la.us/assets/docs/newsrelated/37EmergHospitalsReopenProvisions.pdf (last visited April 1, 2008).

extent that it applied to hospitals located in parishes²³ affected by the storm.

2. LA. ADMIN. CODE tit. 48, § 9307 (2003), which provides for procedures for the closure of a hospital upon cessation of business, was suspended to the extent it applied to hospitals located in parishes affected by the storm.
3. A hospital located in a parish affected by the storm that ceased to operate was to notify the Louisiana Department of Health & Hospitals (DHH) in writing when the hospital became operable and capable of providing services to the community, and DHH was to conduct any and all necessary surveys and inspections and/or reviews upon receipt of such notification.

For more information on decommissioning a hospital and subsequent reopening, see section VII of this document.

C. By what authority do institutions credential Emergency healthcare personnel responding to disaster-relief efforts?

Each institution has its own professional bylaws with regard to credentialing. In general, hospital medical staff bylaws are modeled in each state after the state-licensure requirements for hospitals and the accreditation requirements of The Joint Commission (formerly known as The Joint Commission on the Accreditation of Healthcare Operations). The Joint Commission Standard MS 4.110 addresses disaster privileges: Disaster privileges may be granted when the emergency management plan has been activated and the hospital is unable to handle immediate patient needs. In virtually all cases, medical staff and professional bylaws provide for emergency credentialing by the chief executive officer of the institution. This is the mechanism by which out-of-state emergency workers can assist in recovery efforts until the institutional processes can be reinstated and processed in due course.²⁴

²³ Note that Louisiana “parishes” are synonymous with “counties” in other states.

²⁴ For example, in its Emergency Rule 17, the Louisiana Commissioner of Insurance suspended physician credentialing requirements for all licensed physicians who provided medical services to insureds from parishes affected by the hurricane. See 31 La. Reg. 2408 (Emergency Rule 17), available online at www.doa.state.la.us/osr/reg/0510/0510EMR.pdf (last visited April 1, 2008).

IV. Patient Evacuation

A. Preparation Phase

1. What advance arrangements should be made for the evacuation of patients in the event of an emergency that requires closure of the facility?

All hospitals and nursing homes are required by the federal Centers for Medicare & Medicaid Services (CMS) to develop and maintain emergency plans. In addition, The Joint Commission requires the facilities that it accredits to maintain emergency plans that include evacuation procedures.²⁵

Facilities should enter into transfer agreements with other institutions in the area to expedite the transfer of patients to those institutions in the event of an emergency. Facilities should consider how wide a radius within which to identify potential transferee sites, as nearby sites might also be in evacuation mode in the event of a significant local disaster or emergency. The type of transfer agreement will vary by facility type. For example, nursing homes will need to identify facilities that can accept patients who might need to stay for an extended period, particularly if the transferring facility is damaged and cannot take back its residents right away. Hospitals that are part of multi-hospital systems might be able to take advantage of relationships with affiliated entities without the need for formal transfer agreements.

Institutions might consider inquiring with local transport companies with whom they work to identify other facilities that work with that same transfer company. These facilities represent potential transfer-agreement partners. In addition, institutions should identify alternative means of transporting patients, as a facility's contracted transportation providers might be unavailable during a crisis.

Transfer agreements should be as specific as possible in identifying the respective roles of the parties depending on the type of emergency in effect. In particular, inpatient facilities should consider transfer agreements with long term care facilities or other health-care institutions to which inpatients might need to be returned in the event that the inpatient facility enters evacuation mode. For example, in

the aftermath of Hurricane Katrina, nursing homes often sought to evacuate their patients to hospitals, which in turn were facing their own decisions regarding whether to evacuate.

2. With whom should a facility coordinate its evacuation plan?

Facilities should be familiar with the emergency preparedness and response plans established in their local jurisdiction, and (if possible) participate in the drafting and revision of such plans. Local officials likely will be anticipating the role of hospitals and other health-care institutions in the event of an emergency, and having facility personnel involved in the development of local plans will help to ensure that the jurisdiction's plan is based on accurate information and that the facility is aware of its role and expectations placed on it by local authorities. During the 2005 Gulf Coast hurricanes, the role of hospitals as vital community resources was illustrated starkly. This reality should inform local community-preparedness efforts. These initiatives, in turn, should inform the facility's own efforts to develop an internal emergency response plan.

Facilities also should work with other health-care institutions in the area in developing their own evacuation protocols to ensure maximum cooperation during an emergency.

Hospital personnel charged with responsibility for developing and implementing disaster-preparedness plans should make sure that they know the state and local officials responsible for developing local disaster plans and for implementing aspects of those plans. All parties should be familiar with how communications will be affected during an emergency if normal channels are compromised. As facilities' obligations might be altered by pronouncements of local officials, it is critical that the lines of communication remain open. By the same token, if one facility does decide to close and begin diverting patients, that facility may have legal obligations to notify certain officials. Facilities should have relevant contact information for such purposes prior to any emergency event.

It will also be important that personnel responsible for implementing emergency-response protocols have ready access to hard-copy lists of resources and contacts within the community

25 THE JOINT COMMISSION, 2006 HOSPITAL ACCREDITATION STANDARDS, Standard EC 4.10.

that might be needed to effect the evacuation of patients.

Institutions might also consider developing evacuation plans in conjunction with neighboring facilities in order to pool resources. For example, during Hurricane Katrina, a hospital chain, HCA, hired a number of helicopters for use in evacuating patients from several of its facilities in the affected region, and then allowed other non-HCA hospitals to use the aircraft for their own evacuation efforts.²⁶

B. Response Phase

1. How does a facility determine whether to remain open, or close and evacuate patients, in an emergency?

The decision whether to evacuate often will fall to hospital or nursing-home administrators, because these facilities are frequently exempted from general orders to evacuate that are issued by local authorities.

Facilities should ensure that a clear chain of command is in place, including the authority for making a closure determination. Those charged with this responsibility should ensure that they consult applicable local, state, and/or federal authorities regarding the possible existence of a state of emergency or waiver of certain legal obligations. It is also important to identify those authorities that need to be informed of a decision to close.

A facility's emergency response plan may be drafted in such a way that the declaration of a state of emergency by public officials serves as the triggering event for the facility's own plan. In this case, it will be important that facility personnel responsible for invoking the emergency plan are in communication with relevant officials.

The decision whether—and when—to evacuate is a critical one, and the timing of that decision will be of the utmost importance. After more than forty bodies were found at Memorial Medical Center in New Orleans following Hurricane Katrina, questions were raised as to why that facility (and many others) had

not evacuated sooner. When advance warning of an impending emergency is available, hospitals and other inpatient facilities will need to determine whether to begin discharging patients ahead of the onset of the crisis. The decision whether to evacuate or shelter in place will involve weighing several factors, including whether the facility has adequate resources to continue functioning and providing patient care if it does not evacuate, as well as the risks to patients posed by an evacuation.

2. What legal obligations apply to a facility that has closed and is evacuating patients?

In the context of evacuation, the requirements of the Emergency Medical Treatment and Labor Act (EMTALA)²⁷ are preeminent. In addition, the existence of emergency conditions might affect other legal or regulatory requirements applicable to evacuating institutions. For more information on decommissioning a facility, see section VII of this document.

a. EMTALA Obligations – In General

EMTALA requires hospitals to evaluate, stabilize, and treat or transfer patients presenting to the emergency department. The statute applies to all hospitals with emergency departments that participate in Medicare.²⁸ A patient need not present directly to the emergency department for EMTALA's requirements to apply; the statute is invoked when a patient arrives on hospital property or is placed in a hospital-owned ambulance.²⁹ The obligations apply to any patient, not only those covered by Medicare; the duties are unrelated to reimbursement.

EMTALA requires that a hospital provide to any person who requests it an appropriate medical screening examination (within its capabilities) to determine whether an emergency medical condition exists. The screening exam must be performed by "qualified medical personnel."³⁰ This exam may not be delayed in order to ascertain a patient's financial or insurance status.

26 Cinda Becker & Joseph Mantone, *Cries for Help – Hospitals Overwhelmed by Katrina's Aftermath*, MOD. HEALTHCARE 8 – AL, September 5, 2005.

27 42 U.S.C. § 1395dd.

28 EMTALA's requirements do not apply to hospitals without emergency departments, as well as non-hospital facilities, freestanding emergency facilities not affiliated with a hospital, and ambulatory-care facilities.

29 42 C.F.R. § 489.24(b).

30 EMTALA requires that a hospital maintain a list of on-call physicians, and that such physicians respond when called within an appropriate amount of time. 42 C.F.R. § 489.24(j).

If an emergency medical condition exists,³¹ then the hospital must provide treatment to stabilize the condition, or provide for an appropriate transfer to another facility. If the patient is not stable, the hospital may not transfer the patient unless:

- i. The patient requests a transfer in writing after being informed of the hospital's obligations and the risks of transfer;
- ii. A physician or other qualified person certifies that the benefits of the transfer outweigh the risks (and the risks and benefits considered are documented); or
- iii. The transfer is "appropriate" as defined.³²

Medical records must accompany the transferred patient.

b. EMTALA Requirements During an Emergency

The original EMTALA statute did not contain any suggestions that its obligations would vary in the event of a public health emergency or other event. In 2001, CMS suggested in an informal letter³³ that there might be exceptions to the stabilization requirements if a community response plan is in place. The letter also set forth some limitations to the screening requirements if a facility is not designated to receive certain categories of patients in a community response plan. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002³⁴ articulated a more formal policy regarding EMTALA obligations in an emergency situation. The legislation authorized the Secretary of DHHS to waive sanctions for EMTALA violations when the violation comes from an inap-

propriate transfer of an unstable patient during a Public Health Emergency (as defined by a presidential declaration; see section 2). EMTALA regulations³⁵ provide that sanctions for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department that is located in an emergency area, as specified in Section 1135 of the Social Security Act.³⁶

The final EMTALA rule, promulgated on September 9, 2003,³⁷ also addressed situations presenting a public health emergency; nevertheless, similar to the 2001 CMS letter and the 2002 legislation, the final rule did not definitively answer the question regarding the full extent of EMTALA obligations in a crisis situation. The preamble to the rule references the 2001 CMS letter, and notes that the final rule adds a provision to EMTALA dealing with the declaration of a Public Health Emergency. The new provision states that sanctions under EMTALA for an inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area. In the event of such an emergency, CMS would issue appropriate guidance to hospitals.

CMS issued "Interpretive Guidelines" to State Survey Agency Directors on May 13, 2004.³⁸ These guidelines seemed to restate the position taken in the 2001 CMS letter. Referencing the new regulatory provision implemented with the 2003 final rule,³⁹ the guidelines state that, in the event of a national emergency or crisis, if state or local governments have implemented community-response plans designating certain facili-

31 An emergency medical condition is defined as

a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: 1) placing the individual in serious jeopardy; 2) serious impairment to bodily functions; 3) serious dysfunction of any bodily organ or part; or 4) with respect to a pregnant woman who is having contractions, delivery before reaching the receiving hospital or a threat to the health or safety of a pregnant woman or unborn child.

42 U.S.C. §1395dd(e) (1).

32 42 U.S.C. § 1395dd(c) (1).

33 CMS, Survey and Certification Letter, Question and Answer Relating to Bioterrorism and the Emergency Medical Treatment and Labor Act (EMTALA), Ref S & C-02-04, Nov. 8, 2001, available online at www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter02-04.pdf (last visited April 1, 2008).

34 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188.

35 42 C.F.R. § 489.24(a) (2).

36 42 U.S.C. §1320b-5(g) (1).

37 68 Fed. Reg. 53,222 (2003).

38 CMS, STATE OPERATIONS MANUAL (SOM) APP. V PT II, "Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases," available online at www.cms.hhs.gov/manuals/downloads/som107ap_v_emerg.pdf (last visited April 1, 2008).

39 42 C.F.R. § 489.24(a) (2).

ties to handle particular categories of patients, then hospitals in the area that are not designated facilities still must provide a medical screening exam, but may then transfer patients in those categories to a designated facility without triggering EMTALA sanctions.

CMS published additional guidance following the 2005 Gulf Coast hurricanes. In response to the general query regarding whether EMTALA's requirements remain in place during a declared Public Health Emergency, CMS stated:

Generally, yes. However, CMS will not impose sanctions on a hospital located within the jurisdiction of the public health emergency declaration if the hospital redirects or relocates an individual to another location to receive a medical screening examination pursuant to a state emergency preparedness plan or transfers an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency within a limited period of time after implementation of the hospital's disaster protocol. This waiver, however, is not effective with respect to any action taken that discriminates among individuals on the basis of their source of payment or their ability to pay.⁴⁰

Regarding transfer requirements in circumstances in which communications with transferee sites might not be possible, CMS stated:

Under these circumstances, not obtaining acceptance before initiating a transfer would not be an EMTALA violation. If complaints are received, we would ask surveyors to determine whether, given the absence of communication in area, the hospital acted reasonably and in the patient's best interest in transferring the patient without an agreement to accept the patient.⁴¹

Another response posted by CMS addressed whether a hospital that is evacuating may close its emergency department, and (if so) who must be notified:

Under these circumstances, EMTALA would not prohibit the hospital from closing its [emergency department] to new patients (in effect, going on diversion). However, the hospital would continue to have an EMTALA obligation to individuals undergoing examination or treatment in its [emergency department] while the evacuation is underway. In most cases, this would mean that individuals would receive only triage followed by the minimum level of care needed to protect their health and safety while they and other patients are being evacuated to a site where screening and stabilization can be provided. Once the [emergency department] patients and staff have been evacuated and the [emergency department] has no capacity to render treatment, the hospital would no longer be obligated under EMTALA. At that point, its only obligation would be to comply with the hospital Conditions of Participation (COPs) at 42 CFR 482.12(f)(2). That regulation requires hospitals that do not offer emergency services to have policies and procedures in place for appraisal of emergencies, initial treatment, and referral when appropriate.

CMS does not specify who must be notified when a hospital declares diversionary status ...we expect, however, that the hospital would comply to the extent circumstances permit with any State or local notification requirements and that it would follow its own previously established plan for notification when it elects diversionary status.⁴²

Assuming that EMTALA's obligations remain in effect, institutions will need to ensure that they have access to sufficient resources to transfer patients in a compliant fashion in an evacuation. Facilities also will need to ensure that they can adequately document their EMTALA

40 CMS, FREQUENTLY ASKED QUESTIONS (hereafter CMS FAQ), Question ID No. 5694, "Are hospitals required to comply with all of the requirements of EMTALA during the period of the public health emergency declaration?," created Sept. 15, 2005. CMS FAQs are available online at questions.cms.hhs.gov (last visited April 1, 2008).

41 CMS FAQ, *supra* note 40, Question ID No. 6009, "Do EMTALA transfer requirements apply in a situation where an emergency patient requires transfer, but acceptance cannot be obtained because telephone circuits are busy?," created Oct. 5, 2005.

42 CMS FAQ, *supra* note 40, Question ID No. 6008, "May a hospital that is evacuating because of a mandatory or voluntary evacuation order close its emergency department (ED) when it begins its evacuation?," created Oct. 5, 2005.

compliance. Depending upon the type of emergency, institutions may need to alter normal screening protocols (e.g., perform them outside in the event of a contamination threat).

c. 1135 Waivers

Facilities should determine if there are any 1135 waivers or other temporary directives in place that alter normal regulatory requirements.⁴³ The 1135 waivers apply within “emergency areas,” defined as areas in which an Emergency has been officially declared. These waivers serve to alter otherwise applicable Medicare, Medicaid, and SCHIP requirements. The purpose of the waivers is to

ensure (1) that sufficient health care items and services are available to meet the needs of Medicare, Medicaid and SCHIP beneficiaries; and (2) that health care providers that furnish such items and services in good faith, but are unable to comply with certain requirements, may still be reimbursed for such services and exempted from sanction (absent fraud or abuse).⁴⁴

The 1135 waiver may remain in effect for the duration of the declared emergency. It is important to note the example of Hurricane Katrina, however, in which waivers of sanctions under EMTALA in the emergency area ended seventy-two hours after implementation of the hospital’s disaster plan.⁴⁵ The Secretary of DHHS also may determine that 1135 waivers are no longer needed prior to the end of a declared emergency, and may terminate the waivers accordingly.

3. With whom should the evacuation of patients be coordinated?

Ideally, an institution’s emergency response plan will have been developed in coordination with local authorities so that clear protocols are established regarding which officials and agencies must be involved in a closure determination and resulting evacuation. For example, during Hurricane Katrina, the DHH helped in coordinating evacuation

efforts by triaging patients at Louisiana State University before sending them to facilities able to receive them. In addition to public officials, private entities such as state hospital associations may also serve vital coordination roles in the face of an emergency.

A number of external entities might need to be informed of a closure, including other health-care providers, ambulance companies, emergency medical services (EMS), other first responders, and local authorities (e.g., agencies involved in public safety, public health, and facility licensing).

4. What is the role of the National Disaster Medical System?

Institutions may avail themselves of resources through the National Disaster Medical System (NDMS). Formed in 1984, the NDMS is a partnership among several federal agencies, including the Department of Homeland Security (DHS), DHHS, Department of Defense (DOD), and the Veterans Administration (VA). Its purpose is to provide health and other services during emergencies in conjunction with state agencies and other public and private entities. DHS has responsibility for the program’s activation, administration and funding. Under the federal National Response Plan, DHS is empowered to activate the NDMS in response to emergencies, including presidentially declared emergencies or disasters under the Stafford Disaster Relief and Emergency Assistance Act.

The NDMS has three components: medical response (health services at incident sites); patient evacuation (communication and transportation); and “definitive care” (medical treatment beyond emergency care upon admission to a designated NDMS treatment facility). Although medical response is coordinated by DHS, patient evacuation is led by DOD. DOD and the VA share responsibility for managing “definitive care.” The NDMS has agreements with private hospitals to receive evacuated patients. The program currently is not configured to provide assistance in evacuating nursing homes.

43 42 U.S.C. § 1135(b).

44 DHHS, Declaration of Sec. Michael Leavitt, Waiver Under Section 1135 of the Social Security Act, Sept. 4, 2005, available online at www.hhs.gov/katrina/ssawaiver.html (last visited April 1, 2008).

45 Id.

The aftermath of Hurricanes Katrina and Rita in 2005 represented the first times that NDMS was used on a wide scale, moving patients throughout the southern United States. Federal officials estimated that NDMS reception areas received close to 3,000 patients during those disasters.

5. How are transfer sites identified?

Although the institution previously may have negotiated transfer agreements in place with other facilities, it will be critical during an emergency to determine if those agreements can be invoked, e.g., whether the potential transferee site is itself closed and evacuating, or whether it can accept additional patients.

Facilities should anticipate how they will access the NDMS to identify available beds at other facilities in the event of an evacuation.

6. What legal obligations apply to a facility that has not closed but instead is receiving patients evacuated from another facility?

Some institutions that have not closed may nonetheless be affected indirectly by the closure and evacuation of other institutions in the area, particularly if they have transfer agreements with such facilities. Although they may not be compromised by the emergency causing the closure of the other facilities, these recipient facilities may nonetheless soon find themselves overwhelmed with patients evacuating from other places. A key challenge for these facilities may be determining whether to remain open at full capacity (on the assumption that evacuees will be arriving), or to send teams of medical personnel to affected areas to assist. When a disaster situation compromises communication channels, this determination may be particularly difficult to make. Such eventualities should be part of the facility's analysis of its "surge capacity."

In some instances, patients might be directed by public officials (local and/or federal) to facilities that are still able to receive patients. Some disconnect may exist between the obligations imposed by such officials and those in place under EMTALA or other preexisting local, state, or federal regulations. CMS has

posted some guidance regarding such circumstances. In response to a query whether a facility that is operating in excess of normal capacity may close its emergency department without violating EMTALA, CMS stated:

Under these circumstances, EMTALA would not prohibit the hospital from closing its [emergency department] to new patients (in effect, going on diversion). The hospital should follow any applicable State and local notice requirements and its own previously established plan for public notification when it goes on diversionary status. The hospital would continue to have an EMTALA obligation to individuals undergoing examination or treatment in its [emergency department] at the time it stops accepting new emergency patients. In addition, if an individual comes to such a hospital and requests examination or treatment for an emergency medical condition, the hospital would be obligated by EMTALA to act within its capabilities to provide screening and, if necessary, stabilization.⁴⁶

Any 1135 waivers in effect also might affect a facility's options and obligations with respect to accepting evacuees. According to a CMS press release on September 6, 2005,⁴⁷ crisis services provided to Medicare and Medicaid beneficiaries who have been transferred to facilities not certified to participate in the programs will be reimbursed for those services. In addition, hospitals and nursing homes receiving evacuees from the hurricanes were instructed to waive the normal burden of documentation and presume eligibility.

During the 2005 Gulf Coast hurricanes, hospitals receiving evacuated patients were asked to submit to their state hospital associations a record of patients received as a result of evacuation, including the patient's name and other information. This information was collected by the American Hospital Association (AHA) and turned over to the Louisiana Hospital Association in an effort to reconnect patients and families. Although such initiatives may not involve legal requirements, it is important that evacuee facilities gather and retain as much

⁴⁶ CMS FAQ, *supra* note 40, Question ID No. 6010, "If a Hospital remains open during a disaster like Hurricane Rita ... may the hospital shut down its emergency department (ED) without violating EMTALA?", created Oct. 5, 2005.

⁴⁷ CMS Press Release, CMS Actions to Help Beneficiaries, Providers in Katrina Stricken Areas, Sept. 6, 2005, available online at www.cms.hhs.gov/apps/media/press/release.asp?counter=1546 (last visited April 1, 2008).

information as circumstances permit in order to enable efforts such as this. This information might also serve the purpose of demonstrating the facility's efforts to comply with existing or modified legal requirements.

C. Recovery Phase

1. How does a facility determine when it may reopen and allow the return of patients?

As with other aspects of emergency response, the answer to this question may to some extent be dependent upon the declarations of public officials. Because the decision whether to remain open or evacuate typically resides with the institution's officials, the decision to re-open will lie there as well. Considerations will include the physical state of the facility, availability of personnel and supplies, and the need to regain normal operational status to ensure continuing rev-

enues. For more information on decommissioning a facility, and reopening a decommissioned facility, see section 7 of this document.

2. Who should be notified of the facility's reopening?

Generally, the same entities that were notified of the facility's closing should be apprised of its reopening.

