12

Legislative Authorities and Regulatory Issues

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OVERVIEW

Catastrophic disasters disrupt the health and medical system in a variety of different ways. The event itself – a hurricane or earthquake – may cause physical damage to medical infrastructure (e.g., hospitals, clinics, doctors' offices, laboratories, pharmacies, and medical suppliers). The event can also disrupt electrical power or communications capabilities such as Internet and computer services. A disaster can also create new requirements for medical care by injuring large numbers of people when buildings or other structures collapse. Similarly, a pandemic outbreak of infectious disease, or widespread exposure to chemical, radiological, or biological contamination, can overwhelm medical infrastructure and medical providers with the number of patients requiring treatment. Finally, as demonstrated by the 2004 Indian Ocean Tsunami, Hurricane Katrina in the United States (2005), and more recently, in 2012, Hurricane Sandy on the east coast of the United States, a disaster can force the evacuation of hundreds of thousands of people who then become separated from their regular medical care network (e.g., doctors, nurses, prescription medications, and medical records). These evacuees arrive in relocation areas with medical systems unprepared to treat the baseline health and medical needs of so many additional patients, in addition to any traumatic and psychological conditions caused by the disaster.

Catastrophic disasters also challenge the legal basis of the health and medical system. Practitioners may be familiar with legal and regulatory requirements applicable to the provision of medical care in normal times, but in a disaster environment, compliance with some legal requirements becomes problematic. Are regulatory requirements relaxed or changed under emergency conditions, or are practitioners left simply to do the best they can and trust that regulators will choose not to enforce standards? The following scenarios illustrate this dilemma:

- In the United States, federal rules require clinicians to perform a medical screening examination and stabilization of any patient who arrives on hospital grounds requesting medical care. How does this regulation apply when there is a physical plant disruption such as a hospital flood or fire, or a chemical, biological, or radiological contamination on site?
- Virtually all sovereign governments ensure the competence of medical professionals by issuing certificates or licenses to those authorized to practice medicine within their respective borders – yet, in a disaster, medical volunteers and medical providers from other jurisdictions will cross state or national boundaries to treat disaster victims. Under what circumstances do their medical or other health professional licenses allow them to treat casualties? Should they be concerned about violating geographic restrictions contained in their professional malpractice insurance policies?
- Sovereign nations, and provincial and states within sovereign nations, bestow on designated officials broad emergency powers over healthcare and public health systems – upon some sort of designation or declaration of a state of emergency or disaster. Yet, exactly what those powers are, who can exercise them, how timely they can be executed, and how those powers affect institutions and professionals providing medical care can vary dramatically.

This chapter will review disaster legal issues primarily from the perspective of persons or institutions – including individual doctors or nurses, medical practices, laboratories, clinics, and hospitals – who collectively provide medical care to patients in the midst of a catastrophic disaster or other public health emergency. This chapter summarizes the key areas where the legal environment of medical care may change as a result of disasters and other catastrophic events. Some of these changes occur in the specific requirements imposed on practitioners by national, state/provincial and, in some cases, local governments and agencies. Providers must be alert to how those changed requirements will be communicated to them.

Providers must also be familiar with how a disaster may create exposure to economic penalties and liabilities where the care provided in emergencies does not meet normal standards of medical practice. This exposure may be experienced, after the fact, through judicial award of money judgments based on malpractice of medical providers. Providers must also be cognizant

of requirements existing with third-party payers and private credentialing organizations and vendors.

Despite what some may view as a minefield of legal risks – risks of criminal or civil penalties, revocation of critical licenses or credentials, and malpractice or breach of contract judgments – disaster medicine creates an extraordinary and rewarding opportunity to provide medical care to people when they need it most.

CURRENT STATE OF THE ART

Medical Malpractice and Disaster Medicine

Just as they do during non-disaster times, medical care providers must manage the liability risk (for improper or inadequate treatment) during catastrophic events. In litigious countries like the United States, the tort liability system may have as much or more effect on how medicine is practiced than do regulatory standards imposed by the government. Under this tort system, liability attaches to any persons or institutions who participated in care provided to an individual patient who has suffered a significant injury or illness – *if* the injury or illness can be proven, in court after the fact, to be wholly or partially their "fault." Damages awarded can range in the millions of dollars for individual patients, including both "compensatory damages" (such as current and future medical expenses, lost wages, projected future losses in wages, or a monetary reward for pain and suffering), and, in egregious situations, "punitive damages." The impact of malpractice liability on individual practitioners is reduced in nations where medical care is provided by government. In England and Wales, for example, practitioners employed by the National Health Service (NHS) are indemnified from liability; practitioners outside the NHS must arrange for liability protection through a medical defense society or union, and the NHS itself may be vicariously liable for negligent acts of its practitioners.[1]

The liability system is intended to make "tortfeasors" (the label given to the persons whose improper actions or failure to act caused a patient's injuries and illness) pay money damages to make that patient (or the patient's estate) "whole," to the extent possible. The liability system is also intended to create a strong incentive to persons and institutions to act with appropriate care – that is, prudent and reasonable care in accordance with accepted medical practice in the circumstances in which that care is provided.

Medical care providers are generally familiar with the liability system as it applies to the day-to-day practice of medicine. The same principles also apply to the practice of medicine under disaster conditions. In fact, one of the main issues discussed by public health officials and emergency planners is how to assure that medical providers can assist in the response to a catastrophic event without incurring debilitating liability judgments.[2] Liability systems vary considerably in different nations and even in different states or provinces within nations – but it is useful to provide at least an overview of key characteristics of liability systems. An individual or institution can be found "liable" for an injury to a person if the individual or institution owes a duty to provide treatment, fails to fulfill that duty, and thereby causes harm to that person.[3] In many jurisdictions, however, the government – using doctrines like "sovereign immunity" – has limited or even completely immunized not only itself from liability for actions taken during emergencies, but has also immunized other persons or institutions providing medical care in the midst of emergencies.[4]

The "duty" described previously, whose breach leads to liability, can arise from several sources. These include: 1) an agreement (in which a medical provider promises to perform certain services in a particular manner); 2) statutes (in which the legislature has declared that a person has a duty, or responsibility, to act in a particular way); or 3) "common law" resulting from judgments of courts in individual cases determining or denying liability in particular situations and establishing legal precedents.

For medical malpractice liability, the most significant "duty" owed by a medical provider is a duty to diagnose and treat patients without negligence, in accordance with a standard of care. Normally this is the care which is reasonable for a qualified professional providing treatment in similar circumstances.[5] In "normal," non-disaster times, providers generally manage the risk that they might be found negligent by establishing and following standard procedures and protocols. Following these procedures minimizes the likelihood that their actions could, in hindsight, be characterized as "negligent." Providers also protect themselves by purchasing medical malpractice insurance.[6]

During a disaster, however, medical providers' ability to use non-disaster standard procedures and protocols is severely compromised because:

- Facilities are not fully functional due to infrastructure or operational damage.
- Facilities are crowded.
- Care may be provided under austere conditions and in non-traditional settings like alternate care facilities or even the field.
- Supplies and drugs are in short supply.
- Staff is short-handed and fatigued.
- Staff has been imported from other jurisdictions that use different procedures and protocols.
- Medical records are missing or temporarily unavailable.
- Volunteer medical providers are working in unfamiliar facilities and jurisdictions.

The circumstances under which the conduct occurs determine whether it can be classified as "negligent" medical care. A doctor operating in a tent field hospital established by government officials or in an airport concourse may not have the equipment necessary for certain tests that in "normal times" would be standard medical procedure. It would not be "negligence" for a doctor to treat a patient requiring care during this emergency without using unavailable equipment, even if the patient experienced life-threatening complications that would have been avoided had that equipment been used. Rather, the care provided would be reasonable given the environment and situation.

There are, nonetheless, significant liability risks that providers face in providing care during an emergency. For example, a patient's attorney may agree that a doctor did the best he or she could in the middle of a catastrophic event – but argue that the event became catastrophic because of negligence. For example, a medical facility could be found negligent in the development of its emergency plan which led to the loss of electrical power during a surgical procedure and that *this* negligence – not the heroic efforts taken after disaster had struck – is what led to injury. Proper pre-event preparation might have ensured that necessary test equipment was available or training was provided on substitute tests that did not require the equipment.

