Legal Issues Related to Hospital Response During a Pandemic[1]

PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER HOSPITAL ACTION
I. EMTALA			
General **EMTALA** application during pandemic	Though EMTALA is not disregarded during any emergency, EMTALA sanctions may be waived in certain situations. If both the President of the United States and the Secretary of the US Department of Health and Human Services declare a public health emergency, the Secretary may waive EMTALA and other regulatory sanctions. EMTALA is never intended to become a barrier to the provision of equitable and responsible medical care.	Section 1135 of the Social Security Act permits the Secretary of DHHS to temporarily waive or modify the application of requirements of the Medicare, Medicaid, and SCHIP programs, including EMTALA, during an emergency such as a pandemic. The Secretary can waive EMTALA sanctions for: (A) a transfer of an individual who has not been stabilized if the transfer arises out of the circumstances of the	Per CMS, hospitals are not required to request a waiver of sanctions under EMTALA if they are located in the emergency area and have activated their disaster plans and are operating under the general EMTALA waiver. However, hospitals that activate their hospitals disaster plan and are invoking the permitted EMTALA waiver of sanctions must provide notice to their State Survey Agency, who will forward the information to their CMS Regional office. CMS, *Provider Survey & Certification FAQs for Declared Public Health Emergencies (All Hazards)* document, updated 8/31/2008, page 19, Question J-3.

[1] This document was prepared by a workgroup convened by the Greater New York Hospital Association (GNYHA) in coordination with the New York City Department of Health and Mental Hygiene (DOHMH) through a grant of the Centers for Disease Control and Prevention (CDC). It is not intended as legal advice or as a definitive treatment of these issues. This chart was completed in the summer of 2009, and there may be subsequent evolutions in the law.

Over the course of this project, contributors identified general areas of law as well as specific statutes and regulations that would require relaxation or modification in case of a pandemic, including several referenced in this chart. GNYHA and its members are compiling specific recommendations in these areas and providing them to the New York State Department of Health to assist in its legal pandemic planning.

		emergency; and (B) The direction or relocation of an individual to receive medical screening in an alternative location pursuant to an appropriate State emergency preparedness plan or a State pandemic preparedness plan, whichever is applicable. Such a waiver may only be enacted in a geographical region in which there is: (A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and (B) A public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act. An EMTALA waiver shall only be in effect if the provider's actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay. If the public health emergency involves a pandemic infections disease, the duration of the waiver shall be determined based on the	http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf

		duration of the emergency. See 42 U.S.C. 1320b–5**,** Authority to Waive Requirements During National Emergencies http://www.ssa.gov/OP_Home/ssact/title11/1135.htm EMTALA regulations reflect the Secretary's waiver authority. See 42 C.F.R. § 489.24(a)(2) http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=d4200df64442b5decc9e4c40151f9ead&c=ecfr&tpl=/ecfrbrowse/Title42/42cfrv4_02.tpl See also CMS Revised State Operations Manual Appendix V-EMTALA March 21, 2008: http://www.cms.hhs.gov/surveycertificationgeninfo/downloads/SCLetter08-15.pdf March 6, 2009: http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09-26.pdf See additional CMS commentary in the agency's, *Provider Survey & Certification FAQs for Declared Public Health Emergencies (All Hazards)* document, updated 8/31/2008, page 19, Section J.	

		http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf Find commentary issued during the 2009 H1N1 episode in the attached Q&A (question 1): http://www.cms.hhs.gov/Emergency/Downloads/H1N1_QsAs.pdf CMS, Influenza Pandemic Emergency Preparedness – Waiver of Certain Medicare Requirements (March 2009). http://www.cms.hhs.gov/Transmittals/downloads/R454OTN.pdf	
Hospitals may wish to **send patients to locations outside of their Emergency Departments for pandemic screenings**, as occurred during the spring 2009 H1N1 event. They fear EMTALA sanctions for doing so.	In the spring of 2009, CMS Central Office advised New York City hospitals – particularly those experiencing significant increases in their Emergency Department visits – that they could permissibly send patients seeking a flu screening to a specific area of the hospital without violating EMTALA. The CMS staff noted that all existing EMTALA requirements would need to be met, including record keeping and non-discrimination, and that all patients seeking an H1N1 screening would have to be treated the same.	This information was provided over the phone by CMS. It is supported by: http://www.cms.hhs.gov/Emergency/Downloads/H1N1_QsAs.pdf. (See question 4.)	Hospitals should develop an appropriate plan to contend with potential issues related to overcrowding of Emergency Departments. While the information conveyed by CMS is not meant to suggest hospitals can ignore EMTALA, there are appropriate ways to proceed that will meet hospital needs and ensure compliance.
Hospitals are concerned that they	Hospitals may be required to act outside of the confines of a plan,	CMS staff, DOH staff	Hospitals must consider the possibility that they will have to exercise independent