3. How should facility staff be debriefed following an emergency?

Personnel having responsibility for coordinating the institution's emergency response plan should identify issues that arose during the emergency, and revise the institution's plan accordingly in preparation for any future occurrences.

V. Emergency Access to Prescription Medications

Access to prescription medications during an emergency is crucial for patients. Access includes physical availability of the drugs, someone to dispense them, and adequate knowledge of a patient's health condition and current prescriptions. For the person dispensing medications, licensure issues also arise in an emergency.

A. Preparation Phase

What steps must a healthcare provider or pharmacy take to back up existing prescription records, and to ensure access to those records in an emergency?

Facilities should consider maintaining offsite electronic records of patient-prescription data, as well as securing offsite backing-up tapes or posting data to a secure website. Pharmacies may consider incorporating in electronic health records a decision-support system that checks patient allergies and drug interactions, suggests the best evidence-based practices for given conditions, and provides patient reminders as to needed screening or other preventative measures.⁴⁸

B. Response Phase

1. By what authority may a pharmacist dispense maintenance medication to patients affected by an emergency situation when the pharmacist lacks an appropriate prescription?

Federal law, coupled with the actions of federal and state officials, affect access to medications in an emergency. Social Security Act Section 1135 allows the DHHS Secretary to temporarily waive or modify the application of certain requirements of the Medicare, Medicaid, and State Children's Health Insurance (SCHIP) programs "with respect to health care items and

services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency."⁴⁹ See section II of this title. Such waiver may apply to conditions of participation or other certification requirements, program participation and similar requirements, pre-approval requirements, and requirements concerning licensure in the state in which provider furnishes items and services.

Following the Gulf Coast storms of 2005, the DHHS Secretary waived certain Medicare, Medicaid, and SCHIP prescription drug-dispensing requirements to ensure that Medicare, Medicaid, and SCHIP beneficiaries' needs were met.⁵⁰ Under Section 1135, if a healthcare provider furnishes items and services in good faith, but cannot comply with a requirement, then the applicable program pays the provider and the provider is exempt from sanctions, "absent any determination of fraud and abuse."⁵¹

In addition to the waivers at the federal level, the pharmacy-practice statutes of many states allow pharmacists to refill prescriptions for medications in the event a pharmacist is unable to contact the prescriber in the event that, in the pharmacist's professional judgment, the interruption in therapy might reasonably produce undesirable health consequences or cause physical or mental discomfort.⁵² Typically, these state pharmacy acts allow the pharmacist to refill no more than a seventy-two-hour supply in cases of emergency. Following the 2005 Gulf Coast storms, the boards of pharmacy of Texas, Louisiana, and Mississippi announced that, in light of their respective governors' state-of-emergency declarations, pharmacists would be allowed to provide up to a thirty-day supply of medication.⁵³

48 See MedPAC, Report to Congress: Medicare Payment Policy 204 (March 2005) (discussing positives of rapid adoption of electronic health records), available online at www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf (last visited April 1, 2008).

49 42 U.S.C. § 1320b-5(b) (2005).

50 See, e.g., note 44, *supra*.

51 42 U.S.C. § 1320b-5(a)(2) (2005).

52 See MISS. CODE ANN. § 73-21-115(3) (2005); TEX. OCC. CODE ANN. § 562.054 (2005).

53 See Mississippi Board of Pharmacy, Hurricane Katrina Emergency Guidelines, available online at www.mbp.state.ms.us/mbop/pharmacy.nsf (last visited April 1, 2008); Texas State Board of Pharmacy, "Emergency Refills," available online at www.tsbp.state.tx.us/hurricanemain.htm (last visited April 1, 2008); Louisiana Board of Pharmacy, Hurricane Katrina/Rita Emergency Guidelines, available online at www.labp.com/HurricaneKatrina-RitaEmergencyGuidelines.htm (last visited April 1, 2008). See also Tenn. Exec. Order No. 27, An Emergency Order Suspending Provisions of Certain Laws and Rules in Order to Provide Relief to Victims of Hurricane Katrina, Sept. 3, 2005, available online at www.tnpharm.org/KatrinaExecOrder27.pdf (last visited April 1, 2008).

With regard to refilling a controlled-substance prescription, Mississippi's Board of Pharmacy referenced a Drug Enforcement Agency (DEA) notification that a ten-day supply of controlled substances in Schedules II – V could be dispensed in an emergency situation during the period from September 1, 2005, through September 30, 2005. The pharmacist must obtain positive patient identification, as well as a prescription vial or another indication of the patient's controlled-substance prescription in the past.⁵⁴

Additionally, commercial insurers may provide various forms of relief at their discretion. For example, in past emergencies, insurers have treated all pharmacies as in-network, waived early refill limits, and allowed shipment to alternative addresses.

2. If a pharmacy loses access to its prescription records or those records are destroyed, how can it obtain a patient's medication history?

- a. Katrinahealth.org – After Hurricane Katrina in 2005, multiple contributors and participants collaboratively established www.katrinahealth.org, a secure online service giving authorized healthcare providers and pharmacists access to medication and dosage information for Hurricane Katrina evacuees.⁵⁵ Although the resource is inaccessible to patients, the website allows physicians and pharmacies access to review medications, coordinate care, and avoid potential medication errors when renewing or prescribing medications.
- b. Drug Records from Medicare Discount Drug Sponsors – CMS's FAQ lists a number of procedures implemented by Medicare discount drug sponsors during emergencies.⁵⁶ A pharmacy familiar with these procedures could facilitate identification of patient medications and dispensing. The drug sponsors' procedures include:
 - i. Sponsor allowance of replacement discount drug cards, including overnight delivery of cards to beneficiaries in case of emergency;

- ii. Authorization for enrolling beneficiaries without a discount card in hand in drug discount programs;
 - iii. The option for pharmacists or beneficiaries to call sponsor toll-free lines to obtain authorization or a card number;
 - iv. Sponsor's allowing beneficiaries enrolled in national cards to use any national pharmacy in the sponsor's contracted network;
 - v. Through sponsor toll-free lines, allowing a beneficiary to request short-term supplies from non-network pharmacies or via mail order;
 - vi. Knowledge that some sponsors contact beneficiaries prior to hurricanes to notify of temporary drug supplies; and
 - vii. Sending short-term supplies to a beneficiary's alternative beneficiary address.
- c. End-Stage Renal Disease (ESRD) Providers – Following Hurricane Katrina, the eighteen ESRD networks listed their complete contact information on the Internet. In addition to listing questions and answers, the site provided toll-free numbers enabling patients to identify an available facility for dialysis, transportation, dialysis supplies, and renal medications. The website advises that ESRD facilities providing dialysis to patients during the emergency supply each patient with a hard-copy document including clinical information needed by the provider during a subsequent dialysis (e.g., a daily run sheet), a list of actual medications given during the dialysis, and a written prescription to assist the patient in event of relocation.⁵⁷
 - d. Healthcare Providers – In September 2005, DHHS and the Centers for Disease Control and Prevention (CDC) developed the "Keep It With You" Personal Medical Information Form.⁵⁸ This "interim communication tool," intended to be completed by both the patient and the healthcare provider, assists relocated patients. As a preparedness measure, health-

54 Mississippi Board of Pharmacy, Hurricane Katrina Emergency Guidelines, available online at www.mbp.state.ms.us/mbop/pharmacy.nsf (last visited April 1, 2008).

55 Contributors and participants included U.S. Department of Commerce, the DOD, DHHS, DHS, the State of Mississippi Department of Health, the State of Louisiana Department of Health, Harvard School of Public Health, IBM, the Markle Foundation, and Gold Standard, among many others. Chain pharmacy supporters included CVS, Target, Wal-Mart, and Walgreens, among others. Participating pharmacy benefit managers included Caremark, Express Scripts, and Medco Health Solutions. Pilot-site participants included University of Mississippi Medical Center, Special Needs Shelters in Louisiana, and University of Texas at Houston, among others.

56 See generally.questions.cms.hhs.gov/ (last visited April 1, 2008).

57 See www.esrdnetworks.org/ (last visited April 1, 2008).

58 This form is available online at www.bt.cdc.gov/disasters/hurricanes/katrina/pdf/kiwy.pdf (last visited April 1, 2008).

care providers could offer such a form routinely to patients.

- e. National Association of Boards of Pharmacy – Following the 2005 Gulf Coast storms, the National Association of Boards of Pharmacy (NABP) announced discussions with state boards of pharmacy to centralize information regarding pharmacists' temporary licensure, the establishment of temporary pharmacies, and approval for temporary distributions of medications to pharmacies and into states.⁵⁹

3. How may patients identify alternate health-care providers and pharmacies?

Federal and state websites offer advice to patients seeking to identify alternative healthcare providers and pharmacies. CMS advised in multiple FAQs that managed care plan beneficiaries may contact sponsors' toll-free lines in order to resolve a number of issues, including identification of substitute pharmacies or healthcare providers. When discount drug cards were lost in a Katrina-evacuated area, CMS noted that managed care plans relaxed prior-authorization and out-of-network rules, and that the managed care plans reimbursed the patients directly for incurred out-of-pocket expenses.

With regard to patients involved in a series of treatments, including patients receiving chemotherapy, both the American Society of Clinical Oncology and the National Cancer Institute are resources to connect patients with alternative providers.⁶⁰

4. By what authority may a healthcare provider or pharmacy prescribe or dispense medications if it cannot comply with benefit plan requirements?

CMS noted in FAQ No. 5713 that, after Hurricane Katrina, managed care plans made special arrangements, permitted early refills, lifted other restrictions, and arranged for pharmacy chains

nationwide to refill prescriptions. Pharmacies should contact managed care plans if beneficiaries lack prescription vials and do not know the prescribed drug's name. Following 1992's Hurricane Andrew in south Florida and the 2004 Florida hurricanes, Medicare Advantage plans were liberal in their interpretation of "emergent" and "urgent care" immediately following the hurricane.⁶¹

5. Does a patient's presentation to a hospital emergency room and/or request for prescription refills trigger EMTALA requirements?

EMTALA requirements may be suspended or waived as a result of the emergency. See section IV.B of this title for more information. CMS's FAQ No. 5695 clarified that, if a patient presents to a hospital emergency department and requests a prescription refill, then that presentation would not trigger a complete medical screening examination, but rather an examination appropriate to meet the patient's request. CMS further advised that hospitals should adopt specific policies and protocols to address this eventuality as part of developing their emergency preparedness plans.⁶²

6. Where may a healthcare provider/pharmacy/public health department obtain drugs to dispense?

a. Strategic National Stockpile

Most states plan to distribute supplies, including drugs, from the Strategic National Stockpile (SNS). Managed by the CDC, the SNS maintains a "storehouse" of pharmaceuticals and medical supplies, including antibiotics, chemical antidotes, antitoxins, life-support medications, intravenous administration supplies, airway maintenance supplies, and medical/surgical items. The SNS supplements local supplies of critical medical items, and constitutes a part of a state's overall "comprehensive emergency management plan."⁶³

59 See www.nabp.net (last visited April 1, 2008). The NABP received names of pharmacists from state boards of pharmacy, and verified that they were licensed in good standing through the NABP's "Disciplinary Clearinghouse." Id.

60 See CMS FAQ, *supra* note 40, Question ID No. 5810, "I am a cancer patient. How will I get my chemo treatments?," created Sept. 21, 2005.

61 See CMS FAQ, *supra* note 40, Question ID No. 5713, "I am a member of a managed care plan. How can I get my medicines refilled? . . .", created Sept. 15, 2005.

62 See CMS FAQ, *supra* note 40, Question ID No. 5695, "Many evacuees from Louisiana, Mississippi, Alabama and Florida are coming to hospital emergency departments merely to obtain refills of prescriptions...?", created Sept. 15, 2005; see also 42 C.F.R. § 489.24(c).

63 See CDC, Strategic National Stockpile, available online at www.bt.cdc.gov/stockpile (last visited April 1, 2008); see also Mississippi State Department of Health, PLAN FOR DISTRIBUTION OF THE STRATEGIC NATIONAL STOCKPILE (2005), available online at www.msstate.gov/healthsite/index.cfm/44,1136,122,154,pdf/SNSPlan.pdf (last visited April 1, 2008).

Once a state's department of health initiates a request to the CDC for SNS materials, SNS transports materials to the state's "Emergency Management Association" that receives and transports the material to dispensing sites for access and use by local governments. Health Resources and Services Administration (HRSA) grantees, including state hospital associations, may request additional medical supplies through the state or the county Emergency Management Agency.⁶⁴

b. 340B-Covered Entities

Drugs also might be available to "340B-covered entities" operating from a temporary site (other than the site listed on the 340B website).⁶⁵ In the recent Katrina emergency, the Office of Pharmacy Affairs (OPA) and HRSA advised 340B-covered entities that they could receive drugs if they notified the OPA or HRSA of the entity's temporary address within thirty days following the move.⁶⁶ Additionally, the Pharmacy Services Support Center (PSSC) and the OPA updated their lists of eligible 340B hospitals and clinics more frequently than on their usual quarterly timetable.⁶⁷ Entities eligible to dispense 340B-priced drugs must meet patient-definition tests listed in Federal Register guidelines.⁶⁸

c. Legal Issues in Drug Donation

Following Hurricane Katrina, many pharmaceutical companies pledged cash and product donations. Information regarding assistance opportunities has been listed on the Pharmaceutical Research and Manufacturers of America's website.⁶⁹ Drug donation triggers multiple legal issues, depending upon the drug source and the donor's compliance with quality standards including maintenance of the drugs' integrity. The FDA's approval requirements, coupled with state law, govern when charitable clinics may accept and dispense drugs.⁷⁰ The drugs' source and chain of custody affect the legality of donated drugs' distribution.

C. Recovery Phase

What capabilities does a pharmacy or health-care provider have to determine whether prescription medications (devices/supplies/test kits) are not contaminated, and are of sufficient quality to be dispensed?

Following Hurricane Katrina, the FDA listed on its website tips that a pharmacy might use to determine whether products were contaminated and required disposal.⁷¹ The FDA advised that pharmacies should determine individual

64 See HRSA, ANSWERS TO FREQUENTLY ASKED QUESTIONS (hereafter HRSA FAQ), Answer ID No. 513, "How do grantees access the Strategic National Stockpile (SNS) of drugs?", created Sept. 9, 2005. HRSA FAQs are available online at answers.hrsa.gov (last visited April 1, 2008).

65 The 340B Drug Pricing Program was established through the Veterans Health Care Act of 1992. Section 340B of the Public Health Service Act provides discounts on outpatient drug purchases for eligible "covered entities" similar to the Medicaid discounts mandated by the federal government in 1990. The program enables disproportionate share hospitals, community health centers, clinics, and other safety net providers to purchase outpatient pharmaceuticals at discounted pricing, thereby expanding access to care to low-income and vulnerable segments of the population. 340B-covered entities include HRSA grantees, federally qualified health clinics and FQHC look-alikes, family planning clinics, HIV/"Ryan White" clinics, state-operated AIDS drug assistance programs, black lung clinics, hemophilia treatment centers, urban Indian organizations, native Hawaiian health centers, sexually transmitted disease and tuberculosis clinics, and disproportionate share hospitals. See Veteran's Health Care Act of 1992, Pub. L. No. 102-585, at § 602 (codified as amended in scattered sections of 38 U.S.C.). The referenced HRSA 340B website is available online at opanel.hrsa.gov/opa/Login/DSHHospitals.aspx (last visited April 1, 2008).

66 HRSA FAQ, *supra* note 64, Answer ID No. 568, "Because of the current emergency, 340B covered entities may have set up temporary sites ...?", created Sept. 14, 2005.

67 PSSC is HRSA's government contractor for 340B technical assistance. See pssc.aphanet.org (last visited April 1, 2008).

68 See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 60 Fed. Reg. 39,762, 39,764 (Aug. 3, 1995). Although hospitals must meet the first two tests regarding maintenance of records and professional care, other types of 340B entities must also meet a "scope of service" test, requiring that the services provided to the patient must be within the clinic's authorized scope of services. *Id.*

69 PhRMA, Press Releases, America's Pharmaceutical Companies Increase Katrina Donations; More than \$100 Million in Medicines, Cash Donated So Far, Sept. 14, 2005, available online at www.phrma.org/news_room/press_releases/america%2s_pharmaceutical_companies_increase_katrina_donations%3b_more_than_%24100_million_in_medicines%2c/ (last visited April 1, 2008).

70 See TEX. HEALTH & SAFETY CODE ANN. §§ 421.322-323 (2005) (charitable clinic may not accept donated drugs without donor certification of proper storage by donor and original dispenser, receipt of donor's verifiable address, phone number, and photographic identification; only donated drugs approved by FDA may be dispensed and only prior to expiration date or within recommended shelf life; and licensed pharmacist must verify drugs' acceptable integrity). See also World Health Organization, Pan American Health Organization, Technical Guidelines: Drug Donations, available online at www.paho.org/English/DD/PED/te_ddon.htm (last visited April 1, 2008).

71 See www.fda.gov/cdrh/emergency/disposal.html (last visited April 1, 2008).

products' condition and potential safety risks, offering advice regarding exposure to unusual levels of heat and humidity. The site provides information regarding electronic equipment, packaged devices, supplies and test kits, and refrigerated products. Contaminated items include those whose outer packaging show signs of mold, evidences breaks in seals, or indicates water damage.

Part of a pharmacy's emergency preparedness should include steps to retain electrical power in an emergency, as well as to protect supplies and devices from water damage. Pharmacies and healthcare providers also should develop standard procedures for discarding outdated or contaminated products in the event of flooding or a loss of power preventing refrigeration.⁷²

The Louisiana Board of Pharmacy (LABP) released certain guidelines concerning disposal of prescription drugs in pharmacies affected by Hurricanes Katrina and Rita.⁷³ The LABP recommended that such pharmacies use reverse distributors that are equipped to handle material deemed to be contaminated and/or hazardous waste. Non-controlled substance prescription medications that were contaminated (as well as syringes, needles, and the like) were to be "red-bagged" and disposed using medical-waste transportation, processing, and disposal systems. Additionally, the LABP recommended that all hazardous materials be handled by a company specializing in hazardous waste collection and disposal.⁷⁴

72 See FDA, "Information Regarding Insulin Storage and Switching between Products in an Emergency," available online at www.fda.gov/cder/emergency/insulin.htm (last visited April 1, 2008).

73 Louisiana Board of Pharmacy, Hurricane Katrina/Rita Emergency Guidelines (Rev. May 3, 2006), available online at www.labp.com/HurricaneKatrina-RitaEmergencyGuidelines.htm (last visited April 1, 2008).

74 See www.labp.com (last visited April 1, 2008).

VI. Consent to Treat in Emergency and Disaster Situations

Informed consent to healthcare is a basic precept of American law. Failure to obtain informed consent may result in claims for battery or malpractice. When the patient is unable to consent, a surrogate decision-maker may be recognized. Many states (though not all) define by statute those individuals who are authorized to consent for an incompetent patient. Typically, these decision-makers are family of the patient (usually parents in the case of a minor), an individual designated by the patient in an advance directive, or a court-appointed guardian.

Exceptions to the requirement for consent exist, and the most commonly recognized 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.

The chaos of a disaster presents special difficulties in obtaining legally valid consent. During the Gulf Coast storms of 2005, parents were separated from children, often for days or weeks. After evacuation, children and others incapable of consenting required medical care that, while important, did not qualify as an “emergency” to trigger the doctrine of implied consent. Caregivers were faced with the difficult decision of providing care absent consent, or delaying needed care pending consent. Issues of consent may also arise in Public Health Emergencies involving mandatory treatments.

A. Preparation Phase

1. What special legal theories operate during disaster situations which might help clarify consent issues?

A full treatment of informed consent law is well beyond the scope of this document. State law may provide for consent in emergency situations, either specifically with regard to minors when no parent is available or in more general terms. Many states have described certain individuals (other than parents and guardians) who are permitted to grant consent for medical care. Many states permit spouses, parents, and adult siblings to act as surrogates. Others have broader provisions that permit a type of individual (e.g., clergy) to grant consent if no other surrogate is available.⁷⁵ For example, Arizona law provides an exception to the requirement of written consent of the parent “when such parent or legal guardian cannot be located or contacted after reasonably diligent effort...”⁷⁶ Alabama similarly provides an exception to the requirement of informed consent for incompetent patients when delay in treatment would increase the risk to life or health of the patient.⁷⁷ Readers should check local law to determine what provisions may apply in their location.

In some situations, limited screening, testing, and treatment may be mandated pursuant to the state’s public health laws. Many state public health laws permit the imposition of mandatory isolation or quarantine for certain contagious diseases.⁷⁸ Compulsory screening programs for significant public health risks are also contemplated by the Turning Point’s Model State Public Health Act.⁷⁹ This is an area governed by state law. In some states, the

75 TEX. HEALTH & SAFETY CODE § 313.004.

76 ARIZ. REV. STAT. § 36-2271.

77 ALA. CODE § 22-8-1. See also ALA. CODE § 22-8-3 (“Any legally authorized medical, dental, health or mental health services may be rendered to minors of any age without the consent of a parent or legal guardian when, in the physician’s judgment, an attempt to secure consent would result in delay of treatment which would increase the risk to the minor’s life, health or mental health.”).

78 ARIZ. REV. STAT. §§ 36-624, 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...”)

79 See Turning Point Model State Public Health Act, Section 5-106(d)(1), p. 42, available online at www.hss.state.ak.us/dph/improving/turningpoint/PDFs/MSPHAWeb.pdf (last visited April 1, 2008). The Turning Point program was a collaboration of the W.K. Kellogg Foundation and the Robert Wood Johnson Foundation in an effort to improve the public health infrastructure. Information about the program is available online at www.wkcf.org/default.aspx?tabid=75&CID=8&NID=61&LanguageID=0 (last visited April 1, 2008).

imposition of quarantine or isolation does not affect the right of the patient or guardian to consent to or refuse other treatment.⁸⁰ In other states, mandatory treatment may be authorized for certain conditions, usually communicable diseases, although the legal process required to obtain a compulsory treatment order varies.⁸¹

2. What steps can healthcare providers take to minimize issues regarding consent to treat in a disaster situation?

Recent events (e.g., the 9/11 attacks in New York and Washington; the 2005 Gulf Coast hurricanes) indicate that communications networks are likely to fail in an emergency. Healthcare providers should consider the following pre-event preparations in light of likely communications failure.