Moreover, whether the particular care provided was "negligent" even under emergency conditions will likely be a question that a court would decide after the fact. Some medical providers are, accordingly, concerned that actions taken in a catastrophic environment could lead to large malpractice judgments based not on true negligence, but rather on their inability to provide the care that would be considered appropriate under normal conditions. Even though practitioners are held to the standard that care must be reasonable given the circumstances in which it was provided, this may be insufficient protection. Given the delay inherent in litigation, the memory of emergency conditions will fade long before practitioners will be judged for possible negligence.

Malpractice insurance may not provide protection to providers in the disaster environment. To limit an insurer's malpractice exposure, malpractice insurance is typically written to cover a particular type of practice in a particular geographic location. Yet, in a disaster, medical providers may be needed in other jurisdictions, perhaps even in another state or country. They may be asked to practice in temporary or substandard facilities and may perform procedures that are not normally within their scope of practice. Standard malpractice insurance may exclude from coverage medical care provided under any of these circumstances.

To address some of these concerns in the United States, most states and the federal government have enacted legislation that provides some immunity to medical professionals providing care during disasters. State "Good Samaritan" legislation and the Federal Volunteer Protection Act of 1997[7] provide significant immunity protection. For example, in California's Good Samaritan Law, there is "no liability where the licensee in good faith renders emergency care at the scene of an emergency."[8] In many states, liability protection is also extended to medical professionals who volunteer to help state or local public health or emergency management officials. California also has this type of provision: "health providers . . . who render services during any state of . . . emergency, at the express or implied request of any responsible state or local official or agency, shall have no liability for any injury sustained by reason of such services, regardless of how or under what circumstances or by what cause such injuries were sustained."[9] This immunity does not apply when the injury was intentional or resulted from actions (or failures to act) that were clearly likely to cause harm – that is, where the injury results from a "willful" act or omission. Similarly, the Federal Volunteer Protection Act provides that "no volunteer of a nonprofit organization or governmental entity shall be liable for harm caused by an act or omission of the volunteer if . . . the harm was not caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer."[10] Note that protection under this law extends only to the actual volunteer – and not to any organization that dispatches or supports the work of volunteers (e.g., nongovernmental organizations such as the American Red Cross).

Furthermore, providers should be aware that the liability protection offered by Good Samaritan legislation and the Federal Volunteer Protection Act typically does not extend to those who receive compensation for their efforts. Is a physician who is part of a group medical practice, and who receives a fixed share of the profits from that practice, even though much of the profits were earned while the practitioner was "volunteering" in a disaster, covered? Could the immunity provided by a Good Samaritan Act be challenged if a medical care provider receives an allowance for meals and living expenses while serving in a disaster field hospital? Is a pharmacist in the employ of a corporation a "volunteer" if the corporation allows the pharmacist, during his paid vacation, to travel to a disaster and serve as a pharmacist at a shelter for evacuees? The answers to these questions are unclear and make the extent of liability risk uncertain.

Immunity is also provided under the laws of some U.S. states to contractors providing emergency response services "in coordination with" or "under contract to" emergency response authorities.[11] Other statutes may provide immunity to responders in particular circumstances – such as in the administration of smallpox vaccine.[12]

There are often limitations on the scope of immunity. For example, no immunity extends to: 1) caregivers receiving compensation; 2) persons who are unlicensed; and 3) for-profit businesses (such as incorporated providers of medical care). Furthermore, the immunity from liability given to government contractors may also be limited. Although contractors are generally not liable when operating under a government contract that precisely describes the required duties, contractors can be liable if they are permitted to use judgment in performing the contracted work.[13] This exception can be significant, because the provision of medical services frequently requires the application of judgment.

Although liability for volunteers practicing disaster medicine is very limited, there is uncertainty about the definition of "volunteer" and the scope of liability protection provided by existing immunity statutes. There is also controversy about whether the public is served by extending immunity from liability to practitioners whose actions are found to have caused unnecessary injury or even death to patients. For example, to address liability (and other issues), a model law called the Uniform Emergency Volunteer Health Professionals Act, was developed in the United States in 2007. While the intent was to encourage states to provide for legislative immunity, 6 years later, the primary provisions of this model act had been enacted in only twelve of the fifty-two U.S. states and territories, and some states rejected the liability provisions.[14] The accelerated pace of legislative changes and the variety of approaches adopted in many U.S. states illustrate the challenges in finding solutions to the many liability issues.

Despite a lack of clarity under existing law, medical providers can take actions that will eliminate or significantly reduce their exposure to liability when providing volunteer medical services in an emergency. Within the United States, virtually all of these solutions require that a medical provider be registered with an official governmental response organization and become a part of the government response. Government officials increasingly view the coordination of volunteer and private sector response efforts (i.e., public–private partnerships) to be a critical part of disaster preparedness and response efforts. In many U.S. states, statutes immunize actions taken at the direction of state emergency management officials.[15] In some state and federal government programs, volunteer individual practitioners are "hired" as temporary employees for minimal or no salary and the government extends its immunity protection to them and becomes the defendant to pay judgments arising from any remaining liability.[16] For example, if an individual is deployed to assist at a disaster site as part of a national Disaster Medical Assistance Team, the provider becomes "federalized" and is allowed to practice in any U.S. state or territory and has federal liability protections.

The liability protections available under current law and under a number of legislative proposals are primarily directed

to individuals, and particularly to individual volunteers, rather than to the nonprofit organizations and private businesses that may participate in response efforts. Some of the organizations that will assist in medical care provision during disaster events are not traditionally part of the medical system. For example, during a pandemic influenza event, public health officials may request a major employer in a community to assist in the distribution of pharmaceuticals and administration of vaccines to its employees and their families. Current law may provide only limited protection to these businesses. They may refuse to participate in planning and actual response unless they can obtain liability protection or indemnity.

Registration with an official government response organization provides other important benefits, particularly where medical providers will be working in facilities, communities, and states different from those in which their home practice is located. These benefits – discussed in greater detail later – include recognizing the provider's medical license in the new state, generating identification documents and credentials that allow the provider entry into the disaster area, and logistical support.

Healthcare facilities are also exposed to liability should they fail to provide quality care and meet the needs of their patients after a disaster. One type of negligence is corporate negligence, which hospitals face when managing liability claims. Hospitals have four duties: "[1] a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; [2] a duty to select and retain only competent physicians; [3] a duty to oversee all persons who practice medicine within its walls; and [4] a duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the patients."[17] Accordingly, healthcare organizations that hold these duties may be found liable if they fail to safeguard the welfare and safety of patients, employees, and occupants.

Healthcare facilities are further at risk via vicarious liability in that "the negligent acts of a health care provider may be directly imputed to the hospital in which the care is given."[18] Vicarious liability is based on the legal doctrines of *respondeat superior* and *ostensible agency*. It extends liability to employers based on an assumption that the employer has control over the actions of its employees.[19] Therefore, hospitals may be held liable for the conduct of nurses, residents, interns, and other health professionals. Typically, only negligent acts committed within the "scope of employment" are subject to liability. In addition, most courts will not hold a hospital liable for the negligence of an employee if the contract specifically negates an employment or agency relationship. Accordingly, physicians are considered independent contractors in many instances, and this status shields hospitals from any liable acts that they may commit. However, "courts have found that a hospital's imposition of rules and regulations upon staff physicians is enough to undercut the doctors' independent contractor status and expose the hospital to liability."[20]

Even where there is no actual agency, liability can be based on ostensible agency. This occurs when: 1) the patient looks to the entity rather than the specific physician for care and the patient reasonably believes that the healthcare provider is an agent or employee of the hospital; and 2) the hospital affirmatively "holds out" the doctor as its employee or agent, or knowingly permits the provider to project himself or herself as such. This theory applies to care in the emergency department since patients are unaware of and unconcerned with the technical complexities that define the employment relationship and generally seek medical treatment without regard to who the physician will be. Accordingly, "public has every right to assume and expect that the *hospital* is the medical provider it purports to be."[21] Consequently, since few patients presenting for care will specifically request an individual physician and patients during a disaster are likely to seek treatment in emergency departments rather than from individual physicians, the *ostensible agency* theory is likely to be relevant in litigation cases arising from crises.

