RESEARCH

Addressing Gaps in Health Care Sector Legal Preparedness for Public Health Emergencies

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ABSTRACT

Health care providers and their legal counsel play pivotal roles in preparing for and responding to public health emergencies. Lawyers representing hospitals, health systems, and other health care provider components are being called upon to answer complex legal questions regarding public health preparedness issues that most providers have not previously faced. Many of these issues are legal issues with which public health officials should be familiar, and that can serve as a starting point for cross-sector legal preparedness planning involving both the public health and health care communities. This article examines legal issues that health care providers face in preparing for public health emergencies, and steps that providers, their legal counsel, and others can take to address those issues and to strengthen community preparedness. (*Disaster Med Public Health Preparedness.* 2008;2:50–56)

Key Words: health care providers; public health preparedness; legal issues; public health emergencies; public health law

Health care providers play a critical role in community preparedness for and response to public health emergencies: hospitals, clinicians, and other providers were pivotal to the response to the events of September 11, 2001, the anthrax attacks of 2001, the outbreak of severe acute respiratory syndrome (SARS) in 2003, and the hurricane disasters of 2005.[1] Hurricane Katrina necessitated the evacuation of at least 2500 patients from hospitals and nursing facilities in affected areas, and has focused even greater attention on the matter of emergency preparedness for the health care community,[2] as has the threat of an influenza pandemic.

Health lawyers representing hospitals, health systems, and other health care provider components are being called upon to answer complex legal questions for their clients regarding public health emergency preparedness and response issues that many have not previously faced. One expert has underscored this issue, noting that "the challenge for private practice attorneys will be understanding the vast expanse of state and federal laws, regulations, and agencies involved in order that they may best counsel health care clients prior to and during emergencies."[3]

The purpose of this article is to describe the legal issues that health care providers face in the context of public health emergencies, the critical roles their legal counsel play, and steps that can be taken to address and strengthen the legal preparedness of the entire health system for all-hazards public health emergencies. We first outline the roles and capacities of health lawyers to advise their clients on emergency preparedness issues. We then provide an overview of selected legal issues triggered by public health emergencies that have direct implications for the health care sector. We conclude by offering suggestions for actions to engage health care providers and their legal counsel, public health officials, and other community partners in strengthening community legal preparedness for public health emergencies.

HEALTH LAWYERS AND THE PRACTICE OF HEALTH LAW

Health law is "the legal domain that addresses the health care industry in all of its component parts, including providers, insurers, patients, drug companies, and researchers."[4] Health law is a relatively young area of legal specialization and is distinct from public health law in definition and scope of practice. Physicians and hospital administrators in the early 20th century had only limited and discrete uses for lawyers.[4] The 1965 enactment of Medicare and Medicaid stimulated greater legal counsel involvement with matters implicating reimbursement and payment obligations.[5] By the 1970s, hospitals and other providers added in-house counsel to provide legal services and advice on increasingly complex legal issues.[6] By the early 1980s, health law was expanding to encompass such issues as the right to die,[7] HIV/AIDS, and compliance with the growing number of federal and state laws regulating the health care industry.

Today, health law is a distinct, rapidly growing practice area. Some states, including Florida and Texas, offer health law certification to "distinguish those attorneys who practice substantially in the area from their colleagues who practice in complementary areas."[8] Health lawyers practice in major and boutique law firms, as well as in government, in-house, and academic settings. Two national professional associations have emerged in the field: the 9000-member American Health Lawyers Association (AHLA)[9] and the American Bar Association's Health Law Section, one of the bar association's newest and most rapidly growing sections.[10] Many state and local bar associations have specialty health law sections as well.

The health care industry has been called "the classic lawyer's playground."[4] Health lawyers represent clients in an industry that is among the largest and most regulated in the country,[11] comprising an estimated 545,000 establishments.[12] These institutions vary greatly by size, staffing patterns, and organizational structures,[12] but generally share many operational and organizational elements, as well as regulatory issues and challenges.