- a. Coordinate with public health and non-governmental organizations, such as the Red Cross, medical groups focused on pediatrics, and emergency medicine (e.g., the American Academy of Pediatrics, the American College of Pediatricians, the American College of Emergency Physicians, the National Association of Pediatric Nurse Practitioners) to train parents regarding issues related to consent to treatment in disasters and mass-casualty situations.
- b. Encourage parents (and especially parents of special-needs children), as well as patients with significant healthcare issues, to develop a small notebook, easily carried in a purse or pocket, which describes their child's diagnoses, medications, allergies, normal behavioral patterns, and other information intended to help ensure the best possible care of the child.
- c. Develop and distribute emergency cards to patients that include medical history, medications, allergies, and consent-to-treat provisions. One example is the CDC's personal medical information form, called the "Keep It With You Personal Medical Information Form." It was developed to facilitate sharing of vital

medical information in disaster situations.⁸² Encourage inclusion of a card for each member of the household in the disaster pack, and give a copy to each child. A copy of each card should also be on file in any location in which children spend significant time (e.g., school, day care). Healthcare providers are encouraged to retain a photocopy of the form after providing care, to assist in documentation.

- d. Publicize and promote the availability of parental delegation of rights prior to occurrence of a disaster (authorized by most states via legislation). Include in the emergency notification plan a means to distribute parental-delegation forms to parents for completion prior to evacuation, if necessary. Note, however, that these forms are often time-limited.
- e. Work with local judicial officials to develop a streamlined process for identifying an individual to represent the interests of the child and is authorized to consent to treatment of the child. Although a process exists in each state that permits judicial resolution of disputes regarding consent for treatment, typically these processes are inefficient when faced with hundreds or thousands of individuals requiring care. A streamlined process, possibly involving the office of public guardian in the jurisdiction, should be established and tested prior to the occurrence of a disaster.
- f. Develop evacuation tags (similar to triage tags or bracelets) that include basic information about the evacuee, and indicate the level of care subsequent healthcare providers may give without express parental consent (e.g., vaccinations without consent, antibiotics without consent). Bracelets could be color-coded, and would have the advantage of being less likely to be lost in transit. Tags or bracelets would be distributed as evacuees are loaded onto transport.

80 See, e.g., ARIZ. REV. STAT. § 36-114 ("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.")

81 See, e.g., the Turning Point Model State Public Health Act Section 5-107(b); N.Y. PUB. HEALTH LAW § 2120; CAL. HEALTH & SAFETY CODE § 121360; N.H. REV. STAT. ANN. § 141-C:15.

82 See note 58, *supra*.

- g. Evacuation plans should consider issues related to separation and reunion of family members. Evacuation packs should include consent-to-treat documents.
- h. For those patients who have developed electronic health records, encourage inclusion of a document describing treatments that minors may be given in a disaster situation without express consent and/or delegating parental authority. An additional advantage of this approach is that the permission can be updated even as a disaster unfolds, thus resulting in increased flexibility. As was demonstrated in Hurricane Katrina, an electronic health record with off-site backup and a robust disaster-recovery system may be the best way to ensure the availability of critical health information in a disaster.⁸³

Finally, consider seeking legislation which sets forth proxy decision-making authority, and which contains the flexibility necessary to permit effective and appropriate care (including non-emergency care) during disasters. Hurricane Katrina demonstrated clearly that disasters can be long-term events, and legislation to address this issue would be helpful.

B. Response Phase

1. How should healthcare providers approach consent for treatment of incapacitated individuals during a disaster?

a. Evacuating Facility

An evacuating facility must consider the following as it prepares to evacuate patients.

- i. To the extent possible, send pertinent medical information with the patient. If possible, place paper records in a sealable plastic bag to protect from the elements. If it is not possible to send the medical record, a summary sheet at least is helpful.

- ii. To the extent possible, families should be evacuated together; minors should be accompanied by at least one parent or authorized caregiver. Evacuation plans should include contingencies to maintain contact between family members, even if families must be separated during evacuation. Standardized information about each evacuee should be recorded and entered into a centralized database in order to facilitate identification and reunion among separated families.
- iii. Evacuees should be given an identifier as they prepare to board transportation. Consider either an evacuation tag or bracelet. If possible, tags or bracelets should be bar-coded or otherwise able to be tracked. A record of each evacuee and anticipated destination should be kept. Preferably, the identifier will include information to assist in reunion (e.g., names of family members).
- iv. Submit information regarding evacuated individuals to a centralized database as soon as possible. It often will not be possible for the evacuating entity to do this; the disaster plan should address responsibility for this action.

b. Receiving Facility

A receiving facility must consider the following issues as it prepares to receive patients.

- i. If the evacuee possesses a delegation of parental authority, or has provided a written description of the care that may be rendered without express consent, comply with that document. Maintain a copy in the medical record.
- ii. Consider whether the care required is covered under a statute that removes the need for express consent. Treatment to address public health issues may fall under this category.
- iii. If neither of these measures applies, then treat under the theory of implied consent if appropriate.

⁸³ The DHHS Office for Civil Rights recently issued a decision tool, available online at www.hhs.gov/ocr/hipaa/decisiontool (last visited April 1, 2008), to evaluate disclosures under the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) during a disaster or other emergency situation. This tool presents avenues of information flow that could apply to emergency preparedness activities. The tool, however, does not address other federal, state, or local confidentiality laws that may apply in specific circumstances.

- iv. If the incapacitated person is a “mature minor,” consider whether the patient can provide consent.
- v. Consider seeking judicial intervention to identify an individual capable of providing informed consent. An expedited process is preferable, if available. Consider whether state law permits use of the public guardian in this situation.
- vi. Assign 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. Consider using hospital volunteers for this job.
- vii. When in doubt, act in the best interest of the patient.

C. Recovery Phase

What must be done after the catastrophe to comply with law and best limit liability?

Once the most emergent phase of the disaster has passed and reunification of patients with family or guardians has been accomplished, the hospital should focus on clearly communicating what treatment had been provided and what decisions had been made with the parent or guardian. Depending on the basis used by the provider, further documentation may be required. For example, the Texas Consent to Medical Treatment Act requires documentation of specific information in the medical record. Under this act, the surrogate must either countersign the medical record or sign a consent form as shortly thereafter as possible.⁸⁴ In most cases, the parent or surrogate may be provided further medical information; in some cases, however, if the minor was permitted to consent under law, then the consent of the minor also may be required to provide records of the care to a parent.

84 TEX. HEALTH & SAFETY CODE ANN. § 313.004.

VII. Decommissioning a Hospital as a Result of a Disaster

A. Introduction and Definitions

The aftermath of Hurricane Katrina required hospitals to rethink the definition of “decommissioning beyond repair” and to factor this thinking into its disaster-preparedness responses. For purposes of this discussion, “decommissioning” means closure as a result of damage to the hospital’s physical plant. The extent of “decommissioning” of a hospital depends on both (1) the extent of the damage and (2) the availability of post-disaster resources (i.e., labor, materials, management oversight, funding) to repair the damage. Each of these factors can significantly affect the lapse of time between closure and reopening, if reopening is an option. The greater the magnitude of the damage, the more likely that the reopening will occur over time, with individual services being reopened on a phased basis.

The following discussion assumes that a hospital “decommissioning” will have a minimum duration of three months, combined with a concrete plan to reopen within a year of the closure. Although “preparedness” and “response” plans may have common elements regardless of the length of closure, the more extended the proposed reopening date, the greater the likelihood that the scope of the recovery-planning process will differ in the number and the types of challenges faced by the hospital. Other variables that may affect the decommissioning-planning process include the extent to which the affected hospital is an isolated or individual decommissioning (as compared to one closure among many), because of the damage to the overall health-delivery system within the region. Hospital disaster plans may also vary based on the type of facility (e.g., quaternary, tertiary, specialty hospital, community hospital) and on the likely community effect of the closure (which depends on the state of the pre-disaster delivery system). Finally, those hospitals that operate multiple facilities which may have varying degrees of damage should take into account as part of the planning process how to leverage their sites in the hospitals’ response- and recovery-plan efforts.

B. Effect of Decommissioning on Patients

1. Preparation Phase

- a. What should a hospital do to prepare for the possibility that it may be unable to provide care to its patients under normal conditions for an extended period of time?

An institution-specific disaster preparedness plan must take into account its

responsibilities during and immediately after the disaster, as well as how it may eventually recommence operations. In planning, a hospital should anticipate that it may be so badly damaged that it will be decommissioned for a significant period of time.

These decisions will depend on the nature of the emergency. For example, a hospital’s response may be different depending on whether the event is localized (e.g., an explosion near the hospital’s main oxygen line), affects the hospital and surrounding area (e.g., a large-scale flood), or is a major regional event (e.g., a mass-casualty terrorist attack). In all cases, however, hospitals will want to ensure the safest possible evacuation of their patients and appropriate follow-up care; availability of medical information for displaced patients and their caregivers; adequate short-term care for those patients who cannot be evacuated; notification to appropriate governmental bodies that are responsible for patient-care quality or that can mobilize resources to aid the hospital; and a solid foundation on which to reopen.

To be in a position to achieve these aims in the event of a catastrophe, hospitals should accomplish the following.

- i. Enter into patient-transfer or “mutual aid” agreements with other hospitals, nursing homes, psychiatric facilities, cancer centers, and other facilities that provide services similar to those provided at the hospital. These mutual aid agreements should allow for the transfer of patients and the sharing of staff, equipment, supplies, and other services in the event of a disaster affecting either party to the agreement. Hospitals should consider such agreements not only with other local hospitals, but also with more geographically distant hospitals in case a disaster affects a large area. For example, because Hurricane Katrina devastated most of the Gulf Coast region, many patients from New Orleans had to be transferred to facilities in Shreveport, Dallas, Houston, Atlanta, and points even further away.
- ii. Make arrangements, through lease options or other means, to have vans, buses, helicopters, and ambulances available to evacuate patients. Determine whether, in certain situations for patients

- in good condition, hospital employees will be allowed to use personal vehicles to transport patients if all other options fail.
- iii. Purchase adequate generator fuel and communication devices that do not depend on local power sources, telephone lines, or cellular relay stations (e.g., satellite phones, “ham” radios, or “walkie-talkies”). For example, in the immediate aftermath of Hurricane Katrina, one of the most serious problems in New Orleans-area hospitals was the inability to communicate effectively with those outside the hospital, making it very difficult to either continue operations or evacuate the facility.
 - iv. Train hospital staff on patient care and risk-management practices appropriate during an emergency. Although clinicians do not have *carte blanche* during an emergency, hospital staff should not be afraid to provide care to patients in substandard conditions if absolutely required (or to share patient information as necessary), because of undue fears of liability or violations of the Health Insurance Portability and Accountability Act (HIPAA). Hospital staff also should not decide important ethical or legal questions (e.g., issues of informed consent and/or standard of care) “on the fly;” the euthanasia allegations against Memorial Hospital in New Orleans furnish an example of what can go wrong.⁸⁵
 - v. Revisit their HIPAA security policies with a catastrophic disaster in mind. The HIPAA Security Rule is concerned not only with the confidentiality of electronic protected health information, but also with the integrity and availability of that information. This can be critical for patient care and follow-up, particularly for those hospitals whose primary medical records system is electronic.
 - vi. For hospitals with active research protocols, the research administration or the Institutional Review Board (IRB) should consider in advance whether disruption of particular studies could put study subjects at risk, as well as how to mitigate that risk.⁸⁶
 - vii. Prepare a list, with contact information, of every governmental or accrediting body that would need to be notified of adverse patient outcomes or temporary hospital closures. This may include The Joint Commission, CMS, the FDA, the Office of Human Research Protections (OHRP), state health departments, and others.
 - viii. Consider establishing a toll-free number that patients or providers can call for a variety of inquiries in the event of a disaster. If established in advance, this number could be included on documentation given to all patients, such as the hospital’s Notice of Privacy Practices.
 - ix. Formulate a recovery vision for re-establishing clinical services. This should be coordinated with the medical staff reopening plan. What might the hospital’s long-term patient and payor mix be in the event of a large-scale (e.g., city-wide) disaster? What are the hospital’s strongest clinical areas?

2. Response Phase

- a. How should a hospital wind down its patient care activities in the immediate aftermath of a disaster?

For a hospital that has suffered catastrophic damage, the first priority is to safeguard all patients. To do so, the hospital will need to evacuate all patients who can safely be moved—and, if possible, prevent additional patients from presenting for care. Patient evacuation and diversion raise legal issues under EMTALA and other statutes and regulations, as well as under state tort common law.⁸⁷

Ideally, patient evacuation would benefit from the planning processes described earlier (e.g., mutual aid agreements, transportation, communications, and power). Of course, some improvisation may be required based on the nature of the emergency; for example, it may not be safe to evacuate patients in the event of a radiological, biological, or chemical attack, even if adequate care cannot be provided at the hospital. In any case, although local

⁸⁵ For additional information, see *Consent to Treat in Emergency and Disaster Situations*, section 6, *supra*; *Avoiding Malpractice and Criminal Claims in Responding to an Emergency*, section 10, *infra*.

⁸⁶ For more information, see *Academic Medical Center Issues*, section 9, *infra*.

⁸⁷ For more information, see *Patient Evacuation*, section 4, *supra*.

fire, police, and emergency medical service (EMS) personnel may be too occupied with other response activities to offer significant assistance in patient evacuation, they should be at least contacted in order to prevent them from transporting new patients to the hospital. The governmental and accrediting bodies identified earlier also should be notified of the hospital's inability to provide patient care.

- b. How can the hospital ensure the best care for those patients who cannot safely be evacuated or who, despite diversion efforts, are brought to the hospital during or after the catastrophe?

If the hospital needs additional clinicians to care for patients during or after a disaster (e.g., under the auspices of the hospital's "disaster privileges"), at least three resources are available.

- i. The Emergency Management Assistance Compact⁸⁸—adopted by every state (and in the District of Columbia) except Hawaii—allows healthcare providers licensed in participating states to render assistance when the governor of an affected state declares an emergency or disaster and requests aid from a participating state pursuant to the mutual assistance compact. The hospital should check with its state's governor's office for details in the event of an emergency.
- ii. The United States Surgeon General coordinates and deploys Medical Reserve Corps units, which are comprised of practicing and retired health professionals who were organized at the state and local levels after 9/11 to assist their communities during large-scale emergencies. Hospitals needing additional clinicians should contact the U.S. Surgeon General's office for Medical Reserve Corps help.⁸⁹
- iii. In the event of a federally-declared emergency or disaster, the hospital may benefit from the NDMS, which may pro-

vide healthcare teams, supplies, equipment, and patient transportation.⁹⁰

In case of an emergency, or in other situations where the hospital is using volunteer providers, the hospital should be aware of any associated licensing and credentialing issues. In specific situations, in-state licensure requirements may be waived by the governor or through the NDMS.⁹¹

3. Recovery Phase

What are the key patient-related considerations in recovering from a major disaster and reopening a hospital?

Hurricane Katrina demonstrated that a hospital's reopening after a catastrophe may be gradual. The process may begin by reopening an emergency department and a single surgical suite, or it may begin by opening satellite clinics on the "decommissioned" hospital's license. From a patient-care perspective, the most important issue at this phase is ensuring that hospital operating conditions (including means of entry and exit) are safe, appropriate referrals can be made for services that are temporarily (or permanently) out of commission at the hospital, and adequate patient volume is present to support the reopening (in addition to adequate clinical and staff resources to support that patient volume).

The hospital should reassess its HIPAA security practices and policies in light of the disaster, as well as the disaster's effect on the availability and integrity of electronic records.⁹²

C. Effect of Decommissioning on the Community

1. Preparation Phase

- a. How can a hospital work with the community to prepare for the hospital's possible decommissioning due to a disaster?

Two key planning considerations must be evaluated by a decommissioned hospital when addressing community need: (1)

88 Emergency Management Assistance Compact, Pub. L. No 104-321.

89 A similar program has been established by HRSA, called the Emergency System for Advance Registration of Volunteer Health Professionals. This was done as a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Pilot testing of these guidelines began in spring 2005 with ten states. See www.hrsa.gov/esarvhp/ (last visited April 1, 2008).

90 For more information, see section 4.2, *supra*.

91 See *Licensing and Credentialing Issues: Temporary Licensing and Credentialing of Healthcare Workers*, section 3, *supra*.

92 For more information, see *Disaster Recovery Planning for Critical Computer Systems*, section 8, *infra*.

coordination with external disaster-response efforts during the response and recovery phases; and (2) coordinating with “opened” hospitals and healthcare organizations during the recovery phase to ensure access to the fullest possible range of pre-disaster services during the response and recovery phase.

i. Coordinating with Response Efforts

Notwithstanding damage to its own physical plant, the hospital should develop a plan to identify and deliver necessary personnel, critical equipment, and supplies through designated disaster-relief agencies during and immediately after the disaster. To do so, the hospital should designate a lead contact who understands and is familiar with the community’s disaster plan (e.g., where emergency shelters are located; where medical emergency sites will be located; which public health official will be responsible for coordinating emergency medical response). Based on this information, the hospital can design a coordination plan to ensure that its personnel, critical equipment and supplies can be deployed to support the efforts of external relief agencies. To the extent feasible, the hospital should participate in collaborative disaster planning with state and local public health agencies and relief agencies (e.g., the Red Cross), and develop written coordination plans and agreements. These plans and agreements should take into account issues in healthcare reporting compliance (e.g., medical record-keeping, consents, HIPAA privacy), insurance, and indemnification. Similarly, the hospital should consider working with state public health officials in drafting a standard regulatory-waiver request to ensure that emergency personnel are in a position to provide care outside of a traditional, stable healthcare environment.

ii. Community-Wide Response Efforts

Although a decommissioned hospital’s first priority during the recovery phase will be its own reopening, it is critical that the hospital designate an individual to be responsible for assessing the impact of the disaster on the broader health-care-delivery system in the immediate

aftermath of the disaster. Based on its own disaster assessment and the broader community’s damage report, the hospital will need to modify its plans to place clinical/medical staff to address specific community needs. In particular, the hospital should prioritize placement of its emergency room and trauma team, any specialty services of which it is the sole provider, and placement of its primary care staff and key community-based sites. Specific plans should be made to coordinate efforts in order to prevent and inoculate the population against post-disaster outbreak of diseases related to availability of purified water, lack of sanitary conditions, other public health issues, as well as the psychiatric and substance-abuse conditions that are likely to be exacerbated by the disaster.

2. Response Phase

In implementing a hospital closure during an emergency, what effects on the community should be considered?

A hospital will not be in a position to assess the extent of damage to its physical plant and make a final determination with respect to closure until after the response phase is complete. Thus, the key issues in the response phase involve the decision of the hospital to close its facilities to new patients during the disaster, or to preserve its medical assets to the fullest possible extent once a full evacuation/closure decision is made. The ability of a hospital to protect its assets (including pharmaceuticals, equipment, and supplies) for alternative deployment within the community after the hospital is decommissioned may contribute substantially to preventing post-disaster deterioration of community health conditions, but may make it more difficult for the shuttered hospital to reopen. The key focus of the hospital during the response phase should, however, be on the successful implementation of its patient, medical staff, and employee response plans as described in this section. The most difficult judgment call for a hospital confronting closure will be assessing the point at which its potential role as a community shelter and emergency treatment center—and its ongoing acceptance of patient transfers and emergency cases—potentially puts at risk its ability to continue

to ensure the safety of its employees and pre-disaster patients. Closure of the hospital's emergency room should be made consistent with disaster criteria established as part of the planning phase and consistent with local public health requirements and EMTALA; the latter may be modified by waivers issued post-disaster.

3. Recovery Phase

What are a "decommissioned" hospital's community responsibilities post-disaster?

The impact of a hospital closure on the community can be devastating in many respects, including loss of jobs and loss of secondary commerce. A local hospital often is among the largest employers in the community. In addition to direct job loss, the hospital can drive the secondary economy, derived from supply purchases, electricity consumption, and even use of local coffee shops and parking garages. Closure of the hospital not only removes the emergency, bed, diagnostic, and treatment resources provided by the hospital in the normal course of business, but also disrupts the delivery system as a whole. The sudden and unplanned closure of one or more facilities as a result of a disaster seriously taxes the clinical capacity and financial base of the remaining open facilities in terms of trauma support, bed availability, subspecialty coverage, and uncompensated/charity care obligations. Generally speaking, then, the best and most efficient use of a decommissioned hospital's resources is to concentrate efforts on reopening the hospital: the sooner the hospital reopens, in whole or in part, the less damage to the community.

Although the hospital is not legally obligated, with respect to its secondary roles, the hospital should designate a senior manager to oversee the deployment of its medical staff, equipment, and supplies to open facilities and temporary care sites in the community. This effort should be consistent with the hospital's pre-disaster plan to ensure optimal access to care in areas of need, taking into account the degrees and extent of disaster-related devastation to the community and potential depopulation.

D. Effect of Decommissioning on Employees

1. Preparation Phase

- a. What steps can a hospital take in preparing its employees for a disaster?

Unavoidably, the occurrence of a disaster will present many unpredictable circumstances. The following preparation activities will help the hospital function more effectively in the event of a disaster.

- i. Establishing communication lines with employees will be a top priority after a disaster. Hospitals need to have a plan for how they will maintain contact with employees who may be scattered across the region or country.
- ii. Employers comply with a myriad of employment and benefits laws and regulations on a regular basis. Some of these may be difficult to comply with after a disaster, possibly for a considerable amount of time. Disregard for these laws could be problematic in the long term. Hospitals should be aware of exceptions provided in employee benefit laws that it might need to take advantage of during a disaster. For example, following Hurricane Katrina, the Employee Benefits Security Administration released guidance clarifying the availability of regulatory exceptions under the Employee Retirement Income Security Act of 1974 (ERISA), and extending timelines for forwarding participant contributions to a retirement plan.⁹³
- iii. Hospitals may want to develop a plan for gradual reopening, which might specify which departments would receive priority in the recovery effort. These determinations will help guide employment decisions that might have to be made, and will allow hospitals to give more complete information to displaced employees at an earlier date.
- iv. Hospitals may want to review their individual contracts and collective-bargaining agreements to determine if they have provisions dealing with disasters. Hospitals may choose to seek more flexibility from employees in the event of a large-scale event.

93 Statement of Assistant Secretary Ann L. Combs, U.S. Department of Labor, Employee Benefits Security Administration, September 15, 2005, available online at www.dol.gov/ebsa/pdf/KatrinaEnforcementPolicy.pdf (last visited April 1, 2008).