As noted previously, legal protections for volunteer health professionals rarely extend to hospitals and other organizational entities providing healthcare and health services. Some hospitals may possess civil liability protections in their role as government entities or emergency care providers through specific grants of immunity during public health emergencies. These protections would grant these hospitals sovereign immunity because of their status as public institutions or as hospitals affiliated with state government. Sovereign immunity essentially removes the legal routes through which these facilities may be sued. City- or county-run hospitals may be considered state entities by some courts, effectively granting them the same protection from liability as healthcare facilities affiliated with the state. However, other courts consider hospital administration as a corporate undertaking, and therefore not within the sphere of state action and not protected by sovereign immunity. In addition, some states have greatly reduced or even eliminated this type of protection. Furthermore, sovereign immunity is curbed in many states through tort claims acts, which effectively waive sovereign immunity for government actors and agents acting within their official capacities.[22]

As demonstrated by some U.S. states, hospitals do not entirely lack safeguards. In Oregon, designated emergency healthcare facilities enjoy immunity as state agents for any claim arising out of the provision of uncompensated medical care in response to a declared emergency. In Minnesota, the governor can "grant immunity to organizations and individuals providing health care services during a declared emergency when good faith acts or omissions cause harm during emergency care, advice, or assistance." The Department of Health in Hawaii is statutorily empowered to enter into agreements with healthcare providers, including healthcare entities, to control infectious epidemics that require more resources than the department itself can provide. When a hospital acts pursuant to such an agreement, they "are not liable for any personal injuries or property damage resulting from the performance of their duties, absent willful misconduct." The state legislation in Louisiana immunizes hospitals and healthcare entities from liability resulting from injury or damage to people or property during a state-declared emergency, except in cases of gross negligence or willful misconduct. However, the lack of adequate planning for disasters could be considered gross negligence.[23]

Legal Framework for Disaster Medicine and Public Health Emergencies: Public Health Powers

In the United States, the foundation of both the "normal" and "disaster" legal system is the Constitution that created the federal system of government. In this system, it is state governments, and not the federal government, that have primary authority and responsibility to protect public welfare. In the Constitution, states granted enumerated powers to the federal government, including authority over interstate and foreign commerce, national

defense, and the right to tax and spend for the public welfare. Yet the states retain their basic police power – the power to place restrictions on people and property and business to protect the public.

The U.S. system of federalism devised by its founders is reflected throughout the medical system. Acting under its police power authority, states have created licensing and certification requirements for hospitals, physicians, nurses, pharmacists, and other medical professionals. State statutes specify rules for reporting of communicable diseases and other public health concerns (such as unsafe conditions in restaurants), and empower public health officials to take action (impose quarantine, or close restaurants) to protect the public. State law is also generally responsible for determining the standards of care applicable to the medical system and these standards are enforced through state court judgments in the medical malpractice system.

The federal government nonetheless also exerts extraordinary power over the medical care system. Communicable diseases can spread across state and international boundaries – allowing the federal government to exercise its power over international and interstate commerce and impose federal rules to prevent transmission of disease. For example, federal legislation authorizes federal quarantine within a state on findings that a state's quarantine efforts are ineffective.[24] Similarly, because pharmaceuticals and medical supplies are sold in interstate commerce, the federal government has authority to regulate drug manufacture and use. Federal taxes fund the Medicare and Medicaid programs that pay for 23% and 17%[25] of the medical care provided in the United States, respectively. As a result, federal requirements placed on medical care providers who treat Medicare or Medicaid patients are enforced by federal civil and even criminal penalties. These requirements include protection of patient records and service obligations in addition to billing and reimbursement procedures.

In the United States, officials at all levels of government have broadly worded authority to take action in the face of "imminent threats," to "save lives, defend property, and protect the public health and safety." This authority can extend to actions that would normally be viewed as blatant violations of constitutionally protected rights to "life, property and the pursuit of happiness." These actions include seizure or destruction of property (including hospitals, medical supplies, or even animals); voluntary or mandatory evacuation of people from (or detention of people in) a facility or geographic area; or even mandatory treatment of persons.[26,27] For some of these actions, the government may be required to provide compensation. For others, the government may provide discretionary disaster assistance, and for still others, individuals and businesses are not provided any additional resources.

Mandatory evacuation may be difficult to enforce in some societies. There are a wide range of enforcement schemes for mandatory evacuation orders. For example, mandatory detention of tuberculosis patients who refuse to complete a drug regimen may include physical restraints. A "mandatory" evacuation in advance of a hurricane or a fire can be enforced by forcibly transporting evacuees to safe areas or by simply notifying residents of the danger and, if they refuse to leave, requesting them to provide authorities with contact information for their next of kin.

As demonstrated during the 2009 H1N1 influenza pandemic, the U.S. federal government has a procedure to waive federal requirements applicable to healthcare facilities during public health emergencies. At the time, President Obama declared H1N1 influenza a national emergency given that "the rapid increase in illness across the Nation may overburden healthcare resources and that the temporary waiver of certain standard Federal requirements may be warranted in order to enable U.S. healthcare facilities to implement emergency operations plans."[28] This declaration, combined with the Department of Health and Human Services (HHS) secretary's declaration of H1N1 as a public health emergency, allowed healthcare facilities to petition HHS under Section 1135 of the Social Security Act[29] for waivers of regulatory requirements implicated by the emergency.

Provider Obligation to Protect Patient Rights

Privacy

The patient-doctor relationship is a sacred trust and medical files contain a great deal of highly personal information. These files contain data not just about the state of a patient's health, but about the patient's habits, family, finances, sexual practices, and sexual orientation. Proper sharing of patient information (with multiple medical specialists and with third-party payers) is critical to achieve appropriate medical care and for successful healthcare system operations. In the United States, however, disclosure without patient consent in accordance with specific provisions is prohibited, frequently by multiple statutory and regulatory provisions. Most medical providers use well-developed procedures to assure that any exchange of patient information complies with law.

During disasters, sufficient resources to comply with these procedures may be lacking. Circumstances may force additional disclosures, and trigger exceptions to "normal" disclosure requirements. For example, in the aftermath of a catastrophic disaster, locating missing persons, while respecting patient privacy, can be difficult. Finding relatives of family members to authorize treatment and determining what medical information to provide family members and the general public are additional challenges. Disaster conditions also require hospitals and medical personnel to operate in stressful, rapidly changing, and uncertain situations. Despite this environment, the need to share information and keep the public informed must be weighed against the privacy rights of patients and their families. Federal and state laws governing the release of patient information are generally unchanged in the setting of a disaster; however, there are provisions for information sharing in emergent settings. Typically, a provider should obtain patients' verbal permission for a disclosure of health information, and patients should be "informed in advance of the use of the disclosure," when possible.[30]

Federal Health Insurance Portability and Accountability Act Requirements and Protected Health Information in the United States

One of the more detailed regulatory systems governing protection of personal healthcare information is that in the United States. A detailed discussion of this system and its provisions for public health emergencies illustrates the issues that any healthcare system must address. The U.S. regulations on confidentiality were developed in the year 2000 pursuant to the Health Insurance Portability and Accountability Act (HIPAA). This act was primarily intended to address difficulties experienced when employees with employer-provided health

insurance changed jobs – but this required regulators to address how to protect patient privacy when transferring health records to the new employer. This requirement for protecting privacy while addressing the portability of insurance led to a comprehensive federal regulation governing how participants in the medical care system – care providers, laboratories, and third-party payers, such as insurance companies – maintain, protect, and disclose what is defined as protected health information (PHI). To assure appropriate attention to the privacy interest of patients, HIPAA requires that medical care providers and payers have a documented privacy policy and appoint a privacy official and contact person responsible for training the workforce in PHI privacy policy.[31]

HIPAA allows healthcare providers to share a patient's PHI as necessary to provide treatment, payment, or healthcare operations; this sharing of information applies during disaster events just as it does in "normal" times.[32] Treatment includes coordinating patient care with others, such as emergency relief workers or personnel at potential referral receiving sites. Furthermore, where required or necessary to prevent or control disease, injury, or disability, disclosure to a public health authority is expressly authorized by HIPAA.[33]