may have to respond to a **localized influenza event** or otherwise **act outside the bounds of a state emergency response plan.** They fear they will be liable under EMTALA for their independent decisions.	either because one does not exist, one has not yet been activated, or one is not detailed enough to anticipate every possible emergency situation, including localized emergencies. If a hospital must refer/ transfer patients prior to or in the absence of governmental direction, it should undertake some form of medical screening examination necessary to determine whether the patient is in the category of those who should be referred/ transferred. The referring hospital should also coordinate referrals with the recipient faculty or site, not merely send patients out without having established a plan for them. In addition, EMTALA waivers may be specified to a particular geographic area or even to a specific hospital, so it is possible that a hospital may benefit from a waiver of EMTALA sanctions even if the problem they are confronting is not State-wide.	In the proposed IPPS 2010 rule, CMS is "proposing to revise the regulations to state that the Secretary has the authority to apply the waiver of EMTALA sanctions to one or more hospitals in a portion of an emergency area or a portion of an emergency period." CMS notes that his revision is not a change in the Secretary's existing authority but a clarification. See 74 Fed Reg 98 (May 22, 2009), page 24195. http://edocket.access.gpo.gov/2009/pdf/E9-10458.pdf	judgment in an emergency situation. They are encouraged to develop their own emergency response guidelines, which respect the principles of EMTALA while allowing for medically sound and appropriate patient care in an emergency. Hospitals' emergency response plans should anticipate the possibility that the hospital might not be able to provide definitive care to all patients during a pandemic. Hospitals are encouraged to train their staff on their written policies and procedures advance of an emergency. They are also encouraged to communicate with CMS and DOH staff as often as possible in such a situation.

Hospitals are concerned that it will be considered an EMTALA violation if **they do not have medical records available because of the disaster**. Given the potentially large number of presenting patients and the intensity of an emergency situation, they fear that **thorough documentation or maintenance of medical records is unrealistic if not impossible**.	During a declared public health emergency, CMS would take a liberal view of the situation. However, subsequent medical records would have to reflect the lack of prior documentation.	CMS's *Provider Survey & Certification FAQs for Declared Public Health Emergencies (All Hazards)* document, updated 8/31/2008, page 19, J-4 http://www.cms.hhs.gov/SurveyCertEmergPrep/Downloads/AllHazardsFAQs.pdf Discussions with DOH and CMS staff have supported this approach.	In an emergency situation, hospital administrators and ED doctors should remember the importance and utility of maintaining some form of patient tracking system. The need for such a system should be incorporated into a hospital's emergency preparation activities and training in advance of an emergency situation. Following 9/11, DOH recommended that hospitals keep track of patient names and phone numbers to the extent possible. Such an approach seems realistic, given the challenges confronting hospital EDs during emergency situations. After Hurricane Katrina, hospitals and regulators made a wide range of allowances for evacuees who did not have adequate identification with them.

PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER HOSPITAL ACTION
II. VOLUNTEERS & WORK FORCE LIABILITY			
How can **hospitals use volunteers during an emergency situation like a pandemic** influenza with maximum legal protection?	Hospitals should work through existing volunteer programs: **the NYC Medical Reserve Corps and the NY State Volunteer Program, and the Federal Disaster Management Assistance Team (DMAT)** in that order. Requests will initially go to the City, then the State and Federal governments as resources require. Volunteers requested through this process have some legal protections attached and are pre-credentialed in advance. Medical and other volunteers are encouraged to pre-register through the City or State programs, and they are pre-screened and credentialed. Hospitals can then request assistance in time of need: they are to go the City program first by contacting GNYHA, HHC, or OEM; these groups will then coordinate with the MRC manager.	**New York City Medical Reserve Corps Program:** • If activated from the NYC MRC list, volunteers are indemnified through General Municipal Law Section 50-k and will be considered extensions of the City's workforce. • NYC would provide legal defense and indemnification to volunteers, regardless of whether or not their own malpractice insurance was used, provided that volunteers follow all instructions given by NYC and do not perform acts that may be considered grossly negligent. General Municipal Law 50-K http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS See also background information on MRCs: http://www.nyc.gov/html/doh/ht	Hospitals should coordinate with DOH whenever possible to seek and provide volunteers in order to receive the protection of Public Officers Law 17. In addition, hospitals should consider how to approach this issue and integrate it into emergency response plans, training, and education. All would-be volunteers are encouraged to register with a State or local volunteer network before an emergency, thereby lessening the risk of liability to themselves and facilities. In Spring 2009, NYC Medical Reserve Corps will begin to use the NYS Volunteer Management System database to register new volunteers and manage its data. **This will not affect the local affiliation of NYC MRC volunteers;** training and program management for local deployments will continue to be under the direction of the NYC DOHMH. However, interested volunteers will have the opportunity to register as State volunteers if they wish to do so with one easy registration.