- v. Hospitals should identify mission-critical employees and outline their obligations in the planning documents. In planning a strategy for retaining employees, the hospital will need to consider what assistance it is willing and able to offer employees to return to the area. Available assistance might differ based on the employee's classification as a mission critical or non-mission critical employee.
- vi. Hospitals should consider assisting employees in establishing an evacuation plan for their families, and perhaps designating an employee at the hospital to serve as a coordinator both before and during the event for those employees who have concerns about the safe evacuation of family members.
- vii. A hospital's disaster plan should designate ways for its employees to receive information about the status of the hospital, as well as general information affecting their employment.

2. Response Phase

- a. How can a hospital immediately assist its employees during a disaster?

To support and assist its employees during a disaster, hospitals should focus on two major categories: keeping employees as safe as possible during the event, and establishing lines of communication as soon as possible after the event.

- i. During the disaster, it is important to focus on the safety of employees and their families. This is especially important for a hospital, because many of the employees will be needed to stay and work instead of evacuating the area. It also is important to consider the families of those employees being asked to stay. For example, as this document completes development, the New Orleans Police Department is in the process of holding hearings to determine the fate of those officers alleged to have abandoned their posts during the Hurricane Katrina disaster. In almost all instances, the police officers pointed to their family obligations as the reason they did not fulfill their duties as expected.⁹⁴ Anticipating and addressing these concerns will allow critical employees to remain on the job with less distraction.

- ii. Activate all available communications channels to inform employees of the status of the hospital, and what the hospital wants them to do in the current situation. Employees will be concerned about whether they will continue to receive salary and benefits during the closure, and/or when they might be expected to return to their positions. The hospital's website is a convenient place for a hospital to provide initial information; however, the hospital should be sure to have a backup host site. A toll-free information number is another strategy, and this number can be printed on employees' ID badges. As soon as possible, a hospital should provide a contact person who can take calls and specific questions from employees.

- b. If the hospital undergoes a closure, what employment issues require a prolonged response?

A hospital's long-term response to a disaster should begin with making a preliminary assessment of the length of closure, the plan for reopening, and what status, if any, its employees will have during this period.

- i. If a hospital lays off employees for a period of six months or longer, then it may be required to issue a notice under the Worker Adjustment and Retraining Notification (WARN) Act.⁹⁵ The main goal of the WARN Act is to provide sixty days notice to workers of plant closings and mass layoffs. Closings and layoffs resulting from natural disasters are exempt from giving advance notice, but notice must be given after the event. The WARN Act specifies certain information that must be addressed in the notice. The WARN Act requirements are triggered depending on how many and what percentage of employees are laid off.
- ii. As a hospital plans its reopening, it must decide whether to retain employees and whether to continue providing salary or benefits. If the entire area is devastated and recovery is a long-term prospect, it likely will be more difficult to retain employees who have temporarily relocated out of the area and are no longer receiving salary or benefits from the hospital. Hospitals should recognize that any continued payments it provides to its employees may make a difference in the hospital's ability to retain its employees upon reopening. If possible, a hospital may consider transferring employees to other locations.

⁹⁴ Kevin Johnson, *Katrina made police choose between duty and loved one*, USA TODAY, February 21, 2006, at A1.
⁹⁵ 29 U.S.C. 2107(a); 20 C.F.R. Part 639.

iii. A hospital must also decide what payments it already owes, such as wages for time that employees have already worked. Payments may include significant overtime worked during and immediately after the disaster, and may implicate the Fair Labor Standards Act (FLSA)⁹⁶ or collective-bargaining agreements for unionized employees. Many states also have laws requiring wages to be paid within a certain amount of time after the work has been performed.

3. Recovery Phase

a. What employment issues arise when a closed hospital decides to reopen?

If a hospital decides to reopen to a capacity similar to its operations prior to the disaster, then that hospital will be particularly concerned with retaining or rehiring its employees.

- i. If a hospital has laid off employees during the closure, then it may want to have a policy for allowing prior employees to return to their jobs. Hospitals may want to make offers of employment contingent upon the employees returning to the area and beginning work by a certain date.
- ii. Employers should be confident that the Occupational Safety and Health Act (OSHA) (and any similar state occupational-safety act that sets standards for workplace safety and toxin exposure) has been satisfied before allowing employees back into the hospital.

b. What employment issues might arise if a hospital decides to close permanently or reopen at a significantly reduced capacity?

If a hospital ultimately decides that it cannot reopen, or will reopen in a reduced capacity or only in the distant future, then the hospital will face employment issues associated with termination of employees.

- i. If a hospital is forced to terminate employees, then it will need to be aware of any contractual or statutory obligations that may be triggered. Sources of these obligations include collective-bargaining agreements, as well as the WARN Act and similar state laws. The hospital also should develop a consistent policy for, and means of, terminating those employees with whom the hospital has lost contact; one such method may be newspaper notification.

ii. If the hospital decides to reopen on a smaller scale and terminate some, but not all, of its existing employees, then the hospital should develop consistent criteria for determining which employees will be terminated. In order to avoid possible discrimination claims, hospitals may want to have such criteria in place as part their planning documents. For instance, a hospital may know that, in the event of a disaster, certain departments (e.g., the emergency department) will be considered a priority to reopen. Maintaining employees based on their importance to a priority department could be one criterion for continued employment. Employers should document their termination decisions based on the established criteria.

iii. The hospital should be aware of any seniority rights or other conditions in collective-bargaining agreements, as well as how these rights might interact with other criteria the hospital decides are important.

iv. The hospital needs to consider employee willingness to return to the job. If a hospital remains closed for a long period of time, or the entire community is destroyed, then employees are likely to relocate and take other jobs. Before making any final decisions to terminate, the hospital may want to contact those employees it hopes to retain, and confirm that they are willing to come back.

v. If a hospital decides not to reopen, then it should consider any potential liability that could be faced by the hospital (or the hospital's parent company) for employment-based claims. For example, employees may still be able to bring claims under FLSA for overtime worked during the disaster, or under workers' compensation laws for injuries received during the disaster.

E. Effect of Decommissioning on Medical Staff

1. Preparation Phase

a. What preparation should a hospital make regarding its medical staff?

For medical staff functions, the preparedness phase has four key components:

- Developing an accurate profile of the medical staff to facilitate communication and assist deployment decisions during the response and recovery phases;

96 29 U.S.C. § 201 et seq.

- Defining the roles and obligations of the organized medical staff during a closure, and incorporating these provisions into the medical staff bylaws or rules and regulations;
- Developing an emergency-placement and recall plan for reopening; and
- Developing a plan for medical staff communications so that each member is trained in, understands, and accepts her disaster-related obligations.

Each of these components is discussed in greater detail in this section.

i. Medical Staff Profile

As a necessary first step to the planning process, the hospital should develop and maintain an accurate list of medical staff members. This list must contain all relevant information, including emergency contact information and potential alternative placement sites if the hospital must close.

Hospitals typically maintain pieces of the needed information in multiple databases, making it hard to access and enhancing the potential for conflicting or missing data. During and after a disaster, particularly where the physical plant has been seriously impaired, it may be difficult or impossible to access all or some of this information. As a result, recovery efforts can be significantly impaired or delayed if management and administrative time is diverted to attempting to locate and communicate with physicians without accurate information. The hospital might even be dependent upon the physician initiating contact with the hospital to confirm her location. Similarly, without this information, the hospital will not be able to effectively design a recovery and recall plan (as will be described).

Teaching hospitals also should maintain an up-to-date database of all required information that must be provided to the hospital fiscal intermediary in order to release resident slots to a receiving hospital, as well as to allow the receiving

hospital to claim reimbursement under the CMS rules concerning temporary closure.

ii. Defining the Role of the Organized Medical Staff in a Disaster

Few institutions have fully considered the role of the organized medical staff during a disaster and decommissioning. This role will vary by the status the medical staff organization has under state law (e.g., an unincorporated association vs. an entity integrated within the hospital). Some precedent exists for imposing fiduciary duties on department chairs and, indirectly, on other physicians in inpatient hospital positions. In *Nadal-Ginard v. Children's Hospital Corp.*,⁹⁷ the Massachusetts Superior Court held that the chair of the cardiology department was accountable to both the medical staff executive committee and the board of trustees; because this was a relationship of "significant trust and confidency" such that fiduciary duties to the hospital existed.

In an emergency, department chairs and other members of the medical staff leadership group may feel conflicted between (1) their obligation to support their peers and colleagues and (2) their potential obligation to support the hospital recovery plan and act in the best interest of the hospital, even if the individual members of the medical staff may be adversely affected by certain decommissioning decisions. Ultimately, the support of the physician leadership, and their recognition of their obligations to the hospital, will be a critical ingredient as to whether the hospital will be able to reopen.

Hospitals should consider creating a medical staff task force to consider the role of the medical staff during and after a disaster, and to incorporate these requirements into the medical staff bylaws. Issues to be considered should include:

- Establishing a emergency medical staff website for communications;
- Defining leadership decision-making powers during disaster and recovery phases;
- Defining obligations of the medical staff members to contact their department chairs and to support a placement plan, if appropriate;

97 *Nadal-Ginard v. Children's Hospital Corp.*, 1995 WL 1146118 (Mass. Super.), Dec. 1, 1999.

- Designating a liaison to provide credentialing and malpractice information to other institutions to facilitate placement;
- Preparing an appropriate statement (in the event of staff reductions or program closures that result in loss of medical staff privileges) that loss of privileges was not related to clinical competence (in order to facilitate a medical staff member's ability to obtain privileges at a new facility); and
- Codifying the medical staff member's notice obligations and surrender of privileges if she elects not to return.

iii. Emergency Placement and Recall Plans

The most difficult time to develop placement plans is after the disaster has occurred. Management will be focused on restoration of physical plant, damage assessment, and insurance-related issues. Given the lack of resources (including, at times, basic telecommunications and information-technology [IT] support), having the burden of negotiating medical staff and resident-placement plans is a distraction from core rebuilding concerns. If physicians are left to fend for themselves, then an erosion of trust and support may result that could lead to defections prior to reopening.

This situation may be avoided by addressing it as part of the pre-disaster preparation process. Hospitals should develop placement/physician redeployment plans that include facilities or clinical sites located in the immediate geographic area in which the hospital is located, the state in which the hospital is located, and out-of-state. Relocation sites may include other facilities operated under the hospital's license or affiliated facilities within a health system. Teaching hospitals that place residents at other sites on the closed hospital's license (e.g., satellite facilities) will need to consider the impact of the Medicare graduate medical education (GME) partial-closing rules in their decisions. Emergency affiliation agreements can be reciprocal, which should lead to a more collegial negotiation.

The following terms must be addressed in these agreements:

- Duration;
- Availability of temporary housing for displaced physicians and their families;
- Billing and collections;

- Assignment of revenue back to the closed hospital if the closed hospital continues to pay salary support or provides income guarantees to displaced medical staff members;
- No-hire clauses; and
- The recall process.

Affiliation agreements concerning medical students and resident placement must comply with applicable standards of the Accreditation Council for Graduate Medical Education (ACGME) and the Liaison Committee on Medical Education (LCME). Hospitals should consider developing contingent affiliation agreements with local hospitals or affiliated hospitals to facilitate Medicare reimbursement under the affiliated group rules.

In developing its placement plan, the hospital may be faced with difficult decisions with respect to providing income support to medical staff members at a time when no (or significantly reduced) clinical revenue is being earned as a result of the closing. Some assessment should be made during the preparation phase of the cost and availability of emergency lines of credit to support cash-flow obligations in order to provide a framework for decision-making once the extent of damage is known. Because of the Stark, anti-kickback, and tax-exempt organization implications of providing financial support to non-employed physicians, the hospital should consider its legal position. In this event, it should be prepared to ask DHHS for an emergency waiver for these issues and for other technical legal constraints that may pose barriers to the recovery plan.⁹⁸ Note that placing more physicians and residents at a single site will make it more likely that the hospital will retain a core support group.

Finally, the hospital also should develop a recall plan that assumes partial reopening, as well as a staff plan based on the need of physician and ancillary support to staff the emergency department, medical beds, surgery, diagnostics, intensive care, and critical care. These plans should include a sensitivity analysis based on reduced populations and a changed payor mix. In addition, the hospital should develop a plan for support of primary care physicians to ensure the ongoing viability of its referral network.

iv. Medical Staff Communications Plan

As preparedness plans are developed, the medical staff will need to be educated and have input into

⁹⁸ See section 4.2, *supra*, for more information on such waivers.

the process. It is critical that physicians buy in to the plan in order to ensure that the information listed in this section is updated on a regular basis, and that the physicians understand their obligations during and after a disaster. Hospitals should consider distributing a laminated card with “Things to Remember in a Disaster,” featuring at least three key telephone numbers or a website address as resources if a disaster occurs. Scenario testing and role playing are useful tools to educate the medical staff on issues they may confront.

2. Response Phase

What are the medical staff obligations during an emergency?

The medical staff is under two sets of legal obligations. The first is to comply with their existing hospital and medical staff obligations so long as the hospital is operating, subject to specific requirements of the hospital’s overall emergency preparedness plan. These obligations include following evacuation requirements and protocols once a decision has been made to close the hospital. Second, physicians are under common-law, statutory, and/or ethical obligations not to abandon their patients. The law in this area is likely to evolve, as litigation proceeds in varying settings (e.g., nursing homes and hospitals) with respect to owner/operator/provider obligations not to abandon patients.

3. Recovery Phase

a. What is the medical staff obligation to support the hospital during decommissioning?

As noted, no clear legal standard yet exists regarding the duty that a member of the

medical staff owes the hospital. Thus, absent a contractual agreement that obligates the physician to work where directed by the hospital and to assign revenues to the hospital in exchange for compensation, and absent an enforceable non-competition agreement, it is unlikely that the hospital will have significant control over a physician’s decision to remain available to the hospital upon reopening.

b. What steps regarding its medical staff should a hospital take to implement its recovery plan and reopen?

The hospital should consider the following key steps when attempting to implement a recovery plan:

- i. Establish both formal and informal lines of communications, and then communicate on a frequent basis;
- ii. Inform the physicians once the recovery plan is set, notifying physicians as soon as recall efforts are underway;
- iii. Charge department chairs with the responsibility of maintaining ties with department members;
- iv. Identify alternative practice sites consistent with the placement plan, and ensure that the physicians are being supported in these emergency placement sites;
- v. Assist physicians in securing office space, and entering into billing agreements if necessary; and
- vi. Consider financial assistance under appropriate circumstances.

VIII. Disaster-Recovery Planning for Critical Computer Systems

A thorough, comprehensive “Disaster Recovery Plan” or a “Contingency Plan” is a key to the restoration of systems and operations that often are disrupted during an emergency. Developing such a plan requires commitment at the highest levels of the organization, particularly in terms of the significant investment of time that must be devoted to plan development and testing, the training that will bring the plan to life in an emergency situation, and the continual plan updates that will keep the plan viable for the organization. The good news is that the hospital need not start from scratch; many sources of information are available, in both the private and public sectors, and much of this information is available free on the Internet.⁹⁹ A contingency plan, however, must be organization-specific, taking into account the particular vulnerabilities faced by an organization. A generic plan that is not tailored to the critical systems, lines of communication, and specific resources of the organization is likely to fail when most needed.

A. Preparation Phase

1. What steps must a healthcare organization take to prepare a viable disaster-recovery plan?
 - a. Evaluate Oversight and Resources – The organization should begin by adopting a planning policy statement for disaster recovery. This statement should lay out the authority given to those who will lead the effort; give general guidance for the planning process in terms of resource commitment (personnel and fiscal resources); and prescribe the level of oversight by the organization’s board of trustees and management.
 - b. Analyze the Business Effects – This analysis should identify natural, human, and environmental threats and vulnerabilities; evaluate the business impact of those threats and vulnerabilities on critical resources; determine allowable outage times; and develop recovery priorities.
 - c. Identify Preventive Controls – When feasible and cost-effective, the effects of a particular problem can be mitigated or eliminated by adopting preventive measures. Examples include offsite storage of backup data, fire-suppression systems, and methods to provide backup power. When offsite storage is used, the contract with the offsite vendor should be reviewed by the legal department and the IT department to ensure both legal enforceability and adequacy of the technical components of the contract.
- d. Develop Recovery Strategies – When developing recovery strategies, the organization should address all of the potential effects that were identified in the business analysis. Recovery strategies might include regular system backup of data, standing arrangements to obtain replacement equipment, or having redundant equipment available. Available financial and personnel resources must be factored into the recovery strategies that are chosen. Once the recovery strategies are fully developed, individuals and teams should be designated to implement the strategies in the event of a disruption. These teams and individuals should have the information they need in order to clearly understand their goal in the recovery effort, the steps they must execute, and how their team relates to other groups.
- e. Plan Testing, Training, and Exercises – In addition to familiarizing recovery staff with their roles in an emergency setting, plan testing can identify weaknesses in the plan itself. Classroom exercises, where recovery personnel walk through the plan elements, are the most basic form of recovery training. Actual simulations of disasters provide more opportunities for learning, but may represent a time- and cost-intensive effort. Testing and training should be conducted at least annually, and should be undertaken by new hires as part of their orientation process. Recovery personnel should be able to perform their required functions without need to refer to the plan document, in anticipation of an event in which the plan is unavailable.
- f. Perform Maintenance – It is essential that the disaster-recovery plan be reviewed and updated regularly. IT systems in particular undergo frequent changes, and the effects of these changes must be incorporated into the plan. Contact lists of recovery personnel should be updated frequently. A log should be kept of changes made to any part of the

⁹⁹ One free, fairly comprehensive document is available from the National Institute of Standards and Technology (NIST). NIST Special Publication 800-34, entitled Contingency Planning Guide for Information Technology Systems, available online at csrc.nist.gov/publications/nistpubs/800-37/SP800-37-final.pdf (last visited April 1, 2008), was used as the primary basis for the FAQs appearing in this section.

plan, and a method should be developed for communicating changes to all recovery personnel. The hospital should assess periodically the adequacy of outside vendors that have a role in recovery processes.

B. Response Phase

How should the organization activate its plan when disaster strikes?

The recovery plan should be activated by the contingency plan coordinator (designated in the plan) only when the damage assessment indicates that one or more of the activation criteria have been met for one or more systems. Once activated, the organization's sequential recovery procedures will allow for a logical restoration of function in accordance with the system priorities described in the plan.

C. Recovery Phase

After a recovery plan has been activated, what is the process for recovery-phase procedures?

The recovery plan should include detailed procedures for restoring each of the systems addressed by the plan. As appropriate for the organization, these procedures should address issues such as obtaining authorization to access areas of damage; notifying internal and external business partners who could be affected by the damage; providing for needed supplies and work space; obtaining and loading backup data onto information systems; testing the system's functionality; and bringing restored systems back online or operating alternate equipment successfully. Once damaged systems and operations have been restored, recovery personnel should critique the plan and the recovery process, and the plan should be revised to incorporate lessons learned from the disaster.

IX. Academic Medical Center Issues

Academic medical centers and teaching hospitals (collectively, “teaching hospitals”) face several issues less common to other institutions in the event of an emergency. These issues arise because teaching hospitals pursue research and teaching activities in addition to the clinical care common to all healthcare providers. Although many operational challenges for teaching hospitals are posed during an emergency, at least three such challenges deserve discussion: risks to experimental animals; patients or research subjects enrolled in experimental protocols; and the effects of an emergency on medical trainees and the teaching hospitals at which they are based.

A. Teaching Hospitals with Bench Research

As in any element of emergency preparedness, the first step for teaching hospitals is to perform risk assessment. Teaching hospitals should evaluate the risks to their bench-research programs in the event of an emergency, and take action as appropriate to reduce, eliminate, or ameliorate those risks. Three key risks apply to animal research facilities: the risk of data loss; the risk of losing cell cultures or other essential equipment or materials due to power failure; and interruption of the grant-application cycle.

1. Preparation Phase

- a. How can teaching hospitals avoid catastrophic loss of data?

An emergency may result in destruction of crucial research data due to power loss, physical damage, or other causes. Once the data is lost, reconstructing it will be virtually impossible. To avoid losing years of research data and endangering the careers of researchers, crucial data should always be backed up on a periodic schedule. Backup media should be stored in a secure location away from the research facility.

- b. How can teaching hospitals avoid losing cell cultures or other essential equipment/materials due to power failure?

Bench labs use vast quantities of electricity. A loss of power due to an emergency could result in loss of important cell cultures, warming and loss of biological material stored in research freezers, and other catastrophic losses. To avoid this result, research institutions should consider

establishing either a separate emergency generator system for the research facility (to provide enough power to maintain essential equipment) or an uninterruptible power supply (UPS), essentially a room-sized battery (to provide backup power to prevent these losses). Planners should be aware that these approaches are likely to be very costly. Note that each of these solutions only operates the target equipment for a limited period of time; emergency plans should include steps to shut down research in an orderly fashion in the event it is not possible to maintain emergency-power sources or return to normal electricity.

2. Recovery Phase

How can teaching hospitals deal with interruption of their ability to submit grant requests due to an emergency?

Following the Gulf Coast hurricanes of 2005, CMS, acting for grant-making federal agencies, extended many grant deadlines to give affected researchers time to gather needed information and submit their grant requests. Such extensions are likely in the event of future large-scale disasters. For more-localized emergencies, the research institution should contact its grant-making agency and request an extension until normal operations can be restored.

B. Teaching Hospitals Engaged in Animal Research

Teaching hospitals should evaluate the risks to their animal-research programs in the event of an emergency, and take action as appropriate to reduce, eliminate, or ameliorate those risks. Two key risks apply to animal research facilities: the risk of catastrophic loss of the animal populations; and the risk of escape of infected animals.

1. Preparation Phase

How can teaching hospitals avoid catastrophic loss of animals?

Animal vivariums often are placed either in the basement or on the roof of research facilities, to minimize the difficulties of transporting lab animals. More often than not, teaching hospitals choose to locate their vivariums in basement locations, saving the rooftop views and other amenities for humans. As a result, vivariums in particular are subject to catastrophic damage in case of floods, earth-

quakes, or other physical injury to their basement sites. Long-term loss of power or water can be equally catastrophic. For example, as a result of Hurricane Allison, which struck Houston and the Texas Medical Center in 2001, tens of thousands of lab animals were drowned by extensive flooding of basement lab spaces. Many of these animals were part of carefully cultivated, genetically unique strains of mice with particular traits; their deaths meant the loss of literally years (and, in some cases, decades) of scientific investigation.