The scope of health law practice can vary substantially by jurisdiction, specific areas of law, and the nature of duties. Tasks range from providing advice and counsel on paramount federal legal authorities to full-service health law practice.[6] Salient issues emerging during the past decade have resulted from developments such as Congress' enactment of privacy laws (eg, the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) and a series of civil and criminal laws (eg, the Stark law and anti-kickback laws) that prohibit providers from profiting from some of the referrals and tests that they prescribe.

HEALTH LAWYERS AND LEGAL PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

Health lawyers and their clients must be familiar with the laws of the relevant jurisdictions related to public health emergencies and with the legal authorities of public health officials because they may impinge directly upon providers' interests and legal duties, responsibilities, and protected rights during emergencies. Few health lawyers, however, have had any training in public health law, and even fewer can be expected to be familiar with applicable law if called upon to advise their clients on legal issues associated with public health emergencies.[13] Although a large number of law schools offer health law courses,[14] comparatively few offer courses in public health law. Moreover, no law school routinely integrates the perspectives, values, and insights of public health as a discipline into core class requirements,[15] and only recently have law schools and providers of continuing legal education credits begun to recognize the need for offering public health and emergency law in their curricula.[16]

The emergency preparedness plans and policies of most health care providers reflect marginal recognition of legal issues. Many hospitals have on-site emergency managers or preparedness coordinators who provide guidance and direction on preparedness issues for the facility. In other instances, this responsibility falls under "other duties as required" for clinical managers, facilities staff, environmental health and safety officers, or administrative staff. Most hospitals and other licensed health care facilities are required to develop emergency management plans by state law, Occupational Safety and Health Administration requirements,[17] and the Joint Commission's policy.[18] Emergency managers and hospital preparedness coordinators are typically not trained, however, to spot potential liability and other legal issues that may arise in an emergency. Moreover, emergency management plans typically do not address legal requirements for disease surveillance or the implications of certain paramount legal authorities (eg, the Emergency Medical Treatment and Active Labor Act [EMTALA], HIPAA).

CRITICAL LEGAL PREPAREDNESS ISSUES FOR HEALTH CARE PROVIDERS

Recent public health emergencies have prompted some experts to identify specific issues relevant to the responsibilities of health lawyers.[19] Among these are legal issues that can serve as a starting point for cross-sector legal preparedness planning involving both the public health and health care sectors. Key among these issues are the legal requirements for health care providers in detecting public health threats; procedures and consequences of declarations of emergency, including the modification of paramount legal authorities relevant to health care sector response; and legal issues associated with protecting people, including patients, health care workers, and volunteers, and health care facilities during public health emergencies.

Detecting Threats to Public Health

Surveillance of public health conditions provides early warning of infectious disease outbreaks, biological or chemical terrorism, and other public health emergencies.[20] According to one "lessons learned" report, failure by health care providers to make timely reports of unusual symptoms in China's Guangdong Province in autumn 2002 "likely represented a missed opportunity for rapid outbreak investigation and disease control" during the initial stages of the 2003 SARS outbreak.[21] In the United States, health care providers significantly underreport many of the diseases required by law in all states to be reported to public health authorities. Contributing factors include lack of training in the legal requirements and the importance of disease reporting,[22] perceptions regarding the importance of physician–patient privilege, belief that reporting responsibility lies elsewhere,[23] and insufficient reward for reporting and punishment for not reporting.[24]

Health lawyers should proactively learn about disease reporting requirements to help facilitate client compliance. Because specific disease reporting requirements may vary by jurisdiction, this can begin with a review of applicable state statutes and administrative codes, and the rules and regulations of local boards of health and municipalities. Health

https://doi.org/10.1097/DMP.0b013e3181587cff Published online by Cambridge University Press

lawyers and their provider-clients also need to know that although routine public health reporting traditionally focuses on infectious disease threats, some jurisdictions now require reporting of noninfectious conditions, including environmental and toxic substance–related illnesses (eg, poisonings and injuries), biological markers for chronic disease,[25] critical biological agents,[26] and clusters of undiagnosed symptom complexes.[27] Diseases warranting prompt action or those with the potential to cause a public health emergency typically must be reported immediately. Health lawyers also should be aware of which persons and entities are required to report, the nature of such reports, the manner in which reports are made, the entities to which reports must be submitted, and penalties for failure to comply with reporting mandates.