State legislation largely echoes the provisions of federal HIPAA regulations. Some states further delineate permissible activities for sharing PHI. For example, California legislation expressly permits the communication of PHI between emergency medical personnel by radio transmission or other means.[34]

Location/Health Status

HIPAA generally permits providers to share very limited information concerning a patient's location and general condition (including death) as necessary to identify, locate, and notify family members or guardians.[35] Therefore, if necessary, a hospital may inform the police, press, or the public at large to the extent necessary to help locate, identify, or otherwise notify family members as to the location and general condition of the patient. Federal regulations also permit the sharing of basic information, including the patient's identity, residence, age, sex, and condition, to disaster relief organizations without patient consent if necessary to facilitate disaster response.[36] Even when disclosures are permitted by HIPAA, however, providers must be aware of any state statutes that might restrict release of patient information. California law expressly permits disclosure of basic patient information to state or federally recognized disaster relief organizations,[37] and Arkansas has adopted basic HIPAA disclosure provisions,[38] but other states have not done so and may have more stringent restrictions on disclosure. There is some confusion about whether HIPAA rules *permitting* disclosures preempt state laws.[39] What is clear is that, under normal circumstances, when a patient incapable of communication arrives at a hospital, the facility must attempt to make contact with a family member or surrogate within 24 hours – a requirement that is suspended during periods of disaster.[40]

Hurricane Katrina in August 2005 in the United States forced the rapid evacuation of more than 1 million residents. In the process of evacuation, many families were separated. Isolated individuals included parents and other caregivers, children, and grandparents. This disaster exposed the challenges associated with effective federal government evacuee tracking and family member reunification. As a result, in the post-Katrina Emergency Management Reform Act of 2006,[41] Congress enacted legislation requiring the Federal Emergency Management Agency (FEMA) administrator to establish a: 1) National Emergency Child Locator Center (in cooperation with the U.S. Attorney General) within the National Center for Missing and Exploited Children; and 2) National Emergency Family Registry and Locator System. The former provides information about displaced children and serves as a resource for adults who have information about displaced children; the latter focuses on allowing displaced adults to register, furnish personal information to a database, and make this personal information accessible to "those individuals named by displaced individuals."[41] Implementation of this section requires a memorandum of understanding with the Department of Justice, and HHS, the American Red Cross, and "other relevant private organizations."[41] This system should help medical providers in their efforts to locate a patient's next of kin.

Public Health Officials

In the United States, HIPAA allows disclosure of PHI to a "public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions." This authorization also permits disclosures to "a person or entity other than a public health authority" if it can demonstrate that it is acting "to comply with requirements of a public health authority." PHI can also be disclosed to a person who may have been exposed to a communicable disease or is at risk of spreading a disease (for example, sexually transmitted disease), "and is authorized by (state) law to be notified as part of public health intervention or investigation." These specific provisions governing disclosure to public health officials that facilitate public health interventions are even more important during a public health emergency than during "normal" times. The provision in the HIPAA rule authorizing disclosure of PHI to law enforcement officials "to help identify or locate a suspect, fugitive, missing person," and "to provide information related to victim of crime" is even more critical during public health emergencies, particularly those that are triggered by criminal or terrorist activity.[42]

Immediate Danger

HIPAA further permits the disclosure of PHI without consent or prior notification when "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat."[43] This exception is particularly important when communicable disease is involved; it allows disclosure of a patient's communicable disease status without the patient's consent to other persons (such as a patient's spouse or partner) to protect them from exposure.

Reporting and Recordkeeping Requirements

Even where disclosures of PHI are fully authorized, and even if those disclosures are in the midst of a public health emergency, HIPAA requires that the entity making the disclosure track when the disclosure was made, and to whom. Authorities must make this information available to the patient on request.[44] As a result, when developing their emergency plans, medical providers in the United States must pay special attention to ensuring that

they will have systems to document the disclosures that they make, whether required or permitted, of a patient's PHI.

Media

A public health emergency or disaster will generate significant media attention. Despite media inquiries, hospitals must maintain confidentiality of PHI. A hospital reporter must have a patient's consent before releasing any personal information. A facility may, however, disclose general information about a disaster response, such as the number of victims treated at the facility and the general types of injuries sustained, so long as this information is not specifically identifiable to an individual. As mentioned previously, a hospital may disclose specific PHI to the media if this disclosure constitutes an effort to locate family members.

Data Storage and Security

The requirements of HIPAA include a stipulation that "covered entities" institute a data recovery plan ensuring continuity of operations in the aftermath of a disaster.[45] A covered entity is a health plan, a healthcare clearinghouse, or a healthcare provider who transmits any health information in electronic form in connection with a HIPAA transaction.[46] Covered entities include doctors, hospitals, laboratories, and pharmacists, and also the insurance companies and other third-party payers that have access to a patient's PHI. This required system must include a data backup plan for the retrieval and restoration of electronic PHI as well as an operations plan that enables the maintenance of privacy and security safeguards over PHI. These plans for data recovery have become increasingly important since the Health Information Technology for Economic and Clinical Health (HITECH) Act was signed into law in February 2009. The act promotes the adoption and meaningful use of health information technology by reducing the cost for covered entities to implement electronic medical records and establishing penalties for covered entities that do not follow security and privacy rules. The act also commits an investment of $20 billion (USD) in health information technology infrastructure.

State regulations may also require data protection and access in a disaster situation. For example, in California, hospital licensing regulations require hospitals to safeguard their medical records against loss or corruption.[47] California also details specific requirements for organizations maintaining only electronic records. These include off-site backup and retrieval systems.[48]

Although it is preferable to anticipate post-disaster challenges and proactively pass enabling legislation, in some situations the legal requirements have been modified post-event. For example, in the aftermath of Hurricane Katrina, the U.S. Secretary of HHS issued a waiver of penalties for violating certain HIPAA privacy provisions that proved impractical in the disaster setting including:

> Sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 CFR §164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 CFR §164.520); or (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 CFR §164.522).[49,50]

HHS provides a fact sheet confirming that HIPAA is not suspended and explaining what provisions may be waived during a national or public health emergency.[51]

Individual Liberty

Decisions on treatment of patients involving such issues as selection of diagnostic tests, therapeutic agents, surgical procedures, drugs, and diets are generally made by physicians and other care providers only with consent after appropriate disclosure of the risks, costs, benefits, and alternatives. This system reflects the privacy and liberty interests that patients have in their own bodies, and it is enforced not only by numerous regulatory requirements, but also by judicial precedents. The provider may be liable after a patient suffers an adverse effect of treatment, if it was a known adverse effect of that treatment, and it was not fully disclosed to the patient. The rules may change during a disaster. To protect the public health, the government is granted significant power to require testing or treatment of individuals, isolation of patients with a communicable disease, and quarantine of those with suspected or known exposure to communicable disease irrespective of the patients' wishes. Exercise of these authorities requires balancing the threat to the public with the risks to the individual. In addition, enforcement of public health orders in pandemic and other public health emergencies – when authorities are overwhelmed with the sheer number of individuals affected – can be very challenging.

Legal Basis of Mandatory Public Health Measures

Governments have a wide variety of legal tools that address communicable disease. Some, such as quarantine, have a history extending back centuries if not millennia. These public health powers may significantly limit individual patient rights, but as illustrated later, U.S. courts have generally provided wide latitude to public health authorities in adopting them.