To avoid such losses, teaching hospitals should consider at least two practical steps: first, locate animal facilities where they are not subject to the risks of flooding or collapse; and second, separate experimental animals from breeding colonies to reduce the risk of loss of both populations.

Although it may not be fiscally prudent to locate the vivarium where it is not subject to physical risks such as flooding, teaching hospitals should at least consider these risks in deciding on a site. The financial costs of recreating particular animal strains, coupled with the loss of scientific knowledge if they are destroyed, may be enough to justify locating the vivarium somewhere safer than the basement if the teaching hospital's hazard vulnerability assessment indicates that flooding is a high-probability risk. Facilities in Houston, New Orleans, and elsewhere have learned that it is not advisable to locate emergency generators on the ground floor when flooding is a major risk; similarly, teaching hospitals may conclude the same about vivariums. It may be cost-effective in the long run to locate the vivarium away from the flood risk, even if doing so incurs additional short-term costs. At a minimum, teaching hospitals should carefully assess the emergency equipment needed to protect the vivarium in the event of a disaster, such as dedicated sump pumps, protected backup power supplies, and/or increased seismic stabilization.

If it is not possible to eliminate the risk to the vivarium by relocating it, then teaching hospitals should at least consider separating their experimental colonies from their breeding colonies of lab animals. Broadly speaking, teaching hospitals need access to animals with particular traits; animals currently undergoing experimental procedures are part of the experimental colony, and generally are locat-

ed in active lab space. These experimental animals are either developed by in-house breeders or purchased from external sources; both sources use breeding colonies to supply animal subjects. These breeding colonies should be separated physically from the experimental colonies if at all possible. Preferably, they should be located in a place that is not subject to the same risks faced by the experimental colony. Therefore, if the experimental colony is at risk from a flood, then the breeding colony should be located above ground. If the experimental colony is at risk from collapse due to an earthquake, then the breeding colony should be located away from a seismically active zone. By doing so, the teaching hospital reduces significantly the risk of loss of an entire genetic line, though it may still lose the results of the current experimental protocol.

Finally, some consideration should be given to the evacuation of lab animals if a disaster occurs. Ideally, teaching hospitals will have the time, personnel, and resources necessary to relocate lab animals to a safe spot. However difficult it may be to acknowledge the fact, such an evacuation is highly unlikely in practice. First, rescue resources will inevitably be devoted first to protecting human life. Second, the environmental requirements for lab animals cannot easily be duplicated; they cannot be readily moved to another location without subjecting them to stress and compromise that is likely to lead to wide-scale animal death, possible cannibalism, and significant suffering. The hard fact is that only the rare emergency will permit animal evacuation.

2. Recovery Phase

How can teaching hospitals mitigate the effect of lab-animal losses?

Despite the best efforts of teaching hospitals, lab animals may still be lost due to natural disasters or other causes. Part of emergency preparedness involves determining how best to mitigate a loss that cannot be eliminated. In the case of lab animals, mitigation generally involves insurance. Lab animals are insurable, but standard property-insurance policies may contain limitations on coverage or set reimbursement levels that leave the teaching hospital essentially unprotected. The teaching hospital's annual insurance renewal should ensure not only that there is coverage for lost lab animals, but also that the coverage level accurately

reflects the costs of replacement. In particular, teaching hospitals should consider the potentially large costs of recreating a lost breeding line after a disaster.

3. Response Phase

How can teaching hospitals avoid the escape of infected animals?

Depending on the research underway at a teaching hospital, experimental colonies of lab animals may, at any given time, be infected with diseases that could cause harm or even death to humans who come in contact with them. As responsible members of their communities, teaching hospitals must protect against the escape of these animals.

Each facility that engages in animal research sponsored by the Public Health Service (PHS) must have an Institutional Animal Care and Use Committee (IACUC) to oversee its animal-research program and ensure safe practices, for animals and humans coming in contact with them alike.¹⁰⁰ The IACUC has institutional responsibility to ensure that animal research is conducted safely, including in facilities appropriate to contain any infected animals. Most research will take place in a Level 2 vivarium; where specific dangerous organisms are involved (e.g. malaria or tuberculosis), the higher security of a Level 3 facility is required. Some organisms are so dangerous that they can only be handled in a Level 4 facility, and no private institution currently maintains such a facility.¹⁰¹

The first step in protection is ensuring that the IACUC considers the possible effects of a disaster on escape of infected animals. The IACUC should not permit animal research to occur unless it has a reasonable level of assurance that animals will be appropriately contained in an emergency.

Beyond containment, teaching hospitals should also consider a euthanasia policy for infected (and other) lab animals in the event of a disaster. Such a policy could do two things: first, it would protect humans against escape of infected animals; and second, the policy would provide for a humane death for animals that cannot be saved from the effects of an emergency condition. Although it would be preferable to evacuate the animals, such evacuation is

very unlikely, as discussed earlier. Therefore, in the most extreme cases, teaching hospitals should be prepared to humanely euthanize an animal population that will otherwise be subject to starvation, drowning, or other avoidable suffering. Given the need to remove lab personnel from the disaster area, the decision to euthanize should be made early and carried out quickly to spare the animals from unnecessary suffering and allow human personnel to escape themselves.

C. Teaching Hospitals Conducting Research with Human Subjects

Teaching hospitals conduct clinical research on research subjects using protocols approved by Institutional Review Boards (IRB) and administered by a highly trained staff of investigators, research pharmacists, research nurses, and others. Patients enrolled in clinical protocols may be receiving life-sustaining drugs, or may be in the middle of experimental surgical or other protocols. In those cases, interrupting completion of the protocol may threaten their health and ultimately their lives. Therefore, ensuring ongoing access to the clinical protocol, including any study drug, may be vital for these research subjects. Conversely, following a natural disaster, other hospitals may find that patients on research protocols may present for care, without documentation of the protocol, without study drug, and with limited access to information from the teaching hospital sponsoring the study. In this event, the risk is primarily to research subjects: How can teaching hospitals protect them as much as possible, and how can other facilities care for research subjects who come to them for post-disaster treatment?

1. Preparation Phase

- a. How can teaching hospitals prepare to protect research subjects from the effects of a disaster?

Research protocols are complex, requiring substantial infrastructure and personnel for implementation. Although every teaching hospital can predict that it may experience an emergency that would make it impossible to continue to provide care, it is essentially impossible to predict which precise disaster will strike any given teaching hospital—or even whether one will ever strike at

100 7 U.S.C. §2131 et seq.; 9 C.F.R. Chapter 1, Subchapter A, Parts 1, 2 and 3.

101 See CDC & NIH, BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (4th Ed. 1999), available online at www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf (last visited April 1, 2008).

all. Consequently, it is simply infeasible to create duplicate or backup systems that would take over care in the event of an emergency. The most natural system would be to plan for an emergency specific to the teaching hospital, arguing in favor of cooperative relationships with other local teaching hospitals to care for research subjects. Such an approach, however, would have done nothing to protect patients in New Orleans following Hurricane Katrina in September, 2005, because all but three hospitals in the metropolitan area shut down completely, and those three remaining struggled to maintain basic operations.

If redundancy is impossible, then what can teaching hospitals do? Teaching hospitals may take the following three practical measures prior to an emergency.

- i. Maintain duplicate copies of all information on clinical protocols at a site physically separate from, and not subject to the same risks as, the teaching hospital. This duplicate information should include enrollment records, as well as general information on the protocol, especially any study drugs involved. If the teaching hospital still uses paper records, maintaining duplicate records obviously creates a substantial storage issue. Electronic records and the use of an electronic clinical information system make it easier to copy relevant data and retrieve it in the event of an emergency. This duplicate information can be used to provide copies of the protocol and relevant enrollment information to any other facilities at which research subjects seek care after the disaster.
- ii. Give protocol enrollees quick access to information on their protocol (or protocols; many may be enrolled on more than one) by providing a wallet card with a toll-free information number key information on the protocol in which the person is enrolled, using the protocol number and name of the protocol sponsor.
- iii. Ensure that all protocols in use at the teaching hospital are registered with a national clinical trial registry, such as the one maintained by the CenterWatch Clinical Trials Listing Service.¹⁰²

Registration of the protocol ensures that other doctors and hospitals can get access to it when needed if a patient on a protocol seeks care at another facility.

In addition, a teaching hospital may be able to mitigate the effects of a disaster, especially with respect to the supply of needed study drugs. If a teaching hospital must close, as happened to many facilities in the wake of disasters in Texas, Louisiana, and California, then the teaching hospital should work with local emergency management personnel to relocate any study drug supplies to appropriate locations. Initially, it may be necessary to transfer study drugs to a central location, pending redistribution to other facilities caring for enrollees. Study drugs will do no good if they are left behind in a closed facility; in the general chaos of an emergency, it is likely that it will be hard to secure new supplies in short order.

2. Response Phase

- a. When a disaster occurs, how should hospitals deal with research patients who seek care from them?

Normally, research subjects get their care from the teaching hospital that is implementing the research protocol. In an emergency, however, patients may be dispersed through a broad geographic region; in fact, following Hurricane Katrina, victims wound up in virtually every state in the nation. Obviously, a hospital in the San Francisco Bay area dealing with an evacuated research patient from New Orleans needs reliable information on the protocol in which the patient is enrolled. Receiving hospitals should follow the following steps in such a case.

- i. Contact the research sponsor to obtain information on the research protocol, and coordinate with the sponsor to ensure uninterrupted care for the research subject. If the hospital is unable to identify the sponsor, contact the National Institutes of Health (NIH). For example, following Hurricane Katrina in September 2005, the NIH deployed 250 of its staff members to assist in recovery

¹⁰² See CenterWatch Clinical Trials Listing Service, available online at www.centerwatch.com (last visited April 1, 2008). CenterWatch is operated by Thomson Corporation, which also is a large legal publisher.

efforts, including locating research subjects and putting them in contact with institutions that could continue their care. NIH and other sponsors made extensive use of the Internet to disseminate information.¹⁰³

- ii. If ongoing care will be necessary, identify a principal investigator at the hospital who will ensure continuity of care for the research subject. Research protocols require very careful adherence to their provisions. The first step to successfully caring for research patients is a capable principal investigator. Usually, this will mean a physician with specialization in the area of the research protocol.
- iii. Identify a source of any needed study drug. Generally, the protocol sponsor will be the best source of any needed drugs or other supplies.
- iv. Consider whether human subject approval from an IRB will be necessary. Hospitals can best address this question in consultation with the study sponsor (e.g., NIH or a drug company).

For hospitals caring for research subjects displaced by an emergency, the most important factor is to prevent or minimize any interruption in continuity of care under the protocol.

D. Teaching Hospitals and Trainees

In addition to all the issues that other hospitals face, teaching hospitals also have residents, fellows, and other trainees as part of their workforce; consequently, teaching hospitals must plan for their safety and well-being in the event of a disaster. When a disaster strikes close to the start of the academic year, as Hurricane Katrina did in 2005, the disruption can be even more pronounced. Teaching hospitals should (a) include trainees in their planning and preparation for an emergency; (b) respond to the special needs of trainees during the emergency; and (c) protect trainees financially during recovery from a disaster.

1. Preparation Phase

- a. How can teaching hospitals plan to protect trainees in the event of a disaster?
Medical trainees (e.g., interns, residents, and fellows) generally will not be as familiar with the teaching hospital's geographic area as longer-term residents, nor will they generally have

significant personal financial resources to see them through an emergency (most will be recent graduates with major medical-school debt). As a result, teaching hospitals should prepare for an emergency by considering the housing, transportation, and communication needs of their trainees as well as the hospital's long-term staff. Teaching hospitals should give consideration to these questions:

- i. Whether portions of the hospital facility can be converted to house trainees in case the disaster affects residences in the area, keeping trainees from their homes;
- ii. Whether other facilities nearby (e.g., churches, schools, or community centers) that can be converted to short-term housing in an emergency;
- iii. What supplies should be kept on site to convert space temporarily to dormitories for trainees (e.g., bedding, linens, food, toiletries);
- iv. How the teaching hospital can transport trainees in an emergency from their places of residence to the hospital where they can be housed temporarily;
- v. How to establish a toll-free number or website that will make available current information on how to contact the teaching hospital for those trainees who may become cut off as a result of the disaster (e.g., a wallet card with information for trainees to carry in case of an emergency);
- vi. What communications devices, if any (e.g., cell phones or PDAs) to issue to trainees to enable them to maintain contact with the hospital if they are displaced by a disaster; and
- vii. How to support trainees financially if they are forced to obtain substitute housing, transportation, or household goods due to emergency conditions.

2. Response Phase

- a. How can teaching hospitals assist trainees during an emergency?

During recent emergencies such as Hurricane Katrina, teaching hospitals took the following steps to assist trainees.

- i. Some teaching hospitals found substitute housing for trainees displaced as a result of the storm's flooding and destruction.

103 A good first place to check likely will be the Association of American Medical Colleges (AAMC); see www.aamc.org (last visited April 1, 2008).

- ii. The AAMC established bulletin boards and email lists for displaced trainees to use to contact their teaching hospitals, many of whom were themselves dispersed as a result of the storm and therefore difficult to contact.
- iii. Teaching hospitals affected by the disaster quickly announced that they would find alternative placements for trainees unable to work at their original sites.
- iv. All approved GME programs placed a moratorium on new position arrangements without the consent of the original training site, to prevent widespread disruption of training programs and a race to secure displaced trainees.
- v. CMS announced that hospitals taking on additional trainees as a result of the disaster would receive a temporary adjustment to their Medicare training caps if they exceeded the established caps as a result.¹⁰⁴

Overall, these steps were designed to maintain the integrity of established teaching programs, secure alternative locations for training for those unable to train at their original site, and provide for continuity and consistency in a chaotic time.

3. Recovery Phase

How can training sites protect themselves financially as they recover from a disaster?

Training sites that take on additional trainees temporarily as a result of an emergency will incur additional costs and may exceed their allocated resident training caps. To avoid this problem, CMS temporarily adjusted the hospital's full-time equivalent cap on residents to permit the hospital to receive indirect or direct GME payments for displaced residents for as long as the original program was closed. To obtain this accommodation, the receiving hospital must notify its fiscal intermediary within sixty days to request a temporary adjustment to the full-time equivalent (FTE) cap.¹⁰⁵ When this waiver is effective, Medicare payments to the site will temporarily include recovery of costs for the additional trainees.

Conversely, training sites adversely affected by an emergency should communicate clearly

with CMS regarding their recovery plans. For example, the teaching sites affected by Hurricane Katrina have gone to great lengths to make detailed information available to their trainees who are dispersed to other sites, and to resume normal teaching operations as quickly as possible. In at least one case, a teaching hospital secured an alternative location in Baton Rouge, LA, not only to care for patients but also to allow continuation of internal-medicine training programs without interruption. This effective communication about the site's intentions meant it did not lose trainees to other sites, and also did not lose any GME funding from the Medicare program.

E. Changing Requirements for Federal Research Awards After a Disaster

Teaching hospitals usually conduct federally funded research; that funding comes with application deadlines, reporting obligations, and other requirements. After Hurricane Katrina struck in September 2005, the Office of Management and Budget, on behalf of a variety of federal agencies, issued a "Joint Announcement: Hurricane Relief on Federal Research Awards."¹⁰⁶ In this statement, the OMB announced several changes to the usual practice for research awards:

- Flexibility with application deadlines;
- No-cost extensions on expiring awards;
- Abbreviated continuation requests;
- Expenditure of award funds for salaries and other project activities (allowing, e.g., salary continuation payments for grant-funded personnel consistent if other employees were receiving salary continuation);
- Waiver of prior approval requirement for re-budgeting;
- Extension of financial and other reporting deadlines;
- Extension of currently approved indirect cost rates;
- Extension of deadlines for closeout reports; and
- Alternatives for record retention and cost documentation (acknowledging that original records may have been destroyed in the catastrophe).

It is likely that, in a future widespread emergency, similar provisions regarding federal financing will apply.

¹⁰⁴ 70 Fed. Reg. 18,654 – 67 (2005).

¹⁰⁵ CMS FAQ, *supra* note 40, Question ID No. 5296, "If a teaching hospital affected by the disaster closes even temporarily...?", created Sept. 15, 2005.

¹⁰⁶ See management.energy.gov/documents/Flash2006-01ATTACHMENT.pdf (last visited April 1, 2008).

X. Avoiding Malpractice and Criminal Claims in Responding to an Emergency

A. Medical Malpractice and Criminal Negligence – General Considerations

1. What is the basis for a claim of medical malpractice?

A medical malpractice claim arises when a plaintiff alleges that a healthcare provider has breached the provider's duty to provide a certain level of care and skill, resulting in damage to the plaintiff. A prima facie case exists when the plaintiff can prove the relevant standard of care and the defendant's departure from that standard during the patient's treatment.¹⁰⁷ No federal standard of care is relevant to such situations. Rather, each state determines the standard of care to which it holds providers.¹⁰⁸

2. Is the standard of care for medical malpractice altered during an emergency situation?

In certain states, the standard of care required of providers is altered to some extent during an emergency situation. Since September 11, 2001, increasing efforts have been made to change the usual standards of health and medical care in the immediate aftermath of a catastrophic event.

To that end, the Agency for Healthcare Research and Quality's (AHRQ) report, *Altered Standards of Care in Mass Casualty Events in April 2005*,¹⁰⁹ laments that legal issues such as liability have created a reluctance on the part of the healthcare community to plan for emergency situations that would lead to altered standards of care. The AHRQ report emphasizes the importance of overcoming this reluctance, as

changes in the usual standards and the establishment of clear authority to activate altered standards of medical care "will be required to achieve the goal of saving the most lives in a mass casualty event."¹¹⁰ Waivers granted and targeted to the affected geographic area would be limited to a specified, temporary period of time. In the case of a communicable agent, such as a pandemic virus spreading rapidly from one area to another, "flexibility to extend or expand such waivers would be vital."¹¹¹

3. What federal and state legislation has been enacted with regard to immunity or shifting of responsibility for provider actions during emergency situations?

a. Federal "Good Samaritan" Statute

Federal law provides "Good Samaritan" immunity limiting plaintiffs' rights to bring civil actions against individuals appointed by the Secretary of DHHS to serve as temporary members of the NDMS. Such individuals are considered employees of the PHS as long as they act within the scope of their appointment;¹¹² consequently, they are immune from civil suit. A plaintiff must file any claim against the United States,¹¹³ defended by the U.S. Attorney General.¹¹⁴

b. Model State Emergency Health Powers Act and Subsequent State Legislation Providing Immunity to Healthcare Providers in Emergency Situations

In December 2001, the CDC, through the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, released the Model State Emergency Health Powers Act (Model EHPA).¹¹⁵ The Model EHPA includes provisions intended to promote development of

107 Jay M. Zitter, Annotation, Standard of Care Owed to Patient by Medical Specialist as Determined by Local, "Like Community," State, National, or Other Standards, 18 A.L.R. 603 (4th ed. 2005).

108 Some states hold practitioners to a standard determined by their specialized area of medicine generally and others determine the standard "by the practice among a geographically circumscribed subset of his colleagues." *Id.* The standards of care used by the states generally fit within the following categories: (1) the standard of care is based on other like specialists in the same community; (2) the standard of care is based on other like specialists in the same or similar community; or (3) the standard of care is based on other like specialists throughout the nation. A fourth category also has been used as a compromise between local and national standards, and that standard is based on like specialists in within the particular state. *Id.*

109 See AHRQ Pub. No. 05-0043, *Altered Standards of Care in Mass Casualty Events: Bioterrorism and Other Public Health Emergencies* (Apr. 2005), available online at www.ahrq.gov/research/altstand (last visited April 1, 2008) (hereafter AHRQ, *Care in Mass Casualty Events*).

110 *Id.* at 2.

111 *Id.* at 23.

112 42 U.S.C.A. § 300hh-11(d) (2005).

113 *Id.* at § 233(a).

114 *Id.* at § 233(b).

115 See MODEL STATE EMERGENCY HEALTH POWERS ACT, available online at www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf (last visited April 1, 2008).

comprehensive planning for emergencies, to facilitate early detection of emergencies, and to grant state and local officials the necessary powers to handle emergency situations.¹¹⁶

With respect to the states affected by the 2005 Gulf Coast storms, Florida's 2002 amendment to its Good Samaritan Act offers limited immunity to hospitals and physicians treating emergency room or trauma patients during an "unexpected situation or occurrence."¹¹⁷ The immunity does not apply once the patient is stabilized and capable of receiving medical attention as a nonemergency patient.¹¹⁸

The 2003 Louisiana Health Emergency Powers Act contains, in addition to Model EHPA language, a provision not included in the Model EHPA:

[D]uring a state of public health emergency, any health care providers shall not be civilly liable for causing the death of, or injury to, any person or damage to any property except in the event of gross negligence or willful misconduct.¹¹⁹

Thus, interestingly, Louisiana's standard of care already was altered to account for "public health emergencies" when Hurricane Katrina hit in August of 2005.¹²⁰

c. Federal Tort Claims Act Coverage for Deemed Consolidated Health Center Program Grantees

Through the Federally Supported Health Centers Assistance Act of 1992,¹²¹ Consolidated Health Center Program grantees (including their officers, directors, employees, and certain contractors) are deemed federal employees for the purpose of medical malpractice protection. Healthcare providers protected include community health centers, migrant health centers, migrant health programs (also known as migrant voucher programs), programs providing healthcare for the homeless, and public-housing primary care programs. Coverage does not apply to center volunteers.¹²²

116 As of June 30, 2005, forty-four states had introduced bills or resolutions containing at least some portion of the Model EHPA, and thirty-seven states had enacted legislation based on the Model EHPA. See www.publichealthlaw.net/Resources/Modellaws.htm#MSEHPA (last visited April 1, 2008).

117 FLA. STAT. ch. 768.13(b)(1) (2002) states:

Any hospital licensed under chapter 395, any employee of such hospital working in a clinical area within the facility and providing patient care, and any person licensed to practice medicine who in good faith renders medical care or treatment necessitated by a sudden, unexpected situation or occurrence resulting in a serious medical condition demanding immediate medical attention, for which the patient enters the hospital through its emergency room or trauma center, shall not be held liable for any civil damages as a result of such medical care or treatment unless such damages result from providing, or failing to provide, medical care or treatment under circumstances demonstrating a reckless disregard for the consequences so as to affect the life or health of another.

118 *Id.* at 768.13(b)(2).