Process and Consequences of Declarations of Emergency

The official declaration of a public health emergency directly affects health care providers. In advance of such an event, health lawyers should work to better understand how public health emergencies are declared on all levels of government and how they affect health care providers. For example, health care organizations' emergency response plans may be triggered by a state or federal emergency declaration; the emergency release of medical supplies (eg, the Strategic National Stockpile of pharmaceutical and medical supplies), funding, human, and other resources (eg, the Commissioned Corps of the US Public Health Service) can be triggered by an emergency declared under either the Stafford Act[28] or the Public Health Service Act,[29] or both; and declaration of a state public health emergency may also allow for expedited hiring and contracting for services.

Equally important is that a federal or state emergency declaration can enable the health care sector to more effectively provide care and services by temporary modification or waiver of specific requirements of certain laws applicable to the health care sector (Table 1). For example, section 319(a) of the Public Health Service Act allows the Secretary of the Department of Health and Human Services (HHS) to "take such action as may be appropriate to respond to the public health emergency."[30] Such action may include, for example, waivers of special provisions of the Social Security Act, authorization for use of medical products before Food and Drug Administration approval,[31] and enhanced control of dangerous biological agents and toxins.[32]

The developments associated with Hurricane Katrina illustrate relevant implications for health care providers and their legal counsel. In the immediate aftermath of the disaster, the HHS Secretary declared a public health emergency in affected states and waived certain requirements under the State Children's Health Insurance Program.[33] The waiver permitted providers to furnish services and materials to eligible recipients, while being assured reimbursement, even if the providers were unable to comply with all of the applicable laws. This waiver also relaxed sanctions and penalties under HIPAA,[34] EMTALA,[33] Medicaid and Medicare,[35]and the Stark self-referral law[36] (Table 1).

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Patient Protection and Management

Even a small-scale emergency can strain a health care facility's ability to track, treat, and communicate information about patients, as well as complicate admission, transfer, and discharge procedures. Legal preparedness for the health care sector must include planning for these and such issues as medical surge capacity and standards of care, pharmaceutical dispensation when prescription records cannot be located; patient privacy concerns; service as a quarantine and isolation facility; and mass decontamination.[37]

Hurricane Katrina demonstrated the critical need for anticipating legal issues related to evacuation of patients, including people who are critically ill, residents of nursing facilities, and vulnerable populations. For example, the mandatory evacuation order issued on August 28, 2005, by the City of New Orleans excluded hospitals and their patients.[38] Such exclusions are common because most hospitals have generators to maintain critical life support functions and are able to continue operations during emergencies. Furthermore, the evacuation of patients from hospitals or nursing facilities may be complicated by requirements for special transportation and facilities. Nonetheless, some New Orleans health care facilities that continued to operate during Hurricane Katrina ultimately were forced to attempt evacuation when conditions deteriorated. In December 2005 the Louisiana attorney general's office was reported to be investigating 6 hospitals and 4 nursing facilities to ascertain whether patients had been adequately protected or may have been abandoned.[39]

These patient management issues underscore 3 important considerations for providers and their legal counsel. First, ideally, local public health officials should be involved with the development of a health care institution's emergency response plan to ensure that clear protocols are in place to involve the correct officials and agencies in decisions to evacuate or close facilities. Second, public health officials and their counsel should also be invited to participate in the development of contractual transfer agreements to accommodate the transfer of patients during an emergency.[40] Third, health lawyers should review the

https://doi.org/10.1097/DMP.0b013e318158 7cff Published online by Cambridge University Press