A seminal case on restricting individual rights to protect the public health is *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). In 1902, the City of Cambridge, Massachusetts, passed an ordinance finding that "smallpox [was] prevalent in the city and continues to increase." The city ordered vaccination of all its inhabitants, except children with a doctor's note saying that they were unfit subjects for vaccination. Henning Jacobson, a charismatic minister who had emigrated from Sweden, refused to be vaccinated. Reverend Jacobson viewed vaccination as unsafe and ungodly. Side effects of the cowpox vaccine used in vaccination were common. He refused to pay the $5 fine specified for violators, and he appealed his fine all the way to the U.S. Supreme Court.[52]

The court responded with a decision supporting the right of communities to use their police powers to protect the public welfare. In the words of Justice Harlan:

> Real liberty for all could not exist if each individual can use his own, whether in respect of his person or property, regardless of the injury that may be done to others . . . . *Upon the principle of self defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.*[53,54]

Justice Harlan also qualified the scope of the power to restrict liberty for public health: "Police power of state must be held to embrace, at least, such *reasonable* regulations established

directly by legislative enactment as will protect the public health and safety . . . *subject, of course, that . . . no rule . . . or regulation . . . shall contravene the Constitution of the United States, or with any right which that instrument gives or secures.*"[55,56] In other words, within the United States, public authorities have the right to protect their communities from an epidemic of disease, but the actions taken to do so must be "reasonable," with some rational basis grounded in knowledge about treatment for the disease and its incubation period, virulence, and communicability. The requirement that public health measures – even those taken to protect the community from disease – cannot "contravene the Constitution" or any "right which that instrument gives or secures" is also extremely significant. The fifth and fourteenth amendments to the U.S. Constitution preclude a federal or state government from taking a person's liberty or property without "due process." Mandatory treatment, inoculation, quarantine, and isolation measures clearly restrict the liberty of individuals. Therefore, state and federal government use of these powers must be in accordance with due process, which includes both "procedural due process" (following appropriate *procedures*) and "substantive due process" (requiring that officials have a *substantive* reason and a rational basis for restraining individual liberty).

The case of *Best v. Bellevue Hospital New York* is illustrative of these "due process" principles.[57] Mr. Best was diagnosed with tuberculosis but refused to complete his medication regimen and could have developed a drug-resistant strain. The health department issued an order detaining him and requiring completion of his treatment. Mr. Best filed suit against the health department and the hospital where he was confined. Mr. Best was granted a hearing and the courts assessed whether he was a danger to himself and the community. After a prolonged legal process that included four public hearings, significant attorneys' fees, and at least seven administrative, state court, and federal court orders, the court found that the health department and other defendants had indeed provided the due process required by the Constitution. On procedural due process, the federal appeals court described the factors considered in determining constitutionality of detention procedures:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.[58,59]

In general, quarantine and isolation procedures that provide notice and an opportunity for hearing (which can be held after an individual is detained) will satisfy procedural due process requirements. The hearing requirement does not preclude health officers from taking action immediately when there is a risk that the public will be exposed to a communicable disease if a person is not immediately placed in isolation or quarantine.

Courts must also determine whether a public health order violates a person's substantive due process rights; that is, it must review whether the government had a rational, reasonable basis for the order. This analysis involves a balancing of the collective right of self-defense enunciated in *Jacobson* against individual rights to liberty and property. In these cases, courts have traditionally given great deference to the judgment of public health officers. One historical example is provided in an opinion by Judge Hydrick of South Carolina's Supreme Court in 1909: "In dealing with such matters, a wide range of discretion must be allowed the local authorities, and they should not be interfered with, unless it is clearly made to appear that they have abused that discretion to the probable injury to health or life."[60,61]

There are relatively few recent cases defining the Constitutional requirements for mass quarantine; at the time of this writing, the United States has not had occasion to impose a mass quarantine for more than 50 years. In the U.S. legal system, two basic principles that have support in case law can assist public health officials in understanding legal approaches to control of communicable disease. First, the greater the restraint on individual liberty, the greater the responsibility of government to provide for those restrained. For example, when the state confines individuals in prison, or involuntarily commits individuals in a mental health facility, these individuals are no longer able to access their own food or medicines; courts have declared confinement without food or medicine, or in crowded and dilapidated prison conditions to be unconstitutional.[62] When individuals and families are deprived of the ability to meet their basic needs for food, shelter, and medical care by quarantine or other movement restrictions, the state becomes obligated to provide those basic needs.

Second, despite the great deference given public health officials, they cannot justify their orders simply by stating that the actions will prevent the transmission of disease. They must also show that they could not have controlled the spread of disease with different public health measures that would have had less impact on individual liberty. The U.S. Constitution provides that states cannot deprive persons of their "life, liberty, or property without due process." As in the *Best v. Bellevue* case, this language has been interpreted to mean that the public health objective should be achieved with the least restrictive measures possible in all cases, including those for patients with communicable diseases, suspected infections, and known or suspected exposures.[63]

By enforcing "restrictions of movement," the goal of public health officials is to increase the "social distance" between potentially infected persons and uninfected persons. Effectiveness of different movement restrictions in increasing social distance and reducing transmission of disease is highly dependent on disease characteristics. These include incubation period, method of communicability, virulence, treatment options, and whether asymptomatic patients are contagious.

Some U.S. states have adopted statutes that include "the least restrictive means necessary test,"[64] and others have not yet defined the minimum requirements for quarantine. In many cases, strict quarantine procedures are not necessary to reduce disease transmission. Other restrictions of movement that increase social distance, such as school closings, restrictions on public meetings, work quarantine, and wearing of masks or respirators may be just as effective.[65] Because there are a number of less intrusive measures that may be equally or more effective than mandatory detention in a quarantine facility, a public health official may need to provide an affidavit with the quarantine order that explains why these less physically intrusive options were not selected.

Although there are a myriad of measures that reduce disease transmission, some are less intrusive on individual rights than others. For example, restricting public meetings or requiring

use of face masks respects individual liberties much more than placing people in involuntary detention in a quarantine center. The decision about which measures to employ has important legal consequences.

Legal preparation for a large-scale quarantine from a pandemic event extends beyond simply developing a notebook of standardized hearing notices and affidavits to be signed by public health officials. Officials and their attorneys must also enhance the procedural readiness of the judicial system, encouraging the courts to think through the following issues:

- The systems to be used for handling a large number of hearing requests.
- The measures that will be employed to protect the safety of hearing officers and participants from exposure to disease.
- Documentation/affidavits that will be required in a mass quarantine environment.
- How the court and other officials will communicate to the public.

Consent

Generally, rules for consent do not change in a disaster or public health emergency. The medical care system is accustomed to situations in which it is impossible to obtain consent from patients. For children, or those who are unconscious, mentally disabled, or otherwise unable to make an informed choice, consent is generally obtained from parents, a spouse, or a guardian. In an emergency, whether it involves an individual patient or a whole population during a catastrophic event, patient consent for management of an imminent medical crisis is implied. In this context, an "emergency" is a situation in which delay in immediate care would lead to serious disability or death, or immediate treatment is required to relieve severe pain. Frequently, U.S. state statutes provide specific definitions and requirements.

For example, in California, B&P § 2397 protects a medical care provider from liability when treatment is provided without consent if the patient was unconscious, there was insufficient time to inform the patient, or the patient was without the legal capacity to provide consent and there was no time to obtain consent from the patient's legal representative. The term "capacity" is defined by the statute as "a person's ability to understand the nature and consequences of a decision and to make and communicate a decision." Minor patients lack capacity as a matter of law except when the minor has been given "emancipation" status (e.g., by court order, by military service, by marriage, or because the minor has been determined self-sufficient). In some jurisdictions, there are additional exceptions to the rule that minor patients lack decision-making capacity. For example, in California, a patient twelve years of age or older has the legal capacity to make informed consent decisions with respect to communicable reportable diseases, outpatient mental health, substance abuse, and pregnancy-related treatments.

The specific rules of consent can vary substantially in different states. For example, rules regarding pregnancy-related treatment are frequently controversial and there is no national consensus on the age at which a minor no longer requires parental consent. As a result, if volunteers from one U.S. state provide disaster medical services in another state, they should be aware of the specific consent laws that apply in that state.

Authorization to Provide Medical Care

Licensing and Credentialing

LICENSING

Sovereign nations and, in federal systems, state/provincial governments generally regulate the practice of medicine. Thus, providers must be licensed in the state in which they are providing medical care. State licensing requirements generally extend not only to clinical care providers (e.g., physicians, nurses, pharmacists, veterinarians), but also to institutions (e.g., clinics, hospitals, and nursing homes). To obtain a state license, providers or institutions must demonstrate that they meet particular educational, training, and experience requirements. Medical practice is restricted to those skills and procedures commensurate to the training received and authorized under a professional license, a so-called scope of practice.[66] Requirements are established by state laws and agencies; they vary by state, and licenses authorize professional activities only in the state in which the license is granted. When a disaster covers a broad geographic area, nations, and states may find that their existing resources of medical (and other) professionals are insufficient and that they must rapidly obtain assistance of professionals from other localities. Medical professionals from other areas must be qualified to provide disaster relief services.