119 Louisiana Health Emergency Powers Act, S.B. 908, 2003 Reg. Sess. (La. 2003) (codified at LA. REV. STAT. ANN. § 29:771B(2)(c) (2005)).

120 Louisiana also has enacted a "Good Samaritan Law" eliminating liability for any civil damages resulting from (1) a physician, surgeon or physician assistant who "in good faith gratuitously rendered emergency care or services at the scene of an emergency;" (2) a physician, surgeon, nurse, intern, or resident of a public or private hospital "who in good faith responds to an imminent life threatening situation or emergency within the hospital or facility and whose actual duty in the hospital or facility did not require a response to an emergency situation;" and (3) an on-call physician or surgeon who "gratuitously attends, assists, or treats a patient who comes into an emergency room or department . . . with whom there has been no prior physician-patient relationship." LA. REV. STAT. ANN. § 37:1731A (2005). See also La. Exec. Order No. KBB 2005-33, Declaration of Public Health Emergency and Suspension of In-State Licensure for Medical Professionals and Personnel Licensed Out-of-State, Sept. 12, 2005 (order by Louisiana Governor Kathleen Blanco declaring out-of-state medical professionals agents of the State of Louisiana for tort liability purposes), available online at legis.state.la.us/katrina/eoorders/05-33.pdf (last visited April 1, 2008). Similarly, Alabama's statute protects "emergency management" workers, individuals, and partnerships of corporation from torts resulting from emergency management activities (excluding willful misconduct, gross negligence, or bad faith). ALA. CODE § 31-9-16(b) (2005). "Emergency management worker" includes any full- or part-time paid volunteer or auxiliary employee of the state of Alabama performing emergency management services anywhere in the state. ALA. CODE § 31-9-16(d).

121 Federally Supported Health Centers Assistance Act of 2002, Pub. L. 102-501 (codified as amended at 26 U.S.C. §§ 201 and 233). See also HRSA, Bureau of Primary Health Care Program Information Notice 2005-19, Federal Tort Claims Act Coverage for Deemed Consolidated Health Center Program Grantees Responding to Hurricane Katrina (Sept. 6, 2005), available online at bphc.hrsa.gov/policy/pin0519.htm (last visited April 1, 2008).

122 These programs are funded, respectively, under Public Health Service Act §§ 330(e), 330(g), 330(h), and 330(i).

4. What is criminal negligence?

Most states have statutorily defined the term “criminal negligence.” Generally, a person acts with criminal negligence when she fails to perceive a substantial and unjustifiable risk that a result or circumstance described by a statute defining a criminal offense will occur, and when the risk is of such a nature and degree that disregard of the risk constitutes a gross deviation from the standard of conduct a reasonable person would observe in the situation.¹²³

Other statutes define criminal negligence as “an act or failure to act which demonstrates a willful, wanton or reckless disregard for the safety of others who might reasonably be expected to be injured thereby.”¹²⁴ In Louisiana, criminal negligence exists when neither specific nor general intent is present, but there is “such disregard of the interest of others that the offender’s conduct amounts to a gross deviation below the standard of care expected to be maintained by a reasonably careful man under like circumstances.”¹²⁵ Violation of a statute or ordinance will be considered presumptive evidence of criminal negligence in Louisiana.¹²⁶

5. What types of charges may be brought for acts of criminal negligence?

a. Homicide

In most states, homicide that results from criminal negligence is considered criminal homicide. Some states generally classify criminally negligent homicide as a misde-

meanor, although the offense may become a felony if caused by a person driving under the influence of alcohol.¹²⁷ Other states classify criminally negligent homicide as a felony,¹²⁸ with some states including criminally negligent killing within their definitions of manslaughter.¹²⁹

b. Assault and Battery

Generally, criminally negligent assault or battery is limited to situations in which a person causes physical injury to another person by means of a deadly weapon or a dangerous instrument.¹³⁰ In some states, however, felonious battery occurs when serious bodily injury of any person occurs as a proximate result of criminal negligence, and can result in imprisonment, fines, or both.¹³¹ In other states, a person who, with criminal negligence, causes bodily harm accompanied by substantial pain that extends for a period sufficient to cause considerable suffering is guilty of assault.¹³²

c. Abuse of Child or Vulnerable Adult

Generally, a person may be guilty of a felony when acting with criminal negligence if a person (1) causes a child or vulnerable adult to suffer physical injury or death or, (2) having the care or custody of a child or vulnerable adult, causes or permits the person or health of the child or vulnerable adult to be injured, or (3) causes or permits a child or vulnerable adult to be

123 For state statutes defining criminal negligence, see ALA. CODE § 13A-2-2 (2005); ALASKA STAT. § 11.81.900 (2004); ARIZ. REV. STAT. § 13-105 (2005); COLO. REV. STAT. ANN. § 18-1-501 (2005); CONN. GEN. STAT. ANN. § 53a-3 (2005); DEL. CODE ANN. tit. 11, § 231 (2005); MAINE REV. STAT. ANN. tit. 17-A, § 35 (2005); MO. ANN. STAT. § 562.016 (West 2005); N.Y. PENAL LAW § 15.05 (McKinney 2005); OR. REV. STAT. § 161.085 (2003); 18 PA. CONS. STAT. ANN. § 302 (2005); TENN. CODE ANN. §§ 39-11-106, 39-11-302 (2005); TEX. PENAL CODE ANN. § 6.03 (West 2005); UTAH CODE ANN. § 76-2-103 (2005); WASH. REV. CODE ANN. § 9A.08.010 (2005); WY. STAT. ANN. § 6-1-104 (2005).

124 GA. CODE ANN. § 16-2-1 (2005).

125 LA. REV. STAT. ANN. § 14:12 (2005). See also WIS. STAT. ANN. § 939.25 (2005) (defining criminal negligence as “ordinary negligence to a high degree, consisting of conduct that the actor should realize creates a substantial and unreasonable risk of death or great bodily harm to another”); R.I. GEN. LAWS § 11-5-2.2 (2004) (defining criminal negligence as “conduct which is such a departure from what would be that of an ordinary prudent or careful person in the same circumstances as to be incompatible with a proper regard for human life or an indifference to consequences. Criminal negligence is negligence that is aggravated, culpable or gross.”)

126 See LA. REV. STAT. ANN. § 14:32 (2005).

127 For state statutes classifying criminally negligent homicide as a misdemeanor, see ALA. CODE § 13A-6-4 (2005); CONN. GEN. STAT. ANN. § 53a-58 (2005); UTAH CODE ANN. § 76-5-206 (2005); WY. STAT. § 62107 (2005).

128 For state statutes classifying criminally negligent homicide as a felony, see ALASKA STAT. § 11.41.130 (2004); ARIZ. REV. STAT. § 13-1102 (2005); COL. REV. STAT. ANN. § 18-3-105 (2005); DEL. CODE ANN. tit. 11 § 631 (2005); N.Y. PENAL LAW § 125.10 (McKinney 2005); OR. REV. STAT. § 163.145 (2003); TENN. CODE ANN. § 39-13-212 (2005); TEX. PENAL CODE ANN. § 19.05 (West 2005); WASH. REV. CODE ANN. § 9A.32.070 (2005).

129 For examples of state statutes defining manslaughter to include criminally negligent homicide, see MAINE REV. STAT. ANN. tit. 17-A § 203 (2005); MO. ANN. STAT. § 565.024 (West 2005); S.C. CODE ANN. § 16-3-60 (2005).

130 For examples of state statutes defining criminally negligent assault, see ALA. CODE § 13A-6-22; ALASKA STAT. §§ 11.41.220, 11.41.230 (2004); COL. REV. STAT. § 18-3-204 (2005); CONN. GEN. STAT. ANN. § 53a-61 (2005); WASH. REV. CODE ANN. § 9A-36-031 (2005).

131 R.I. GEN. LAWS § 11-5-2.2 (2004).

132 WASH. REV. CODE ANN. § 9A-36-031 (2005).

placed in a situation in which the person or health of the child or vulnerable adult is endangered.¹³³ This standard does not apply to healthcare providers who permit the patient to die, or allow the patient's condition to deteriorate by not providing healthcare, if the patient refuses the care directly or indirectly through an advance healthcare directive, surrogate, or court-appointed guardian.¹³⁴

6. When is a corporation liable for the criminal negligence of its workforce?

Generally, corporations are held criminally responsible for the acts of their employees if the employees act (1) within the course and scope of employment and (2) with intent to benefit the corporation. If the intent to benefit the corporation exists, actual benefit to the corporation is irrelevant.¹³⁵ A corporation may be liable for acts of its employees that are contrary to the corporation's express policies and procedures. The existence of policies and procedures, however, may be considered in determining whether the employee in fact acted with the intent to benefit the corporation.¹³⁶

With regard to federal prosecution, in 2003, Larry D. Thompson, then Deputy U.S. Attorney General, issued a memorandum entitled "Principles of Federal Prosecution of

Business Organizations." In this memorandum, Thompson outlined a revised set of principles to guide Department of Justice prosecutors in making decisions concerning whether to seek charges against a business organization.¹³⁷

B. Preparation Phase

What steps should a provider take to minimize medical malpractice and criminal negligence claims after an emergency?

After adopting an emergency preparedness plan,¹³⁸ providers should prepare for an emergency on a community basis. In developing emergency preparedness plans, healthcare providers and suppliers in the community are viewed not only as organizations in their own right, but also as part of the community's healthcare system. Preparedness measures should be adopted with a community-wide perspective.

The AHA's March 2000 Final Report on Hospital Preparedness for Mass Casualties (with the support of the DHHS Office of Emergency Preparedness) recommended that disaster plans link with various community elements, including local health departments and their leadership, as well as police and fire officials as first responders.¹³⁹ The Joint Commission echoed this community-wide concept in its "Management of the Environment of Care," Standard EC.4.10, requiring that hospitals and the

133 For similar definitions of child/vulnerable adult abuse, see ARIZ. REV. STAT. § 13-3623 (2005); COL. REV. STAT. ANN. §§ 18-6-401, 18-6.5-103 (2005). Other definitions and standards exist with regard to criminally negligent treatment of children and vulnerable adults, including D.C. CODE ANN. § 22-934 (2005) (applies to a person who "knowingly, willfully or through a wanton or willful indifference fails to discharge a duty to provide care and services necessary to maintain the physical and mental health of a vulnerable adult, including but not limited to providing adequate food, clothing, medicine, shelter, supervision and medical services that a reasonable person would deem essential for the well-being of the vulnerable adult"); N.Y. PENAL LAW § 260.32 (McKinney 2005) (applies to a caregiver for a vulnerable elderly person who causes physical injury to such person by means of a deadly weapon or dangerous instrument, including where the act is committed with criminal negligence); TEX. PENAL CODE ANN. § 22.04 (2005) (applies to a person who, with criminal negligence, causes a child, elderly individual, or disabled individual bodily injury or serious mental deficiency, impairment, or injury, and applying this standard to an owner, operator, or employee of a group home, nursing facility, assisted living facility, intermediate care facility for persons with mental retardation, or other institutional care facility); LA. REV. STAT. ANN. § 14:93.3 (2005) (defining "cruelty to the infirmed" as the intentional or criminally negligent mistreatment or neglect by any person, including a caregiver, that causes unjustifiable pain, malnourishment, or suffering to the infirmed, a disabled adult, or an aged person, including but not limited to a resident of nursing home, mental retardation facility, mental health facility, hospital, or other residential facility).

134 See ARIZ. REV. STAT. ANN. § 13-3623 (2005).

135 See *United States v. Beusch*, 596 F.2d 871 (9th Cir. 1979) (citations omitted), in which the Ninth Circuit held that "[m]erely stating or publishing such instructions and policies without diligently enforcing them is not enough to place the acts of an employee who violates them outside the scope of his employment."

136 *Id.* at 878 (citations omitted).

137 See Department of Justice, *Principles of Federal Prosecution of Business Organizations*, (Memorandum to Heads of Department Components, United States Attorneys, Jan. 20, 2003), available online at www.usdoj.gov/dag/cftf/corporate_guidelines.htm (last visited April 1, 2008).

138 For more information on developing a plan and associated legal issues, see AMERICAN HEALTH LAWYERS ASSOCIATION, EMERGENCY PREPAREDNESS, RESPONSE AND RECOVERY CHECKLIST: BEYOND THE EMERGENCY MANAGEMENT PLAN (2004), available online at www.healthlawyers.org/checklist (last visited April 1, 2008).

139 See AHA, *Hospital Preparedness for Mass Casualties*, available online at mipt.org/pdf/aha082000062001.pdf (last visited April 1, 2008).

community jointly establish priorities among potential emergencies, identify the hospital's role in relation to the community-wide emergency management system, and link the hospital's command structure with the community's.¹⁴⁰ In April 2005, the AHRQ's Bioterrorism and Other Public Health Emergencies report recommended development of a "Community-Based Planning Guide for Mass Casualty Care" offering not only suggestions, but also tools and resources to guide triage and allocation of scarce resources.¹⁴¹

C. Response Phase

1. What steps should a provider take during an emergency as a defense to medical malpractice claims and criminal negligence claims after an emergency?

a. Prepare for Patient Evacuation

In the event that patient evacuation is required, the organization must have in place triage planning to identify the order of patient evacuation (e.g., whether to first evacuate intensive care patients or maternity patients). The Joint Commission Elements of Performance for Standard EC.4.10 require that, effective January 1, 2006, a hospital must have a process for evacuating the entire building "when the environment cannot support adequate care, treatment and services."¹⁴²

b. Maintain Communication with Local, State, and Federal Officials regarding the Emergency's Development and the Organization's Status

During the emergency, the hospital's Incident Commander or her designee should maintain communication by whatever possible means with local, state, and federal officials to ensure that those persons understand the physical condition of patients; the organization's situation, its risks, its ability to continue adequate and safe patient treatment, its need for additional staffing, and its need to implement certain measures if/when necessary (e.g., decontamination, isolation, or quarantine); the status of the organization's supply

stores; and the existence of possible waivers of legal requirements under which the organization operates.

c. Document Strategies and Meetings During Emergency

Although potentially a "double-edged sword," it is critical that a hospital document the institution's activities during the emergency. Naturally, patient-chart documentation is important; moreover, documentation of strategy sessions by those in the Incident Command System, meetings regarding staff and supply status, and potential patient evacuation also are important. The organization must be able to track patients and document that the organization met the appropriate standard of care. With regard to chart documentation, template computer screens could be printed in advance to enable paper registration, if necessary.

d. Ensure Assignment of Staff Roles and Responsibilities During the Emergency

Access to medical equipment, drugs, and supplies should be assigned to specific categories of staff, with alternative staff designations identified. The Joint Commission Elements of Performance for EC.4.10 require that an emergency preparedness plan identify "alternate roles and responsibilities of staff during emergencies."¹⁴³

D. Recovery Phase

How should providers debrief local, state, and federal officials?

During the recovery period after the emergency, leaders in the Incident Command System should debrief local, state, and federal officials regarding events about what happened in the organization's facilities during the emergency period. This debriefing will serve to communicate situations occurring during the emergency, including, e.g., issues involving facility operations, staffing, facility damages, and patient treatment, as well as injuries occurring to patients due to the organization's inability to supply utility needs and/or adequate medical resources.

140 THE JOINT COMMISSION, 2006 HOSPITAL ACCREDITATION STANDARDS, Standard EC 4.10(2).

141 See AHRQ, Care in Mass Casualty Events, supra note 109.

142 THE JOINT COMMISSION, 2006 HOSPITAL ACCREDITATION STANDARDS, Standard EC.4.10(12).

143 THE JOINT COMMISSION, 2006 HOSPITAL ACCREDITATION STANDARDS, Standard EC.4.10(19).

XI. Federal Financial Assistance Programs

A. By what provisions may Medicare provide financial assistance to participating providers in the aftermath of a major natural disaster?

1. Interest-Free Loans

In the aftermath of a major natural disaster such as Hurricane Katrina, healthcare providers should expect a significant interruption in their revenue cycles. Medical records will be incomplete, patients will have received emergency transfer mid-stay, courses of treatment will be interrupted, and electronic billing processes likely will be compromised by the demise of electronic communications. In order to deal with these existing circumstances, fiscal intermediaries have the authority to grant emergency interest-free loans to providers. The CMS Provider Reimbursement Manual provides a formula for the maximum amount of such loans, which is roughly equivalent to one month's average revenue from Medicare.¹⁴⁴ The loans carry a maximum term of ninety days. They are secured by future Medicare receivables and, thus, Medicare has the right to set off future payments against the outstanding balance of the loan.¹⁴⁵

Although the affected state(s) probably would have the authority to make similar steps (in accordance with their gubernatorial authority for executive order under a state of emergency), no such action was taken during the Gulf Coast hurricanes to the authors' knowledge. Additionally, the authors are not aware of any private payor providing similar arrangements to providers. The authors are only aware of this situation occurring with regard to Medicare payments to hospitals and health systems. In addition, the authors are not aware that it occurred for physicians, skilled nursing facilities, or other healthcare providers.

2. Stark Waiver

If the provisions of the Stark Law are waived in connection with an emergency,¹⁴⁶ then hospitals and certain other healthcare entities legally would be able to offer special arrangements to physicians who have been displaced by the hurricane. Under the waiver, arrangements that otherwise would not meet the specific criteria for an exception would be permitted, provided that such arrangements would not lead to program or patient abuse, and that other safeguards exist that may be applicable to the specific arrangement under consideration. Following the Gulf Coast hurricanes of 2005, CMS announced that it intended to consider Stark waiver requests on a case-by-case basis, and will waive Stark Law provisions in such circumstances as it deemed appropriate. Its continuing focus will be on ensuring access to care, and assisting displaced physicians in the areas affected by the hurricane.

3. Extraordinary-Circumstances Exception

The Medicare inpatient prospective payment system (PPS) includes payment for hospital inpatient capital costs, which is made on a per-discharge basis. The extraordinary-circumstances exception provision provides an additional payment if a hospital incurs unanticipated capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control.¹⁴⁷ For most hospitals, the exception payments for extraordinary circumstances are based on 85% of Medicare's share of allowable capital cost attributed to the extraordinary circumstance.¹⁴⁸ The payments are made for the annualized portion of the extraordinary circumstance costs over the useful lifetime of the asset, not in a lump sum. A hospital must make an initial written request to its CMS Regional Office within 180 days of the extraordinary circumstance causing the unanticipated expenditures.¹⁴⁹

144 See DHHS, Summary of Federal Payments Available for Providing Health Care Services to Hurricane Evacuees and Rebuilding Health Care Infrastructure, available online at www.hhs.gov/katrina/payfederal.html (last visited April 1, 2008).

145 A number of Gulf Coast hospitals accessed this program in order to stabilize their cash flow until the provider and payor infrastructures were normalized for customary billing and collection purposes.

146 On September 29, 2005, DHHS Secretary Michael O. Leavitt waived sanctions for noncompliance with the Stark Law in states that have received a Section 1135 waiver. See DHHS, Supplemental Waiver Under Section 1135 of the Social Security Act, Sept. 29, 2005, available online at www.cms.hhs.gov/Emergency/Downloads/Stark1135.pdf (last visited April 1, 2008).

147 42 C.F.R. § 412.348(f) (1).

148 42 C.F.R. § 412.348(f) (3).

149 42 C.F.R. § 412.348(f) (2).

B. What federal assistance is available upon the federal declaration of an Emergency or a Major Disaster?

The President can direct federal agencies to provide the following assistance.

1. Federal equipment, supplies, facilities, personnel, and other resources.¹⁵⁰
2. Technical and advisory assistance to state or local governments.¹⁵¹
3. Medicine, food, and consumables (to state or local governments, or relief/disaster assistance organizations).¹⁵²
4. Debris removal; search and rescue; emergency medical care; emergency shelter; provision of food, water, and other essential needs; temporary facilities for schools and essential community services; demolition of unsafe structures; dissemination of public information; and technical advice.¹⁵³
5. Contributions to state or local governments, or to private nonprofit facilities to carry out disaster relief/recovery efforts.¹⁵⁴
6. Coordination of all disaster relief assistance provided by federal agencies, private organizations, and state and local governments.¹⁵⁵
7. During (or in anticipation of) an emergency or major disaster establish temporary communications systems, and to make such systems available to state and local government officials and other persons as he deems appropriate.¹⁵⁶
8. Directing that DOD resources be utilized for up to ten days to assist in disaster relief/recovery efforts.¹⁵⁷

The federal share of such assistance shall be not less than 75% of the eligible cost of the assistance.¹⁵⁸ For a single Emergency, total

assistance shall not exceed \$5 million, unless the President determines that: (1) continued emergency assistance is immediately required; (2) there is a continuing and immediate risk to lives, property, public health, or safety; and (3) necessary assistance will otherwise not be provided on a timely basis.¹⁵⁹

C. Is there additional federal assistance available upon the federal declaration of a Major Disaster?

1. Hazard Mitigation

The President may contribute up to 75% of the cost of hazard mitigation efforts that are determined (by the President) to be cost effective and that substantially reduce the risk of future damage, hardship, loss, or suffering in an area affected by a Major Disaster.¹⁶⁰

2. Repair, Restoration, and Replacement of Damaged Facilities

The President may make contributions to a person who owns or operates a private nonprofit facility damaged or destroyed by a Major Disaster for the repair, restoration, reconstruction, or replacement of such facility, and for associated expenses incurred by such person.¹⁶¹ The federal share of assistance shall be 75% to 100%.¹⁶²

If it is determined that the public welfare would not be best served by repairing, restoring, reconstructing, or replacing the facility, then the person may receive a monetary contribution not to exceed 90% of the estimated federal share. This contribution must be used to repair, restore, or expand other nonprofit facilities; construct new nonprofit facilities; or fund hazard mitigation measures.¹⁶³

¹⁵⁰ 42 U.S.C. §§ 5170b(a)(1), 5192(a)(1).

¹⁵¹ 42 U.S.C. §§ 5170a(3), 5192(a)(3).

¹⁵² 42 U.S.C. § 5170b(a)(2).

¹⁵³ 42 U.S.C. §§ 5170b(a)(3), 5192(b).

¹⁵⁴ 42 U.S.C. § 5170b(a)(4).

¹⁵⁵ 42 U.S.C. §§ 5170a(2), 5192(a)(2).

¹⁵⁶ 42 U.S.C. § 5185.

¹⁵⁷ 42 U.S.C. § 5170b(c).

¹⁵⁸ 42 U.S.C. §§ 5170b(b), 5193(1).

¹⁵⁹ 42 U.S.C. § 5193(b).