TABLE 1

Selected Federal Laws and Related Waivers Implicated During Hurricane Katrina

Law	Citation	Status in Normal Times	Effect of Waiver as a Result of Emergency Declaration
Stark self-referral law	42 USCS § 1395nn et seq.	Prohibits physicians from referring patients to any health care entity where they or an immediate family member have either an ownership interest or compensatory relationship	HHS Secretary waived the sanctions that may be imposed under certain sections of the law. The waiver was intended to apply only to providers who furnished designated health services in good faith, but were unable to comply with the law as a result of the emergency. The waiver, however, was discretionary, and CMS retained the right to determine when a waiver would be appropriate, and the law was waived only to the extent necessary to ensure the availability of health care items and services to Medicare, Medicaid, and SCHIP enrollees.
HIPAA Privacy Rule	45 CFR Parts 160 and 164	Establishes regulations for covered entities' use and disclosure of PHI; when disclosing PHI, covered entities must ensure compliance with privacy rules and regulations	The waiver allowed patient information to be shared to assist in disaster relief efforts and to assist patients in receiving care. HHS guidelines suggest that providers covered by the HIPAA privacy rule could share pertinent information as necessary to provide treatment; identify, locate, and notify family members, guardians, or anyone else responsible for the individual's care; and prevent or lessen a serious and imminent threat to the health and safety of the person or public. Health care facilities maintaining a directory of patients were also authorized to tell people who inquired about individuals whether the individual was located at that facility and his or her general condition.
EMTALA	42 USCS § 1395dd et seq.	Establishes medical screening requirements for Medicare-participating hospitals with emergency departments Prohibits transfer of a patient with an emergency medical condition that has not been stabilized, unless individual consent is received or the benefits of transfer outweigh the costs	The waiver exempted hospitals from liability arising from noncompliance with EMTALA regulations. However, as applied to Hurricane Katrina, HHS Secretary only waived sanctions for noncompliance, indicating that a private cause of action could still be made against the particular hospital. The waiver did not exempt from sanctions discriminatory treatment of patients on the basis of ability to pay.
Medicare	42 USCS § 1395	Establishes a federally funded medical-assistance program for older adults, disabled workers, and people with end-stage renal disease	The waiver allowed Medicare Advantage enrollees to use out-of-network providers during an emergency. A presumption of eligibility replaced normal Medicare documentation requirements.
Medicaid	42 USCS §§ 1396 et seq.	Provides federal financial assistance to states with means-tested medical-assistance programs	Under the waiver agreement, Louisiana gained access to an uncompensated care fund to help pay physicians, hospitals, nursing facilities, and other providers who gave emergency medical treatment to victims of Katrina. The fund covered needed services, prescriptions, and medical equipment for those who are normally not eligible for Medicaid, including adults without children.

CMS indicates Centers for Medicare & Medicaid Services; SCHIP, State Children's Health Insurance Program; HIPAA, Health Insurance Portability and Accountability Act of 1996; PHI, protected health information; EMTALA, Emergency Medical Treatment and Active Labor Act.

requirements of EMTALA and other federal, state, and municipal laws as they participate in their clients' public health emergency planning.

Emergency Health Care Staffing

Hospitals in the United States employ nearly 5 million people and rank second as a source of jobs in the private sector.[41] A major challenge facing the health care sector in the context of public health emergencies is ensuring an adequate supply of health care workers. The 2003 SARS outbreak illustrated that disease epidemics can cause massive disruptions in and substantial health risks for the health care workforce.[42] In highly affected countries health care workers reportedly accounted for 37% to 63% of cases of suspected SARS.[43] Hospitals, providers, and others in the health care sector need to consider options for law-based strategies and

https://doi.org/10.1097/DMP.0b013e3181867ff Published online by Cambridge University Press

policies for potentially severe staff shortages; where appropriate, public health officials could be encouraged to seek opportunities to work with health care partners to address these needs.[44]