On declaration of a disaster or state of emergency in the United States, the governor of a state generally has the power to adjust the state's licensing requirements to allow practice by professionals from out of state. In some states the governor has the power to completely suspend the state's licensing scheme,[67] although in practice this power is not invoked except through procedures that assure professional qualifications. More commonly, a governor will exercise an emergency power that temporarily recognizes professional licenses issued in another state. For example, after declaring an emergency in California, the California Emergency Services Act bestows on the governor broad emergency powers that include the ability to grant "any person holding a license issued by any state for professional skill permission to render aid involving such skill to meet the emergency as fully as if the license had been issued in California."[68] In the United States, the Emergency Management Assistance Compact automatically provides for "cross licensing" to professionals who are deployed to a state as "state personnel" under this agreement. During Hurricane Katrina, existing laws allowing cross-licensing of professionals did not work as quickly or as broadly as needed, and several efforts to broaden these rules were initiated. The Commission on Uniform State Laws developed the Uniform Volunteer Emergency Health Practitioners Act in 2006 and 2007. This act, which is only effective in a state after it is introduced to and enacted by the state, provides automatic cross-licensing of health professionals volunteering through a recognized credentialing system during emergencies.

HOSPITAL CREDENTIALING

In addition to the licensing requirement, practitioners need "privileges" to be permitted to work in a specific healthcare facility. The Joint Commission (formerly known as the Joint Commission on the Accreditation of Healthcare Organizations) is an independent, not-for-profit, U.S.-based organization nationally recognized for setting certain hospital performance standards and granting accreditation and certification to those hospitals meeting these standards. Joint Commission International, established in 1997, "extends The Joint Commission's mission

worldwide by assisting international health care organizations, public health agencies, health ministries and others to improve the quality and safety of patient care in more than 80 countries."[69] The Joint Commission's Hospital Accreditation Manual includes standards for administrators to grant disaster privileges (i.e., authorization for practitioners to work in their hospitals). When the healthcare facility emergency management plan has been activated and the hospital capacity is exceeded by the immediate surge in patients, "the CEO or medical staff president or their designee(s) has the option to grant disaster privileges."[70] The official authorized to grant disaster privileges has broad discretion. To receive these privileges, however, the provider must present: 1) a current picture hospital identification card; or 2) a current license to practice issued by any state, federal, or regulatory agency; or 3) identification indicating that the individual is a member of a federal Disaster Medical Assistance Team; or 4) there must be a current hospital or medical staff member with personal knowledge regarding the practitioner's identity.[71] This standard requires that individuals authorized to grant hospital privileges be specifically identified and that there is a mechanism for managing personnel operating under temporary disaster privileges. The requirement further specifies that there must be a means for allowing staff to readily identify these personnel and that verification of credentials and privileges begins as soon as the immediate patient surge has resolved. This process is identical to the process established under Joint Commission standard M.S.4.100 for granting privileges to meet an important patient care need.[72] As an alternate to the Joint Commission process, the executive branch of state government may also have authority to grant hospital privileges in the setting of a declared emergency.

Financial and Reimbursement Issues

Regional disaster plans may include memoranda of understanding between healthcare facilities for staff sharing during emergencies. In some models, the facility requesting assistance provides reimbursement directly to temporary employees; in other systems, the regular employer continues to pay salaries and receives reimbursement from the hospital that benefited from the shared services. For example, the District of Columbia Hospital Association and the District of Columbia Emergency Healthcare Association, both in Washington, D.C., maintain agreements among their members to assist hospitals in emergency management. These agreements address the logistics of personnel and equipment sharing and the transfer of patients. They also assign credentialing responsibilities and legal liability to hospitals receiving assistance from others.[56,73,74]

Federal rules for reimbursement in the United States under Medicare, Medicaid, and state children's health insurance programs were relaxed in the aftermath of Hurricane Katrina. This was primarily because compliance with prior provider enrollment in these programs, recordkeeping, and licensure in the same state in which services were provided was both impractical and counter to public policy. Six days after the storm made landfall, HHS issued a waiver of various requirements for participation in federally funded healthcare programs including:

1. Certain conditions of participation, certification requirements, program participation or similar requirements, or pre-event approval requirements for individual healthcare providers or types of healthcare providers, including as applicable, a hospital or other provider of services, a physician or other healthcare practitioner or professional, a healthcare facility, or a supplier of healthcare items or services.
2. The requirement that physicians and other healthcare professionals hold licenses in the state in which they provide services, if they have a license from another state (and are not affirmatively barred from practice in that state or any state in the emergency area).[75]

Although this post-hoc administrative response was less efficient than having pre-event procedures in place, the government recognized the importance of encouraging flexibility in staffing to provide adequate healthcare delivery in the midst of a mass-casualty incident. To accommodate an increasing patient surge, this waiver also extended to hospital bed classification requirements allowing "non-medical beds" to be used for patients requiring medical services. The government reimbursed these services according to relaxed billing requirements. During the time of disaster relief, paper billing and substitute data were accepted for those records that were destroyed or unrecoverable.

Healthcare Facilities

The Joint Commission standards require hospitals, acute care facilities, and acute care psychiatric facilities to maintain and regularly update disaster plans and to train and test staff preparedness.[76] Medicare in the United States also promulgates federal hospital emergency management plan accreditation requirements. Although Medicare "conditions of participation" for critical care facilities do not contain specific requirements for disaster management plans, the Interpretative Guidelines issued by Medicare to its state survey teams require the adoption of "emergency preparedness plans and capabilities."[77] These guidelines for hospitals include "critical access hospitals" – a safety network of hospitals identified by Medicare to ensure access to healthcare services in rural areas. They require that the hospital formulate and implement a disaster plan to "ensure that the safety and well-being of patients are assured" during a disaster.[77] Such plans must include coordination among all levels of government emergency preparedness authorities with specific identification and response to likely risks in their general areas, such as earthquakes, floods, and so forth.[78] The Interpretative Guidelines are detailed in their list of issues to be addressed in the disaster plan and include consideration for security of walk-in patients; security of supplies (including pharmaceuticals, water, and equipment); communications systems; provisions in the event of gas, power, and water disruptions; and mechanisms for the transfer of patients.

The U.S. Occupational Safety and Health Administration asserts authority to regulate "any reasonably anticipated disaster that could create a hazard for employees" at the workplace.[79] Such hazards include workplace injuries, fires, blood-borne pathogen exposure, and radiation and other hazardous materials exposures.

The U.S. 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) mandates that state and local governments and other eligible entities, such as hospitals, "develop and implement emergency management plans that are consistent with evidence-based benchmarks and standards developed by the Department of Health and Human Services."[80] It authorizes HHS to "withhold emergency preparedness funds from hospitals that do not meet certain benchmark requirements."[81]

HHS also administers the Hospital Preparedness Program (HPP). A major goal of this program is to "strengthen health care partnerships at the community and substate levels."[82] A requirement of the program is that funding for HPP must be directed through state health departments so community response entities work together to develop community emergency management capabilities. Consequently, hospitals are required to participate in regional cooperation to receive funding for the program. In addition, the program encourages hospital involvement in community coalitions and community emergency response networks. HPP is based on capabilities and requires recipients of funding to develop and demonstrate specific benchmarks by the end of the funding cycle. The goal is to create objective and reproducible ways of measuring hospitals' emergency management abilities.

U.S. states also impose hospital disaster plan requirements. For example, California hospital licensing regulations require a "disaster and mass casualty program," which must be approved by the medical staff and administration, practiced by conducting at least two drills per year, and available for review by representatives of the California Department of Health Services.[83] California regulations require the plan to contain a hazard vulnerability analysis, community linkages with an all-hazard command structure, specific procedures during a disaster, a mechanism for plan activation, a process for reporting emergencies to external authorities, a command structure, and a means to notify and activate personnel.[84] Even though hospitals may fulfill these disaster regulations, they could be out of compliance with a multitude of requirements placed on them during non-disaster operational periods. For example, patient–nurse ratio requirements in the State of California (designed to provide individual patients with optimum nursing care) are unlikely to be practical in the setting of mass casualties and may actually be harmful to the affected population. Staffing ratios should not determine hospital capacity, as is often the case in non-disaster settings when nursing shortages frequently dictate the maximum number of patients that may be cared for at a facility. During a disaster, however, it would be difficult to obtain timely waivers of legislated nurse–patient ratios. Hospitals should be encouraged to prepare agreements with its nursing staffs and unions prior to and in anticipation of a patient surge during a disaster. Discussions between hospital administration and nursing should also explore means to increase staffing during emergencies.