¹⁶⁰ 42 U.S.C. § 5170c; 44 C.F.R. § 206.434-35.

¹⁶¹ 42 U.S.C. § 5172(a)(2).

¹⁶² 42 U.S.C. § 5172(b).

¹⁶³ 42 U.S.C. § 5172(c)(2).

As a condition of any disaster loan or grant, the recipient must agree that repairs and construction will be in accordance with applicable standards of safety, decency, and sanitation and in conformity with applicable codes, specifications, and standards.¹⁶⁴

3. Debris Removal

The President may contribute to grants that may be offered to owners or operators of private nonprofit facilities for the purpose of removing debris or wreckage resulting from a Major Disaster.¹⁶⁵

D. What types of disaster declarations activate Small Business Administration disaster assistance?

Disaster assistance for businesses is coordinated through the SBA. In order to qualify, the business must be in a declared disaster area.¹⁶⁶

Two types of disaster declarations activate SBA disaster assistance efforts.

1. Presidential Declaration

A presidential declaration is made when damages are significant, as discussed in section II, *supra*. In the case of a presidential declaration, SBA offers physical and economic injury loans in the declared counties, in addition to economic injury loans in contiguous counties.

2. SBA Declaration

If the damages are less extensive, the governor may request a SBA declaration. In a SBA declaration area, primary and adjacent counties are eligible for the same assistance. There are two types of SBA declarations.

a. Physical Disaster Declaration:

- i. At least twenty-five homes (primary residences) and/or businesses in a county have uninsured losses of 40% or more of their estimated fair market value; or
- ii. At least three businesses have uninsured losses of 40% or more of their estimated fair replacement value, and

(as a direct result of the damages) 25% of the workforce in the community would be unemployed for at least ninety days.

b. Economic Injury Declaration:

- i. The governor certifies that at least five small businesses in a disaster area have substantial economic injuries as a result of the disaster and need financial assistance that is not otherwise available;
- ii. The Secretary of Agriculture designates an area as an agricultural disaster area; or
- iii. The Secretary of Commerce makes a commercial fishery failure or fishery resource disaster under Section 308(b) of the Interjurisdictional Fisheries Act of 1986.

E. What types of Disaster Assistance Loans are available from SBA?

The SBA makes the following three types of disaster assistance loans to business.¹⁶⁷

1. Physical Disaster Business Loans

Loans up to \$1.5 million are made to qualified large or small businesses that suffer physical damage as the result of a disaster. These loans cover uninsured physical damages. Any business located in a declared disaster that incurred damage during the disaster may apply for a loan to help repair or replace damaged property (i.e., real property, machinery, equipment, fixtures, inventory, and leaseholds) to its pre-disaster condition. Loans to repair or replace real property or leasehold improvements may be increased by as much as 20% to protect the damaged real property against possible future disasters of the same type.

Interest rates are determined by the ability of the business to obtain credit from non-federal sources. If the business is unable to obtain credit from other sources, the law sets a maximum interest rate of 4% per year. Loans cannot exceed a thirty-year term.¹⁶⁸

¹⁶⁴ 42 U.S.C. § 5176.

¹⁶⁵ 42 U.S.C. § 5173.

¹⁶⁶ See SBA, Understanding How Disaster Declarations Are Made, available online at www.sba.gov/disaster_recov/basics/declarations.html (last visited April 1, 2008); 13 C.F.R. §§ 123.2 – 123.3.

¹⁶⁷ See 15 U.S.C. §§ 636(b), (c); 13 C.F.R. § 123.5.

¹⁶⁸ See www.sba.gov/disaster_recov/loaninfo/physdisaster.html (last visited April 1, 2008); 13 C.F.R. §§ 123.200 – 123.204.

2. Economic Injury Disaster Loans

Loans are provided to small businesses located in a declared disaster area that suffer substantial economic injury, regardless of physical damage. Small businesses and small agricultural cooperatives that have suffered substantial economic injury resulting from a physical disaster, or an agricultural production disaster designated by the Secretary of Agriculture, may be eligible for economic injury disaster loans. "Substantial economic injury" is the inability of a business to meet its obligations as they mature and to pay its ordinary and necessary operating expenses.

Economic injury disaster loans are provided only to businesses unable to obtain credit elsewhere. Up to \$1.5 million in disaster assistance can be obtained, including assistance for both economic injury and physical damage. The loans can be used to provide a business with operating funds until it recovers. The interest rate on these loans cannot exceed 4% per year, and the term of the loans cannot exceed thirty years.¹⁶⁹

3. Pre-Disaster Mitigation Loans

These low-interest, fixed-rate loans are made to small businesses for mitigation measures to protect business property from damage that may be caused by future disasters. A "mitigation measure" is something done for the purpose of protecting real and personal property against disaster-related damage. Examples of mitigation measures include retaining walls; sea walls; grading and contouring land; elevating flood-prone structures; relocating utilities; and retrofitting structures against high winds, earthquakes, floods, wildfires, or other disasters.

The Pre-Disaster Mitigation Loan program is a pilot program, which supports the FEMA Pre-Disaster Mitigation Program. Loans are available to businesses whose proposed mitigation measures conform to the priorities and goals of the mitigation plan for the community in which the business is located (as defined by FEMA). Because the program has been approved only for limited funding, approved

loan requests will be funded on a first-come, first-served basis up to the limit of the program funds. Applicants with the financial capacity to fund the project with their own resources are not eligible for Pre-Disaster Mitigation Loan assistance. Interest rates on Pre-Disaster Mitigation Loans will be fixed at or below 4% percent per annum. The law authorizes loan terms up to a maximum of thirty years.

Loans in excess of \$10,000 require the pledging of collateral to the extent that it is available. Generally, the collateral will consist of a first or second mortgage on the business property, although collateral may be required on other property (including property personally owned by the business' principals). The SBA takes real estate as collateral where it is available. In addition, personal guaranties by the principals of the business are required. The SBA will not decline a loan on the basis of a lack of collateral, but available collateral must be pledged.

Borrowers of all secured loans (Pre-Disaster Mitigation Loans over \$10,000) also must purchase and maintain full hazard insurance for the life of the loan. In addition, borrowers whose business property or collateral property is located in a Special Flood Hazard Area (SFHA) must purchase and maintain flood insurance for the full insurable value of the property for the life of the loan.¹⁷⁰

F. What is the application procedure for SBA Disaster Assistance Loans?

The SBA website describes the types of loans available and how to apply for them. Pertinent forms include: SBA Form 5 (Loan Application); SBA Form 739A (Verification of Business Property); SBA Form 1368 (Additional Filing Requirements, Economic Injury Disaster Loan); SBA Form 413 (Personal Financial Statement); IRS Form 8821 (Tax Information Authorization); and SBA Form 2202 (Schedule of Liabilities). In addition, the website provides an update list of disaster declarations by state.¹⁷¹

169 See SBA, Economic Injury Disaster Loans for Small Businesses, available online at www.sba.gov/disaster_recov/loaninfo/econinjury.html (last visited April 1, 2008); 13 C.F.R. §§ 123.300 - 123.303.

170 See www.sba.gov/disaster_recov/loaninfo/pre_disaster_mitigations.html (last visited April 1, 2008); 13 C.F.R. §§ 123.300 - 123.412.

171 See www.sba.gov/services/disasterassistance/basics/recentdisaster/serv_disupdates.html (last visited April 1, 2008); 13 C.F.R. §§ 123.6 - 123.21. Application forms are available online at www.sba.gov/tools/Forms/smallbusinessforms/daforms/TOOLS_SBF_DISAST_ASSIST_FORMS.html (last visited April 1, 2008).

G. What types of disaster assistance are available to individuals?

Individual disaster assistance is coordinated through FEMA. Disaster aid to individuals usually consists of the following:

1. Disaster housing;
2. Funding for housing repairs and replacement of damaged items needed to make homes habitable;
3. Disaster grants to cover necessary expenses not covered by insurance and other aid programs, (e.g., replacement of personal property, transportation, medical care, dental care, and funeral expenses);
4. Low-interest disaster loans for repair or replacement of homes, automobiles, clothing, or other damaged personal property (note: loans are administered through the SBA);

5. Crisis counseling;
6. Disaster-related unemployment assistance;
7. Legal aid and assistance with income tax, Social Security benefits, and veteran's benefits; and
8. Hazard mitigation.¹⁷²

For most assistance offered to individuals, application is made directly through FEMA. For SBA loans, individuals who are homeowners or renters must first register with FEMA to obtain a FEMA Registration Identification number. Generally, FEMA establishes local Disaster Recovery Centers to coordinate assistance. After an application for assistance is received, the damaged property is inspected to verify the loss. The deadline for most individual assistance programs is sixty days following the President's declaration of a Major Disaster.¹⁷³

¹⁷² See 42 U.S.C. § 5174-83; www.fema.gov (last visited April 1, 2008).

¹⁷³ See www.fema.gov (last visited April 1, 2008); www.sba.gov (last visited April 1, 2008).

XII. Payment for Medical and Hospital Services Provided During a Disaster

An issue of great concern regarding the response to the aftermath of Hurricane Katrina was development of mechanisms for reimbursement for healthcare services rendered. To the great credit to hospitals and healthcare providers, care was provided to those in need, even when reimbursement could not be anticipated based on the information available. Despite this uncertainty, hospitals and other health facilities opened their doors to those in need. Reimbursement in many cases was forthcoming, due to waivers of certain requirements by CMS and private insurers.

A. Preparation Phase

What should healthcare providers do to avoid reimbursement problems during a disaster?

Documentation will be crucial to reimbursement. Paper documents may, however, well be lost or destroyed as a result of the emergency. Recreating the information contained in those lost documents could be extremely difficult and costly.

It may be possible to convert paper documents into electronic reproductions. Once scanned, an offsite backup copy of important data should be maintained. Under the HIPAA Security Rule,¹⁷⁴ Covered Entities are required to develop and implement effective plans for disaster recovery and business continuity. Testing of these plans is critical.

If scanning is not an option, healthcare providers should use the results of its Hazard Vulnerability Assessment to physically locate documents in a safe place in the context of the risks faced by the institution. Often, medical records and IT departments are consigned to the basement, where they may be vulnerable to flooding.¹⁷⁵ For certain essential documents, fire- and water-resistant cabinets may be warranted. To the extent possible, healthcare providers should maintain critical cor-

porate documents in one area (preferably in easily moved containers), and evacuate those documents in an emergency. Providers also should consider maintaining a duplicate of the most important of these documents offsite.

Another concern is the inability to receive mail following a disaster. Direct deposit of reimbursement typically can continue uninterrupted, and establishing direct deposit prior to an emergency can help avoid cash-flow issues.

B. Response Phase

1. Are documentation requirements for reimbursement waived as a result of a disaster?

Despite every precaution, documentation may still be lost. For example, many healthcare providers in areas directly affected by Hurricane Katrina and its aftermath suffered the loss of most, if not all, of the documents necessary for reimbursement. Already overwhelmed by providing necessary services during the emergency, those providers then faced the added peril that they might not receive reimbursement. Fortunately, CMS and the Secretary of DHHS have (and used) the authority to waive certain requirements of law in the event of an emergency, and commercial insurers likewise may modify their documentation requirements to facilitate care and reimbursement.

a. Section 1115 Waivers

Section 1115 of the Social Security Act authorizes the Secretary of DHHS to grant waivers of certain requirements related to Medicare, Medicaid, and SCHIP (among other programs), if such waiver is “likely to assist in promoting the objectives” of that program.¹⁷⁶ Upon issuance of the waiver, costs which would otherwise not be permissible can be reimbursed, and funds may be exempted from certain limitations on expenditures.¹⁷⁷

¹⁷⁴ 45 C.F.R. § 164.308(a)(7).

¹⁷⁵ See Flood Ravages Houston Labs, *SCIENCE NOW* 2 (Jun. 11, 2001); FEMA, Memorial Hermann Hospital Flood Protection Project, Houston, Texas, available online at www.fema.gov/library/viewRecord.do?id=1954 (last visited April 1, 2008). See also *N.Y. TIMES*, *THE AFTERMATH OF HURRICANE KATRINA*, available online at www.nytimes.com/pages/national/nationalspecial/index.html (last visited April 1, 2008).

¹⁷⁶ 42 U.S.C. § 1315(a).

¹⁷⁷ Section 1115 waivers were important tools in the response to Hurricane Katrina, allowing coverage of evacuees without applying normal requirements regarding residency, verification, and documentation. States that provided care to evacuees also were permitted to include the full costs of care under the waiver in cost reports.

b. Section 1135 Waivers

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, or SCHIP programs, including Conditions of Participation, pre-approval requirements, healthcare provider licensure requirements (so long as the provider is licensed in their home state and not excluded from practice in the host state), sanctions related to EMTALA violations, sanctions related to violations of HIPAA, and limitations on payments to managed care enrollees for services provided by non-participating providers. Deadlines and timetables imposed by the programs may be modified, but not waived. The waiver applies “with respect to health care items and services provided by a health care provider . . . in any emergency area...during any portion of an emergency period....”¹⁷⁸ In most cases, the Section 1135 waiver persists so long as a state of Public Health Emergency persists.

Following the Gulf Coast hurricanes of 2005, Section 1135 waivers addressed the following specific issues. It is likely that, in future similar Major Disasters, similar specific waivers would be enacted, including:

- i. Three-day hospital stay requirements;
- ii. Critical access hospital length of stay requirements;
- iii. Inpatient rehabilitation facilities;
- iv. Long term care hospitals;
- v. Modification of documentation and submission requirements;
- vi. Use of specialty beds;
- vii. Permitted waiver of copays;
- viii. Dialysis;
- ix. Accelerated payments;

- x. Resident caps for teaching hospitals;
- xi. Waiver of three-day stay for skilled nursing facility admission;
- xii. Waiver of spell-of-illness requirements;
- xiii. Coverage under the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA);¹⁷⁹
- xiv. Payment of ambulance transport;
- xv. Extended inpatient care;
- xvi. Coordination of billing between facilities; and
- xvii. Coverage of vaccinations.

2. What requirements may commercial insurance companies modify as a result of a disaster?

America’s Health Insurance Plans (AHIP) is a national association that represents a large number of commercial insurers. In response to Hurricanes Katrina and Rita, AHIP compiled summary information regarding policy changes by commercial insurers intended to assist those affected by Hurricanes Katrina and Rita. The following actions (among others) were taken:

- a. Suspension of prior authorization and pre-certification requirements;
- b. Suspension of requirements of physician referral for primary care;
- c. Waiver of in-network care requirements, thus permitting beneficiaries to see any physician necessary to obtain care;
- d. Payment of all claims as “in-network;”
- e. Waiver of prescription refill limitations;
- f. Waiver of prescription copayments;
- g. Shipment of prescriptions to alternate addresses;
- h. Suspension of utilization review;

¹⁷⁸ 42 U.S.C. § 1320b-5. Following the Gulf Coast storms of 2005, DHHS issued Section 1135 waivers for those geographic areas subject to declarations of Major Disaster, Emergency, or Public Health Emergency. The waivers eased many documentation requirements, permitted self-attestation of eligibility for benefits, and permitted assumptions of eligibility. Certain provisions of the HIPAA Privacy Rule, related to notification to family members and distribution of Notices of Privacy Practices, were relaxed. Treatment provided in non-certified or alternate facilities was covered, and ambulance transfers between facilities were payable. Pre-authorization and network requirements for Medicare, Medicaid, and SCHIP managed care plans were waived, and licensure requirements were relaxed. Beds customarily used for specialized services (e.g., psychiatric and rehabilitation beds) were converted to acute-care beds. In general, as long as the services were provided in good faith, an inability to comply with program requirements due to the impact of Katrina did not prevent payment. Of course, the government reserved the right to refuse payment for fraudulent or abusive claims. For information on Section 1135 waivers, see section 4.2, supra; see also DHHS, Waiver Under Section 1135 of the Social Security Act, Sept. 23, 2005, available online at www.cms.hhs.gov/Emergency/Downloads/1135waiverundertheSSA.pdf (last visited April 1, 2008).

¹⁷⁹ Consolidated Omnibus Budget Reconciliation Act of 1986, Pub. L. 99-272, Apr. 7, 1986, 100 Stat. 82.

- i. Establishment of special teams and toll-free numbers to assist beneficiaries;
- j. Grace periods and flexible payment options for payment of premiums;
- k. Extending time period for filing claims;
- l. Modifying documentation requirements, where records were destroyed by the hurricane or its aftermath; and
- m. Re-enrollment for lapsed policies upon payment of past-due premiums

Although these changes were primarily voluntary on the part of the insurer, in some cases the state Department of Insurance was authorized to suspend application of statutory or regulatory requirements.¹⁸⁰ Suspended or modified rules included limitations imposed on the ability of insurers to increase premiums and to cancel policies.¹⁸¹ Among other approaches, alternative dispute resolution forums for hurricane claims have been established.¹⁸² Similar approaches may be taken in future disasters.

3. May beneficiary payment requirements be suspended by insurers during an Emergency?

In an Emergency, health insurers may (but are not required to) suspend or modify otherwise applicable requirements of health insurance policies. In the aftermath of Katrina and other Gulf

Coast hurricanes, a number of health insurance carriers suspended beneficiary payment requirements for approximately 100 days. During such time, the beneficiaries, who were displaced and were not accessible by carriers, were not required to make regular, monthly insurance payments. If the beneficiary sought medical or hospital services (either in or out of area), then the beneficiary was treated as being insured continuously by the health insurance carrier. At the end of the grace period, the beneficiaries were asked to reestablish their coverage and commence making customary monthly payments. The authors are aware of some situations in which beneficiaries declined to reinstitute coverage or payments, and the health insurance carrier suspended future coverage. Additionally, in isolated cases, the authors understand certain health insurance carriers made the suspension of coverage retroactive to the last date of coverage, without regard to the suspension.

The Louisiana Commissioner of Insurance issued Emergency Rule 15, which suspended cancellation, non-renewal, and non-reinstatement notices related to insurance. It also prohibited the cancellation or non-renewal of a policy because of a claim resulting from the hurricane.¹⁸³ However, nothing in Emergency Rule 15 exempted or excused an insured from the obligation to pay the premiums due for actual insurance coverage provided.

180 La. Exec. Order No. KBB 2005-70, Limited Transfer of Authority to Commissioner of Insurance and Rules Directive for Patient's Compensation Fund, Oct. 24, 2005. See www.Idi.state.la.us/whats_new/70execAmendKBB2005.pdf (last visited April 1, 2008).

181 See, e.g., 37 La. Reg. 66 (Emergency Rule 23), available online at www.doa.state.la.us/osr/reg/0601/0601EMR.pdf (Louisiana) (last visited April 1, 2008); Miss. Dept. of Ins., Press Release, Insurers directed to grant grace periods in hurricane impacted areas, Sept. 1, 2005, available online at www.doi.state.ms.us/pressrel/pressrel9105.pdf (last visited April 1, 2008) and Miss. Dept. of Ins., Bulletin 2005-13, Extension of Coverage for Damaged Property Due to Hurricane Katrina, Nov. 4, 2005, available online at www.doi.state.ms.us/bulletins/200513bull.pdf (Mississippi) (last visited April 1, 2008); Tex. Dept. of Ins., Commissioner's Bulletin No. B-0045-05, Sept. 14, 2005, available online at www.tdi.state.tx.us/Bulletins/2005/b-0045-05.html (Texas) (last visited April 1, 2008).

182 See, e.g., 37 La. Reg. 61 (Emergency Rule 22), available online at www.doa.state.la.us/osr/reg/0601/0601EMR.pdf (Louisiana) (last visited April 1, 2008); Miss. Dept. of Ins., Emergency Reg. No. 2005-2, Temporary Special Mediation For Personal Lines Residential Insurance Claims Resulting From Hurricane Katrina, available online at ms.iaa.org/pdf/Mediation%20Regulation.pdf (Mississippi) (last visited April 1, 2008).

183 31 La. Reg. 2402, available online at www.doa.state.la.us/osr/reg/0510/0510EMR.pdf (last visited April 1, 2008).

XIII. Resources Available to Support Recovery From Emergencies and Major Disasters

Many of the reimbursement provisions noted in the previous section have persisted into at least the early recovery phase. However, certain provisions were not available during the hurricane, but might be anticipated to assist with recovery efforts.

A. The Assistance for Individuals with Disabilities Affected By Hurricane Katrina or Rita Act

The Assistance for Individuals with Disabilities Affected by Hurricane Katrina or Rita Act of 2005¹⁸⁴ authorized reallocation of vocational rehabilitation funds and payment for vocational rehabilitation services provided to individuals with disabilities who had been affected by either Hurricane Katrina or Rita, even if those individuals did not qualify under the state's "order of selection" criteria under Section 501(a)(5) of the Rehabilitation Act of 1973.¹⁸⁵

B. Medicare Extraordinary Circumstances Exception for Hospital Capital Costs

Medicare's portion of hospital capital costs are typically based on a per-discharge basis. Certain hospitals may qualify for additional funds in the event of unanticipated capital expenditures of greater than \$5 million net or of other funding sources, due to "extraordinary circumstances beyond the hospital's control."¹⁸⁶ For most hospitals, these additional payments are based on 85% of Medicare's share of allowable costs attributed to the extraordinary circumstance; for sole-community hospitals, the minimum payment is 100%. Disbursements are annualized over the useful life of the assets. Eligible hospitals must submit a written request for these funds to the CMS Regional Office within 180 days of the occurrence of the extraordinary event.

C. Health Professional Shortage Area Bonus Payments

Physicians providing services in designated Health Professional Shortage Areas (HPSAs) qualify for bonus payments. An expedited process for approval of HPSA designation has been established for the areas affected by the hurricanes. Documentation requirements have also been eased for this process, and DHHS may grant a temporary HPSA designation based on available data, which can be validated at a later date.¹⁸⁷

D. National Health Service Personnel Deployment and HRSA Clinics

Deployment of National Health Service personnel and Nurse Loan Repayment personnel will focus on areas affected by the hurricanes or that have substantial evacuee populations. HRSA will expedite applications for free clinics in these areas as well, and will extend liability coverage to volunteers providing care in these facilities.¹⁸⁸

E. Crisis Counseling and Emergency Response Grants

The federal Substance Abuse and Mental Health Services Administration (SAMHSA), a part of DHHS, has provided grants to train and fund provision of crisis mental health and substance abuse services in the affected areas.¹⁸⁹

F. DHHS Medical Travel Center

The DHHS Medical Travel Center has been established to assist evacuees with medical needs in returning to affected areas. The Medical Travel Center will arrange appropriate transportation back home (which may be a private institution) or, if home is not available, to an interim location. If the individual is transported to an interim location, then the Medical Travel Center also will return the evacuee to her home of record when it is safe to do so.¹⁹⁰

184 The Assistance for Individuals with Disabilities Affected by Hurricane Katrina or Rita Act of 2005, Pub. L. 109-82.

185 29 U.S.C. § 721(a)(5).