Relevant steps in preparedness for health care providers and their legal counsel include reviewing human resource polices to ensure that actions taken during a public health emergency comport with federal and state employment laws, particularly those related to medical leave and privacy. Certain federal laws, including the Family and Medical Leave Act, the Americans with Disabilities Act, and HIPAA, and many states' laws may restrict an employer's ability to require medical testing, to obtain health information, to deny leave, and to disclose employee health information to a third party. Health care workers' and volunteers' concerns about liability protections, reimbursement for costs associated with isolation and quarantine, and workers' compensation are also heightened during public health emergencies. As suggested in the HHS Pandemic Influenza Plan, preparedness planning on the state and local level should include a review of laws related to reimbursement for workers placed in quarantine or isolation and of workers' compensation laws specifically as they apply to health care workers.[45]

Health Care Facility Management

Many state legislatures and health departments have amended their public health emergency statutes or regulations based, in part, on the DRAFT Model State Emergency Health Powers Act (MSEHPA), commissioned by the Centers for Disease Control and Prevention and drafted in fall 2001 by the Center for Law and the Public's Health at Georgetown University and the Johns Hopkins University.[46] MSEHPA is a template for use by state and local governments to review and, where appropriate, update existing public health emergency–related laws or regulatory schemes to facilitate an effective public health response.[46] Among the topics addressed in MSEPHA with major implications for health care facilities is governmental access to and control of facilities and property during a public health emergency, contained in Article V, section 502 of the Act.[46] During a public health emergency pursuant to this section of the MSEHPA, health care facilities and supplies may be commandeered by order of the state public health authority. As of July 15, 2006, this section or portions thereof of the MSEHPA had been adopted by 16 states.[47]

Ideally, access to, management of, or control of a health care facility during a public health emergency will be a collaborative decision. Health lawyers should carefully review state emergency health laws and be prepared to counsel health care clients to ensure cooperation and compliance with relevant orders of public health authorities. To illustrate, New Mexico's Public Health Emergency Response Act authorizes the Secretary of Health, in coordination with the Secretary of Public Safety and Director of Homeland Security, to use, secure, or evaluate health care facilities (including laboratories, research facilities, pharmacies, and laundry, training, lodging, and food service facilities when used for or in connection with health-related activities) for public use and also authorizes the Secretary to regulate or ration health care supplies during a public health emergency.[48] New Mexico's public health emergency statute also addresses compensation to owners of health care facilities and for supplies that are acquired by the government under such circumstances.[49]

Volunteer Health Professionals

The availability and utilization of volunteer providers during public health emergencies can also implicate myriad legal concerns for providers and their legal counsel. For example, following the September 11, 2001 terrorist attacks in New York City, services volunteered by thousands of health care professionals could not be accepted because disruption of communications systems prevented verification of their licenses or credentials.[50] In 2002 Congress required HHS to create the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP) to assist state and local authorities in verifying the status of volunteer health care workers by developing standards for a national system of state-based registries and providing one-time supplemental funding and technical assistance to states for the development of their systems.[50] Although federally funded, the ESAR-VHP system is state operated and state run, and each system must include readily available, verifiable, and up-to-date information regarding volunteers' identity and licensing, credentialing, accreditation, and privileging in hospitals or other medical facilities.[51]

In September 2005, 13 states had rudimentary ESAR-VHP systems, with an additional 7 systems operating temporarily in response to Hurricane Katrina.[52] In spite of this, many volunteers who responded to hospitals' urgent calls for medical personnel through organized governmental programs (eg, ESAR-VHP, Medical Reserve Corps), private-sector efforts (eg, American Red Cross, Orthopaedic Trauma Association Mass Casualty Teams), the US Public Health Service, or as temporary federal employees, were initially delayed in their deployment due to specific legal uncertainties.[53] Furthermore, although more than 8300 health professionals were able to volunteer their assistance to victims of Hurricane Katrina,[52] there were indications that lack of understanding of public health emergency powers and legal protections for volunteers led to health care sector hesitation in the utilization of volunteer health care professionals.[53]