Medical Screening Exams in Disasters

The requirement for medical screening varies by country. These differences have implications for the management of disaster victims. Article 25 of the Universal Declaration of Human Rights states that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."[85] However, it does not specifically mention any universal requirement for the medical screening of individuals who present to a healthcare facility requesting assistance.

In the United States, individuals who present to an emergency department are required to receive a medical screening exam by law. The U.S. Emergency Medical Treatment and Active Labor Act (EMTALA) was passed in 1986 in response to reports that hospitals were refusing to treat individuals with emergency conditions if they did not have insurance.[86] EMTALA requires Medicare-participating hospitals to provide any individual presenting to hospital grounds for care a medical screening, stabilizing services, and appropriate transfer to a higher level of care if indicated. In addition, EMTALA sets forth civil monetary penalties on hospitals and physicians for:

1. Failing to properly screen an individual seeking medical care.
2. Negligently failing to provide stabilizing treatment to an individual with an emergency medical condition.
3. Negligently transferring or releasing from care an individual with an emergency medical condition (including active labor).[87]

Waivers to EMTALA mandates, even in the setting of a mass-casualty event, have not been well developed. Project Bioshield legislation (enacted in the United States in 2004) provides some relief from EMTALA when the federal government declares an emergency.[88] This legislation allows HHS and the Centers for Medicare and Medicaid Services to temporarily waive EMTALA standards relating to:

1. Transfer of unstable emergency patients if required by the circumstances of a declared emergency by a hospital in the emergency area during the period of the emergency; and
2. Directing or relocating patients for medical screening to alternate locations in accordance with the state emergency preparedness plan.

The U.S. federal government issued an EMTALA waiver during Hurricane Katrina that suspended the requirement for hospitals in the designated disaster area to screen and stabilize patients if the disaster situation prevented it, provided that these patients were redirected to another facility for the medical screening examination and stabilization.[89] As the Agency for Healthcare Research and Quality notes, EMTALA requirements are not entirely clear, particularly with respect to transfer or "surge" facilities. The Agency for Healthcare Research and Quality recommends that elements of EMTALA "be reduced/waived for a temporary/limited service surge facility."[90] For example, the benefits of transfer to a surge facility would be to create capacity for other patients needing tertiary hospital services, not necessarily for the benefit of the transferred patient; the patients would not necessarily be asked to consent to transfer to the surge facility.[90]

In the United States, EMTALA regulations could be suspended if a Section 1135 waiver were issued. According to regulation 42 CFR 489.24(a)(2), when an 1135 waiver has been granted, "sanctions . . . for an inappropriate transfer or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department" if certain conditions are met.

Emergency Management and Public Health Systems

Through the end of the twentieth century, there was relatively little effort to connect the public health and medical care systems with the emergency management system. Public health officials worked independently, operating under public health laws and authorities to protect public health and transmission of communicable diseases. Similarly, emergency management officials

worked in isolation and were not prepared to assist in response to a major public health emergency such as an epidemic that had the potential to overwhelm the healthcare system. There was rarely coordination of disaster program development between public health, medical, and emergency management officials.

In the United States, there was a major philosophical shift after the terrorist attacks of September 11, 2001. The federal government mobilized massive resources to focus attention on preparing the nation for catastrophic events. Within a year of the attacks, Congress had enacted legislation creating a new federal department, the Department of Homeland Security (DHS), with the mission of protecting the nation from terrorist attacks and other threats. By Executive Order, President Bush directed the new DHS to establish a National Response Plan (later renamed the National Response Framework) that would coordinate emergency response efforts of the entire federal government, in collaboration with states.[91] The president also required DHS to establish a National Incident Management System (NIMS) and directed that *every* federal agency (not just DHS) require state and local governments to be "NIMS compliant" as a condition for receipt of federal preparedness grants.[92] Congress passed legislation adding new emergency healthcare authorities, with particular emphasis on preparation for a bioterrorism event.[93] Federal funding for state and local governments, first responders, and, to some extent, hospitals expanded dramatically to address the healthcare impact of potential terrorist attacks. Applicants for these billions of dollars in preparedness funding[94] had to demonstrate that they were "NIMS compliant." Although the emergency management system had traditionally focused only on *government* actions, legislation passed after September 11, 2001, required that all first responders, including the private owners of critical infrastructure, like hospitals and other medical facilities, be included in any emergency management plans and responses.[95] Other countries also re-examined and updated policies and procedures sometimes using the U.S. system as a model. Nevertheless, there remains no international consistency in approach, and the ministries with the lead for different types of events vary by country.

U.S. Federal Disaster Assistance Programs

If a catastrophic event creates emergency or disaster conditions that exceed the response capacity of state and local governments, the governor of a state may request the president of the United States to declare a "major disaster" or emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act).[96] This declaration, once issued, triggers eligibility for a number of different federal assistance programs, including both grant assistance and direct federal assistance. Several of these programs may be important for medical providers.

First, under the Stafford Act's Public Assistance Program, the federal government will provide a grant to "eligible applicants" of "not less than 75%" of the "eligible cost" of 1) performing certain emergency work to save lives, property, and the public health and safety; and 2) "repairing, restoring, replacing, or reconstructing" any damaged state or local government facilities, and eligible facilities of nonprofit organizations.[96] The Stafford Act's public assistance program, administered by FEMA within the DHS, can be critical to the financial survival of eligible entities affected by a declared disaster event. These include government and nonprofit healthcare providers, such as hospitals, clinics, ambulance services, and nursing homes.

Entities must meet certain requirements to be eligible for FEMA grant assistance. For example, the provision of emergency medical care is considered part of the normal business of a medical facility and the associated costs are not generally eligible for FEMA reimbursement, except in the most catastrophic of events.[97] The cost of creating additional facilities for emergency treatment may, however, be eligible for federal reimbursement during a catastrophic disaster.[98] Disaster assistance grants provided by FEMA are considered federal grants, subject to all of the boilerplate requirements of federal regulations,[99] including a requirement that all contracts for work be competitively bid.[100] Federal support will only be provided to supplement (not replace) assistance available from insurance, including employer-provided and individual policies, and Medicare/Medicaid.

U.S. Government Emergency Powers over Healthcare Facilities

State emergency statutes are drafted extremely broadly and provide enormous power to governors and other designated state officials for emergency response. As previously discussed, the scope of these powers allows substantial restrictions on individual liberties by evoking quarantine, isolation, and mandatory treatment or inoculations. The governors' powers over private property are similarly expansive. For example, in Georgia (and in many other states) the governor may "Commandeer or utilize any private property if he finds this necessary to cope with the emergency or disaster."[101]

Although the power to commandeer property is clear, any exercise of this power is subject to two critical requirements identified in the Fifth Amendment to the U.S. Constitution: "a person shall not *be deprived of life, liberty, or property, without due process of law . . . nor shall private property be taken for public use, without just compensation.*" Thus, an owner can object to seizure of the property and is entitled to due process to determine whether the seizure is justified. Similarly, the owner will be entitled to government compensation, measured by the value (as determined in court) of the property taken. In emergency circumstances, the due process and compensation hearings will occur after the government has taken possession of the property.

Although it may be authorized in law, commandeering of property in emergencies is highly disfavored. Effective catastrophic response by governments requires development of response plans, training of those who will implement them, and exercising those plans to ensure that they work. Governments recognize that the voluntary involvement of the private sector is fundamental to effective disaster response. In fact, the U.S. Congress has added a number of amendments to federal emergency management laws since Hurricane Katrina, directing FEMA and other agencies to include the private sector in emergency response plans and exercises. These statutory directives are repeated in Presidential Directives on National Preparedness.[102] Moreover, the emphasis in emergency planning is to identify emergency response needs in advance of the disaster and, if private sector response resources are required, to invite bids and proposals for contracts under which resources will be provided in an emergency. The cooperation from the private sector that is necessary for effective emergency planning and response is incompatible with any plan that relies on commandeering of property except in the most unusual of events – where a need could not have been anticipated, and circumstances precluded negotiation of contractual arrangements.