186 42 C.F.R. § 412.348.

187 See www.hhs.gov/katrina/fedpayment.html (last visited April 1, 2008).

188 Id.

189 See FY 2006 SAMHSA Grant Awardees, SM06-010: Hurricane Katrina-Related Suicide Prevention Grants, available online at www.samhsa.gov/Grants/2006/SM_06_010.aspx (last visited April 1, 2008).

190 See DHHS, Fact Sheet for Transportation of Evacuees With Medical Needs, available online at www.hhs.gov/katrina/factsheet.html (last visited April 1, 2008).

G. FEMA Public Assistance Program

FEMA can reimburse public and private nonprofit entities for repair of non-insured damage to the infrastructure caused by disasters. FEMA assistance also is available for the costs of sheltering medical personnel necessary to the recovery effort.¹⁹¹

H. USDA Rural Development Grants

Loans or grants are available through the United States Department of Agriculture (USDA) Rural Development (USDA-RD) program for acquiring, building, or repairing health centers and other public structures. The grant cannot exceed 75% of the project cost, but interest rates are low, and repayment can extend for up to forty years. Facilities eligible for this grant may be used by for-profit individuals or entities (e.g., physicians), if that use ensures that the structure fulfills its intended purpose. USDA-RD Rural Business Enterprise Grants are made to municipalities to

permit development of small business opportunities in rural areas. The USDA-RD Business and Industry Loan Program is available to larger communities (population up to 50,000) through local lenders. USDA-RD guarantees up to 80% of the loan, which cannot exceed \$25 million.¹⁹²

I. FHA/HUD Mortgage Insurance for Hospitals

The Federal Housing Administration (FHA) program, in cooperation with the Office of Housing and Urban Development (HUD), offers mortgage insurance for new construction, expansion, modernization, equipment purchases, and/or refinancing.¹⁹³

J. HRSA Loan Guarantee for Community Health Centers

HRSA offers a \$100 million loan-guarantee program, which can guarantee up to 80% of the loan for construction of community health centers.¹⁹⁴

191 For general information about FEMA Public Assistance Program, see www.fema.gov/plan/ehp/noma/projects2.shtm#projects2a (last visited April 1, 2008).

192 See USDA Rural Development, Disaster Recover Guide for People and Communities, Sept. 20, 2005, available online at www.rurdev.usda.gov/rbs/LA%20Disaster%20Recovery%20Guide%209-20-05.pdf (last visited April 1, 2008).

193 12 U.S.C. § 1715z-7, 24 C.F.R. Part 242. For general information about Section 242 Mortgage Insurance, see www.hud.gov/offices/hsg/hosp/hsghospi.cfm (last visited April 1, 2008).

194 See www.caplink.org/newdesign/resources/BPHCLGPoverview.pdf (note: website not maintained by the federal government) (last visited April 1, 2008).

XIV. Conclusion: Addressing Documentation Challenges Resulting from the 2005 Gulf Coast Hurricanes

Many providers have been unable to complete documentation requirements related to reimbursement in a timely manner. The following modifications to documentation submission have been approved.

A. Establishing New Practice Location

CMS established a streamlined process to permit establishment of a practice at a new location.¹⁹⁵ Physicians were directed to bill based upon the actual location at which care was rendered.

B. Past Medical History and Related Information

The Medical Director at the appropriate fiscal intermediary was authorized to obtain the online claims history for patients to attempt to ascertain prior billed diagnoses; ongoing therapy, including medication, dose, and frequency data; and other information.¹⁹⁶ Durable medical equipment that was damaged or destroyed in the hurricane or its aftermath was eligible for replacement.

C. Missing Minimum Data Set Data

In many cases, patients were transferred from nursing facilities without medical records. To assist receiving facilities, CMS compiled critical clinical information from the minimum data set (MDS) records of residents of nursing facilities that had been evacuated, an effort that made more information available to receiving facilities.¹⁹⁷ Evacuating facilities were directed to determine whether evacuees would be permitted to return to the original facility within thirty days; if so, the receiving facility was not required to complete a new MDS. If the resident was unable to return to

the original facility within thirty days, then the original facility would discharge the resident, and the receiving facility would admit the resident and complete the MDS within the thirty-day limit.

D. IRF Patient Assessment Instrument

Inpatient rehabilitation facilities (IRFs) are required to file Patient Assessment Instruments within specified time periods, or suffer imposition of a 25% penalty. CMS authorized a waiver of the IRF penalty, beginning in January 2006.

E. Home Health Agency Assessment Modifications

Various modifications to the assessment required of home health agencies (HHAs) were approved, including suspension of the discharge assessment and the transfer assessment, as well as abbreviation of the resumption of care and recertification assessments. However, adequate documentation to support services provided and requests for payment was still required.¹⁹⁸ For home healthcare provided in the affected areas, abbreviated assessments were not required to meet the requirements regarding the five-day completion date or the seven-day lock date; however, HHAs were expected to "return to business as usual as soon as possible."¹⁹⁹

F. Laboratory Certification

Laboratories that relocated or were established to provide emergency services were required to work with the appropriate state agency and/or CMS regional personnel to complete certification requirements under the Clinical Laboratory Improvement Act.²⁰⁰ New laboratories were permitted to begin providing services as soon as the CLIA application was completed and transmitted to the state agency or CMS Regional Office, as

195 See CMS FAQ, *supra* note 40, Question ID No. 5685, "What special consideration is given to physicians and other health care providers who have experienced severe destruction to their facilities?," created Sept. 15, 2005.

196 See CMS FAQ, *supra* note 40, Question ID No. 5700, "Beneficiaries are presenting to medical facilities for treatment To what extent can Medicare contractors provide medical information and claims history related to the individual in question?," created Sept. 15, 2005.

197 See La. Dept. of Health and Hospitals, Hurricane Katrina - MDS Guidance for Nursing Homes Receiving Residents, available online at www.dhh.louisiana.gov/offices/page.asp?ID=112&Detail=5183 (last visited April 1, 2008).

198 See CMS FAQ, *supra* note 40, Question ID No. 5685, "Under the State licensure authority, there have been waivers What adjustments to Medicare requirements can be made for the completion of the assessment process?," created Sept. 15, 2005.

199 See generally.questions.cms.hhs.gov (last visited April 1, 2008).

200 Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100-578, Oct. 31, 1988, 102 Stat. 2903. See also 42 C.F.R. § 493 - Laboratory Requirements. For a comprehensive listing of the CLIA regulations, as well as other relevant information, see www.cms.hhs.gov/clia (last visited April 1, 2008).

appropriate. Relocating laboratories merely were required to advise the state agency and/or CMS of the new location.²⁰¹ Laboratories staffed with volunteers were expected to require proof of certifications/qualifications, and those conducting moderate complexity tests and other positions of responsibility were required to demonstrate competency prior to providing services.²⁰²

G. Hospital Quality Data

CMS waived data-submission requirements related to the Hospital Quality Data for Annual Payment Update for Fiscal Year 2007 for the second, third, and fourth quarters of 2005 for hospitals located in counties directly impacted by Hurricanes Katrina and Rita. Other hospitals may qualify for the waiver based on individual circumstances.²⁰³

H. Termination of Operations/Retention of Provider Number

Many healthcare providers were unable to remain in operation in the aftermath of the hurricanes. CMS noted that

participation as a Medicare-certified provider is based on the ability of the provider to demonstrate they can furnish services in a manner that protects the health and safety of beneficiaries... However, CMS will exercise discretion and flexibility when determining to inactivate a provider's agreement and number, when the cessation of business is due to a catastrophic natural disaster.²⁰⁴

In determining whether a provider that resumes business at a different location is a relocated provider, or instead should more properly be considered as a terminating business at the

prior location and beginning business at a new location, CMS will consider the following factors:

- Whether the provider's new location is in the same state, and complies with the same state licensure requirements;
- Whether the provider remains the same type of Medicare provider after relocation;
- Whether the provider maintains at least 75% of the same medical and nursing staff, other employees, and contractor personnel;
- Whether the same persons are legally responsible for operations at the new location (e.g., same governing body);
- For institutional providers, whether the medical staff bylaws and policies and procedures (including nursing, pharmacy, administrative, and other policies and procedures) are essentially the same;
- Whether at least 75% of the services offered by the provider at the prior location during the prior year also are offered at the new location;
- The distance between the prior location and the new location;
- Whether the provider continues to serve at least 75% of the original community at the new location;
- Whether the provider complies with all CMS and other federal requirements at the new location; and
- Any other relevant information.²⁰⁵

201 See CMS FAQ, supra note 40, Question ID No. 5641, "What should newly established laboratories that are providing emergency services (e.g., FEMA laboratories) and laboratories that are re-locating to continue existing services, do to obtain or retain CLIA certification?", created Sept. 13, 2005.

202 See CMS FAQ, supra note 40, Question ID No. 5749, "If I open an emergency services laboratory using volunteer laboratory personnel, how should they be qualified and their competency assessed?" created Sept. 15, 2005.

203 See, e.g. ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/PPS_Hurricane_Waiver.pdf (last visited April 1, 2008).

204 See CMS FAQ, supra note 40, Question ID No. 6499, "I am a provider who has been adversely impacted by Hurricane Katrina ... Can I relocate, and what are the procedures for certification if relocation is necessary?", created Jan. 4, 2006.

205 Id.

APPENDIX

Reference Websites

The following disaster websites are a useful reference.

Disaster Help – U.S. Government site with general disaster information:
www.disasterhelp.gov/portal/jhtml/index.jhtml
 (last visited April 1, 2008)

Red Cross Disaster Services:
www.redcross.org/services/disaster/0,1082,0_319_00.html (last visited April 1, 2008)

CDC Emergency Preparedness and Response:
www.bt.cdc.gov/ (last visited April 1, 2008)

Help After Disaster – FEMA Publication:
www.fema.gov/pdf/about/process/help_after_disaster_english.pdf (last visited April 1, 2008)

State Of Louisiana's official website for dissemination of information concerning hurricanes Katrina and Rita:
www.katrina.louisiana.gov/ (last visited April 1, 2008)

EPA - Hurricane Response 2005:
www.epa.gov/Katrina/index.html (last visited April 1, 2008)

Emergency System for Advance Registration of Volunteer Health Professionals:
www.hrsa.gov/esarvhp/ (last visited April 1, 2008)

HHS Hurricane Katrina help:
www.hhs.gov/katrina/ (last visited April 1, 2008)

IRS - Tax Relief in Disaster Situations:
www.irs.gov/newsroom/article/0,,id=108362,00.html (last visited April 1, 2008)

U.S. Small Business Association – Disaster Assistance:
www.sba.gov/disaster_recov/index.html (last visited April 1, 2008)

American Bar Association – Links to disaster help sites:
www.abanet.org/environ/katrina/genhelp.html (last visited April 1, 2008)

Network for Good – Links to charities providing disaster relief services:
www.networkforgood.org/topics/animal_environ/hurricanes/?source=USAT (last visited April 1, 2008)

ABOUT THE AUTHORS

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Elisabeth Belmont is Corporate Counsel for MaineHealth. She is a summa cum laude graduate of the University of New Hampshire, and a graduate of the University of Maine School of Law, where she served as Associate Editor of the Maine Law Review. She is a member of the American Health Lawyers Association (Health Lawyers) where she serves as President for the period 2007-2008, as well as the Health Law and Electronic Communications and Internet Issues committees of the Maine State Bar Association. As Chair of the Public Interest Committee at Health Lawyers, she initiated the Public Information Series, a national award-winning collection of publications through which Health Lawyers shares its expertise on topics of interest to its members, their clients and the public. Ms. Belmont also co-authored and edited several publications within the Series. At Health Lawyers, Ms. Belmont served as Chair and Vice Chair of the Health Information & Technology (HIT) Practice Group (1997-2002), and was the founding Editor of HIT News. She is a member of the editorial

boards of Medical Malpractice Law & Strategy published by Law Journal Newsletters and the Health Law Reporter published by The Bureau of National Affairs, Inc. Ms. Belmont was named by NEW ENGLAND IN-HOUSE/ MASSACHUSETTS LAWYERS WEEKLY as one of the 2008 Top 15 In-House Leaders in the Law; by MODERN HEALTHCARE as one of the 2007 Top 25 Most Powerful Women in Healthcare; and by HEALTH LAW 360, the Newswire on Health Law and Policy, as one of the 2007 Outstanding Women in Healthcare.

Jennifer A. Belt is a partner in the health law group of Shumkaer, Loop & Kendrick. Her practice includes transactional and litigation matters for health systems, hospitals, long term care providers, physician groups, physicians, and healthcare networks. Her principal areas of practice include regulatory compliance, fraud and abuse, reimbursement, hospital-physician relations, HIPAA, managed care, and licensure and certification. She has written articles and lectured on various health law topics, including HIPAA, the Medicare Modernization Act, compliance programs, fraud and abuse, and risk management. Ms. Belt is listed in The Best Lawyers in America in

the health law category and has been recognized as a Rising Star by Ohio Super Lawyers in 2006-2007. Ms. Belt is a member of the Toledo, Ohio State, American Bar Association, and the American Health Lawyers Association. She is President of the University of Toledo College of Law Alumni Association and Chair of the Health Law Committee of the Ohio State Bar Association. Ms. Belt received her B.A., cum laude, in 1992 from Miami University and her J.D., magna cum laude, from the University of Toledo College of Law in 1995.

Richard G. Cowart is Chairman of the Health Law & Public Policy department of Baker, Donelson, Bearman, Caldwell & Berkowitz, Nashville, TN. Mr. Cowart was the recipient of the American Health Lawyers Association David R. Greenburg Award (2007-Lifetime Service Award to Health Law) and was the 2004-2005 President of the American Health Lawyers Association. He was the 2008 the recipient of the National State Board of Accountancy Center for Public Trust "Being a Difference" award and has been listed in The Best Lawyers in America (Health Law) since 1991; Chambers, "Best Business Lawyers;" Corporate Counsel, "Best Lawyers: Healthcare;" Nightingale's Healthcare News, "Nation's Best Hospital Attorneys;" and Who's Who of American Law. Mr. Cowart is a nationally known speaker and writer on healthcare issues and is a recognized authority in advising clients on the legal, regulatory, and business issues related to healthcare services.

Michelle M. Garvin is a partner at Ropes & Gray LLP, Boston, MA and was Chair of the healthcare practice from 2002-2007. Ms. Garvin has represented a wide range of healthcare industry representatives, including universities and academic medical centers, community hospitals, physician group practices, pharmaceutical manufacturers and health plans. Ms. Garvin's practice focuses on general regulatory compliance, governance issues, academic medical center and medical school relationships, international program compliance, clinical joint ventures, including electronic health records and physician integration strategies, and third party reimbursement including managed care contracting and pay-for-performance issues. Ms. Garvin received her B.A. from the College of William and Mary and her law degree from Suffolk University Law School. She also has a Ph.D. in sociology from Boston College. Ms. Garvin is listed in the healthcare law section of The Best Lawyers in America; Chambers USA: America's Leading Lawyers; Lawdragon 3000; New England Super Lawyers; Massachusetts Super Lawyers; and Massachusetts Super Lawyers "Top 50 Women."

Julianna S. Gonen is an associate in the Health Care and Life Sciences group at Epstein Becker & Green, PC, Washington, DC. Prior to joining EBG, Ms. Gonen held positions at the American's Health Insurance Plans and the Washington Business Group on Health. She has been an adjunct faculty member in the Department of

Government at American University, and in the Department of Population and Family Health Sciences at Johns Hopkins Bloomberg School of Public Health. She is a member of the Board of Directors of the Mautner Project, the National Lesbian Health Organization. Her practice areas at EBG include ERISA/Benefits, litigation/government investigations, and managed care. Ms. Gonen received her B.A. from Cornell University, Ph.D in political science from American University, and her J.D. from Georgetown University Law Center.

Clinton D. Hermes, is Senior Vice President and General Counsel at St. Jude Children's Research Hospital, Memphis, TN. He was previously at the law firm of Ropes & Gray in their Health Care Group where he worked with universities, hospitals, academic medical centers, pharmaceutical and device manufacturers and health plans on healthcare regulatory issues. While at Ropes & Gray, his principal areas of practice included medical information privacy and security, human subject research and federal grants, compliance program design and evaluation, health plan regulation, hospital quality initiatives, mental health and patient care. He was named one of the fifteen "Outstanding Young Healthcare Lawyers" (under 40) nationally by Nightingale's Healthcare News and was listed in Massachusetts Super Lawyers as a Rising Star in Health Care Law in 2005. Mr. Hermes also received the Deb Levi Award for Outstanding Pro Bono Service in 2005. Mr. Hermes graduated magna cum laude from Yale University and received his J.D., magna cum laude, from Harvard Law School in 2001, where he served as editor of the Harvard Journal of Law and Technology.

Melissa L. Markey is a shareholder in Hall, Render, Killian, Heath and Lyman, Troy, MI. Ms. Markey leads the Life Sciences team at Hall Render. She has a particular interest in 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 emergency legal preparedness, HIPAA, patient care issues, and compliance. She is a member of the State Bar of Texas and its Computer and Technology and Health Law sections, the State Bar of Michigan and its Health Care Law, Computer Law, and Intellectual Property sections, and the American Health Lawyers Association where she is Chair of the Teaching Hospitals and Academic Medical Centers practice 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.

Anne M. Murphy is a Partner and Chair of the Health Law Team at the law firm of Holland+Knight, Chicago, IL. She is a member of the firm's National Health and Life Sciences Team and its Global Compliance and Governance National Practice Team. Her practice focuses on resolution of complex regulatory, compliance, legal risk management, corporate governance and transactional matters, on behalf of health care and life sciences industry clients. Previously, Ms. Murphy was senior counsel to the Illinois Attorney General where she advised the Attorney General on legal and policy matters, including legislative and enforcement initiatives in the healthcare arena. Ms. Murphy also was chief counsel for the Illinois Department of Public Health, simultaneously serving as privacy officer, ethics officer, and general counsel to the Health Facilities Planning Board, and chair of the Governor's HIPAA Task Force.

Dinetia M. Newman is a partner in the health law group at Phelps Dunbar, LLP. She represents hospital and physician clients on Medicare and Medicaid payment issues, Anti-kickback Act and Stark I and II issues. She assists clients in structuring business arrangements in compliance with Medicare and Medicaid billing rules, including change-of-ownership provisions, preparation and negotiation of contractual arrangements between hospitals and physicians, establishing and representing managed care organizations, advising on state certificate-of-need laws and other state licensure issues, developing and implementing corporate compliance programs regarding Medicare billing issues, Anti-kickback Act and Stark. Ms. Newman is a member of the American Health Lawyers Association Board of Directors and is Chair of its Practice Groups Committee (2007-2008). She was former Chair of the Association's Quality Council as well as the Regulation, Accreditation and Payment Substantive Law Committee (Chair 2001-2004). She was President of the Mississippi Chapter of the Healthcare Financial Management Association (2004); Mississippi Bar (Health Law Section – Chair 1993/1994); and Outstanding Young Lawyer of Mississippi by the Young Lawyers' Division of the Mississippi Bar (1993). Ms. Newman graduated from the University of Mississippi, J.D., *summa cum laude*, 1989 and was Symposium Editor, *Mississippi Law Journal*. She graduated from Rhodes College with a B.A. in History, 1965.

Montrece McNeill Ransom is Senior Public Health Analyst with the Centers for Disease Control and Prevention's (CDC) Public Health Law Program which works to improve the understanding and use of law as a public health tool for community and state public health leaders, public policy makers, public health attorneys, educators and applied researchers, and CDC programs. She currently leads the Community Public Health Legal

Preparedness Initiative at the CDC Public Health Law Program. Ms. Ransom also served as an Operations Analyst in the Emergency Operations Center at the CDC immediately following the October 2001 anthrax incidents. Ms. Ransom is a member of the Georgia Bar, holds an undergraduate degree in Speech Communications from Columbus State University, received her J.D. from the University of Alabama School of Law where she served as the Lead Articles Editor for the *Law and Psychology Review*, and is currently pursuing a Masters of Public Health from Emory University. Ms. Ransom serves as Chair of the Public Health Law and Policy Interest Group of the Health Law Section of the American Bar Association.

Jeffrey M. Sconyers is Senior Vice President and General Counsel at Children's Hospital and Regional Medical Center, Seattle, WA. He is past president of the Washington State Society of Healthcare Attorneys and founding co-editor-in-chief of the *Washington Health Law Manual* (first published 1996). He is a former member of the Board of Directors of the American Health Lawyers Association (2001-2007) and was chair of its In-House Counsel Seminar program committee (1999-2005). He is a member of the Advisory Commission on Childhood Vaccines, appointed by the Secretary of Health and Human Services, and is currently in his second term as Chair of the Commission. He is not a real lawyer but he plays one at his hospital. On a good day, he can spin gold from straw.

Sarah L. Trautz is an Associate in the corporate department of Ropes & Gray, Boston, MA. Ms. Trautz graduated from the University of Virginia School of Law and received her undergraduate degree in biology from the University of Pennsylvania.

Colin J. Zick is Counsel at Foley Hoag LLP, Boston, MA. His practice is focused on healthcare and compliance issues and the intersection of those two subjects in administrative proceedings or litigation. His work has particular emphasis on compliance issues related to pharmaceutical and medical device companies, hospitals, practitioners (including physicians, dentists, optometrists, psychologists, veterinarians), and provider organizations. Mr. Zick defends clients in disputes alleging kickbacks, overpayments, and billing and coding problems. Mr. Zick's practice also includes healthcare transactional matters, including joint ventures, new entities, employment contracts, and clinical trial agreements, and health and business information privacy and security (HIPAA). He was named New England "Super Lawyer" in 2007 and Massachusetts "Super Lawyer" 2004-2007. He received his B.A. in political science with highest distinction from the University of Michigan, and his J.D., *cum laude*, from the University of Michigan Law School.



1025 Connecticut Avenue, NW, Suite 600
Washington, DC 20036-5405
(202) 833-1100 Fax (202) 833-1105
www.healthlawyers.org