The Uniform Volunteer Health Practitioners Act is another law-based tool created to more effectively manage volunteer health professionals during a public health emergency. Approved by the National Conference of Commissioners on Uniform State Laws and the American Bar Association in summer 2006, with support from a number of public health and health care professional organizations, its 3 purposes relate to the establishment of a system to enable volunteer health professionals to offer services even when communica-

tions are disrupted, safeguards to ensure that volunteers are appropriately licensed and regulated, and state authority to regulate the scope and extent of services provided by volunteer health practitioners in a public health emergency.[54] The act is being circulated to state legislatures across the country by the National Conference of Commissioners on Uniform State Laws and, as of July 18, 2007, 7 states and 1 territory had introduced the measure.[55]

ACTIONS TO ENGAGE HEALTH CARE PROVIDERS AND THEIR LEGAL COUNSEL IN PUBLIC HEALTH EMERGENCY LEGAL PREPAREDNESS

Community legal preparedness depends on the coordinated application of legal authorities across the public health and health care sectors and across jurisdictions. To this end, health lawyers and other representatives of the health care sector should take part in state and community preparedness task forces and in drafting state and community emergency response plans. Jointly developed legal preparedness checklists, educational programming, and other tools can also help to strengthen public health–health care linkages and improve community public health preparedness.

For example, following the 2003 SARS outbreak, the AHLA's Public Interest Committee convened a task force of health lawyers and public health lawyers to produce the comprehensive Emergency Preparedness and Response Checklist: Beyond the Emergency Management Plan for use by health lawyers.[56] In late 2005, based on legal lessons learned as a result of hurricanes Katrina and Rita, AHLA formed a similar task force to develop a supplement to the 2003 checklist entitled "Lessons Learned from the Gulf Coast Hurricanes."[57] Recognizing that health lawyers and other members of the bar will "be called upon to assist in, comment on, or offer advice with respect to" community public health preparedness efforts, the American Bar Association's House of Delegates passed a resolution in August 2004 submitted by its Health Law Section, urging members and lawyers throughout the country to improve their knowledge of public health law to better serve their clients and the public.[15] The AHLA checklists and American Bar Association resolution represent significant steps at the national level to strengthen legal preparedness for public health emergencies.

To be of practical value, however, these checklists, resolutions, and other resources must be coupled with networking and training opportunities. By including health lawyers and their clients in emergency preparedness exercises, workshops, and educational programming, the public health community can provide health lawyers and their clients with opportunities to explore cross-sector legal issues and to expand their legal competencies. For example, through December 2006, more than 1000 lawyers and their clients had participated in customized community workshops based on the Community Public Health Legal Preparedness Initiative, a collaborative project of the Centers for Disease Control and Prevention, the American Bar Association, and the nonprofit Public Health Law Association.[58] The initiative seeks to inform health lawyers about the laws pertinent to public health emergencies in their own jurisdictions, clarify the legal issues their clients may face in a public health emergency, and form working partnerships between public health and health care legal counsel in a given jurisdiction. In many communities these workshops represent critical first opportunities for health lawyers and their clients to engage with public health officials and public health legal counsel on these issues. These legal preparedness workshops and other, similar training opportunities offer an approach to building practical partnerships to aid health lawyers and their clients in understanding legal issues triggered by public health emergencies, including but not limited to those issues presented in this article.

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The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention or the Department of Health and Human Services. The article is not intended to provide a legal interpretation or opinion about federal or individual state laws, nor does it constitute legal advice. Readers who seek legal interpretation or advice on federal, state, or local law should consult a qualified attorney in the relevant jurisdiction.

Received for publication June 7, 2007; accepted August 15, 2007.

ISSN: 1935-7893

DOI: 10.1097/DMP.0b013e3181587cff

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