Emergency Waiver of U.S. State Laws

In addition to commandeering property, governors in many U.S. states have authority to temporarily suspend state laws and regulations that may interfere with the response or that become impossible to implement due to emergency conditions. California law states that "the Governor may suspend any regulatory statute . . . or the orders, rules, or regulations of any state agency . . . where he declares that compliance would . . . in any way prevent, hinder, or delay the mitigation of the effects of the emergency."[103] This provision can be applied to procedural and paperwork requirements of agencies, to medical staffing or other state regulatory requirements governing medical care, to substantive licensing provisions, or virtually any regulatory statute. For example, during the 2004 hurricane season (after Florida was struck by Hurricanes Charlie, Francis, Ivan, and Jean), Florida's state coordinating officer (with authority delegated from the governor) issued sixty-one Supplemental Orders that overrode statutory and regulatory requirements encompassing such varied subjects as property valuations for ad valorem taxes (taxes based on the value of real estate or personal property), the cancellation of homeowners' insurance policies, staffing requirements for home care services, and the reconstruction of facilities for cattle auctions.[104] Medical providers should be aware of this provision so that they can request waiver or suspension of requirements if necessary during a catastrophic event.

RECOMMENDATIONS FOR FURTHER RESEARCH

Comparative Research on Public Health Emergency Laws

The legal and regulatory issues that arise in catastrophic events are highly dependent on the particular legal system of the jurisdiction in which the catastrophe occurs. There are necessarily significant differences in the legal requirements faced by medical practitioners in a country with a national healthcare system (such as the United Kingdom), than in a country (such as the United States) where medical care is provided by private practitioners and healthcare facilities, albeit with heavy government involvement as insurer and regulator.

Despite these differences, each healthcare system needs to address the underlying legal issues discussed in this chapter during catastrophic events:

- How do the powers of government over healthcare practitioners and healthcare facilities change in catastrophic events?
- How does a nation or state modify its licensing and credentialing systems to allow practitioners, arriving from beyond its borders in the midst of an emergency, to help the nation's overwhelmed medical system in providing care to disaster victims?
- How does a nation protect the privacy of individual patients and their medical records when care is provided in catastrophic events?
- What limitations are there on the state's authority to order mandatory actions against consent of individuals and families (e.g., quarantine, isolation, evacuation, cordon sanitaire, mandatory treatment, mandatory inoculations, closure of gathering places)?
- How does the state modify its liability to assure that medical practitioners volunteer to assist in catastrophic events – without jeopardizing incentives to act with care under the circumstances?

This chapter focuses primarily on the ways in which the United States and its constituent states have addressed these issues. In the years since the September 11 terrorist attacks and Hurricane Katrina, the United States has dedicated extraordinary resources and attention to improving disaster readiness. Much of the guidance cited in this chapter was prepared by or partially funded by the U.S. DHS and HHS, including CDC.

Other nations will necessarily follow a different path in addressing these critical questions. Some of the practices of the United States may be unique to its peculiar, mixed public and private, fee for service, insurance-centric medical system – mixed together with a highly litigious legal system. But all nations either explicitly or implicitly, directly or by default, have laws, rules or practices that determine how the authorities of government over the medical care system change in emergencies, how catastrophic events will impact individual rights with respect to movement and treatment, and how medical practitioners and providers work together with health authorities to provide treatment to those in need.

Accordingly, an important area for future research is a comparative study of how different nations address the key issues faced in public health emergencies. This will help inform which legal regulatory issues in emergencies are a function of a particular legal or medical system – and which are simply a function of the challenge faced by *any* medical and legal system when its resources and facilities are damaged and overloaded in catastrophic events.

Public Health Emergency Legal Drills and Exercises

Whatever the form of the national medical system, it is critical that those participating in it understand the rules prior to the event that overwhelms the medical system. An emergency plan cannot guide response consistent with law, and protect medical responders from legal violations, if the rules that apply in emergencies are not known. Legal issues encountered in catastrophic events are extremely dependent on who is the client and how that client may be affected by the event – either as a person or entity suffering loss, as a government seeking to protect the welfare of residents and businesses, or as a medical worker providing services on a contract or volunteer basis to assist those in need.

The kinds of legal issues encountered include "zero sum gain" situations where different individuals or entities seek to redistribute the cost or pain of the catastrophe by imposing liability so that negligent providers must pay the injured patient for the loss caused by their acts. This can include nonmonetary or regulatory issues, where those subject to regulatory requirements are simply trying to ensure that they do not run afoul of the law when their world has been disrupted by a catastrophic event.

To reduce ambiguity in the aftermath of a disaster, it is useful to clarify the rules prior to an event. It is harder to act confidently if liability is a concern. The knowledge that authorities will grant a waiver of a rule when a disaster has rendered compliance much more difficult would improve a responder's ability to care for patients. A directive by the Uniform Law Commission to develop and then encourage legislative adoption of a Uniform Emergency Healthcare Practitioners Act is one example of a project that addresses these issues. Changing legislation may

not be the most important challenge. The U.S. CDC's Public Health Law Program convened a group of experts to develop a National Action Agenda for Public Health Legal Preparedness.[105] Although summit participants identified some areas in which new laws would be useful, they did not believe that developing new law was the first priority. Instead, they maintained that those who make, use, and are affected by the laws should become more familiar with the scope, substance, and application of existing laws.

Attention should not be limited to the written rules and laws that provide authority for officials to act. In the United States, after the ineffective management of Hurricane Katrina, studies found that the government may have had adequate legal *authority* to manage public health emergencies. However, public health and medical personnel may have had an inadequate *understanding* of existing laws and how they could be applied in the unusual environment of a public health emergency. Furthermore, even in cases when providers do comprehend the statute, existing laws have not necessarily been enacted with consideration for scenarios in which patient care needs massively exceed available medical and health resources, creating a scarce resource environment. Further work is needed to define an effective approach to these circumstances.[106,107]

Healthcare personnel will attempt to provide the best possible care during a disaster. Through the ethical principles of beneficence and non-malfeasance, medical providers aim to care for patients to the best of their abilities despite the lack of usual resources that exists during catastrophes. Accordingly, even if providers do comprehend existing laws, it is most likely not in the forefront of their minds when caring for the patients in front of them. In order to increase awareness of possible legal issues during disasters, exercises such as tabletop or full-scale drills need to be completed before the event.

These simulations serve to test emergency plans, train emergency responders, and familiarize all organizations that will be involved in emergency response with the other organizations, governments, and businesses with whom they will work during a catastrophic event. In most of these exercises, relatively little attention is paid to the kind of legal issues that are important to the government response – let alone that by private and nonprofit organizations. Future research in the area of legal issues in disasters will be significantly advanced through the careful development of a legal issues tabletop exercise.[108] Here, a potential public health emergency scenario is presented, and participants drawn from organizations that must respond determine what regulations and laws might interfere with providing medical care effectively. The result of the tabletop exercise would be the identification of legal obstacles that are as yet unresolved and require further research.

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8. Cal. B&P § 2395.
9. Cal. GC § 8659.
10. 42 U.S.C. § 14503.
11. Fla. Stat. § 252.51.
12. 42 U.S.C. § 239(2).
13. In the World Trade Center Disaster Site Litigation, 521 F.3d 169 (2d Cir. 2008), at pages 196–198 (Finds no immunity of government contractor for health damages suffered by employees who did not wear effective masks to protect lungs from toxic substances at disaster site, because government did not require contractor to abandon normal safety procedures.).
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59. *Id.*
60. *Kirk v. Wyman*, 83 S.C. 372 at 394 (1909)(dissenting).
61. *Id.*
62. *Wellman v. Faulkner*, 715 F.2d 269. In this case, the judge held that inadequate medical care and overcrowding in prison was unconstitutional.
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