		ml/em/mrc.shtml http://www.medicalreservecorps.gov/HomePage **New York State Volunteer Program:** • If activated as part of the State program, the State would provide legal defense and indemnification to volunteers, provided that volunteer performed services within the scope of his/her duties and did not engage in intentional wrongdoings. Public Officers Law 17 http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS • The State program is composed of health professionals from across NY State who agree to volunteer on behalf of the NY State Department of Health (NYSDOH) throughout NY State when local resources are nonexistent or depleted. • Managed by the NY State Department of Health (NYSDOH); county health departments may obtain the	

		names of State volunteers registered from their area who also wish to be considered local volunteers. See background information on ServNY: https://apps.nyhealth.gov/vms/appmanager/vms/public	

Will volunteers have **malpractice insurance or indemnification** in an emergency like a pandemic influenza?	The type of volunteer indemnification provided is contingent upon who activates and deploys the volunteer to the emergency response site.	If activated from the NYC MRC list, volunteers are indemnified through General Municipal Law Section 50-k and will be considered extensions of the City's workforce. NYC would provide defense and indemnification to volunteers, regardless of whether or not their own malpractice insurance was used, provided that volunteers follow all instructions given by NYC and do not perform acts that may be considered grossly negligent. Under State law, medical professionals will be provided secondary indemnification under Public Officers Law 17 if dispatched by the State as part of a state-sponsored volunteer program in an emergency. This indemnification extends to professionals dispatched to any location, whether in or outside of a hospital. This indemnification applies to all appropriately dispatched New York State licensed medical professionals. All volunteers will still be required to follow standards of care established by the profession, regardless of the site of service.	It is recommended that all NYC-based providers register with the NYC MRC and participate in the ServNY program.

What **Federal protections are in place to protect health care volunteers from liability** for claims arising from the administration and use of specified countermeasures?	**The Public Readiness and Emergency Preparedness Act (PREP Act)** provides significant immunity protections in those situations where it applies. However, **there is incomplete coverage for activities related to responding to Pandemic Influenza.** There is lack of clarity as to the full extent of its coverage at any given moment given the mutable nature of declarations under the Act and lack of testing in court. The Volunteer Protection Act of 1997 (VPA), P.L. 105-19, became effective September 16, 1997. It immunizes individuals who do volunteer work for nonprofit organizations or governmental entities from liability for ordinary negligence in the course of their volunteer work. It also limits punitive damages and non-economic damages against volunteers who are held liable. During Hurricane Katrina, HHS deployed volunteer healthcare workers who had been through a Federal credentialing process. These employees were considered "non-paid temporary employees" and were authorized to work in designated regions requiring disaster assistance. These volunteers were then	Section 319F-3 of the Public Health Service Act, 42 U.S.C. §247d-6d The Act empowers the Secretary of HHS to issue emergency declarations absent a declared state of emergency, to provide immunity for liability for claims (other than those for "willful misconduct") arising from the administration and use of specified countermeasures to specified conditions. As of the July 6, 2009, declarations have been issued for Pandemic Influenza vaccines; Tamiflu and Relenza for Pandemic Influenza; any drug (etc.) that is either licensed, undergoing clinical trials or available for use under an Emergency Use Authorization for Anthrax, Botulism, Smallpox, and Acute Radiation Syndrome; and personal protective equipment, specific diagnostics and respiratory support devices used for pandemic influenza.	For the purposes of planning for Pandemic Influenza, the current declarations are limited as to their coverage. Reliance on PREP Act coverage is made difficult by virtue of the fact that the protections are dependent upon the content of declarations by the Secretary of HHS and those declarations can be amended by the Secretary at any time. In addition, the Act is untested in court and, therefore, the full extent of the protections is unclear for novel fact patterns. For example, the current declarations specify that the Act does not protect government planners if the countermeasure had been seized under eminent domain; however, the Act is not clear as to whether a governmental entity would still lose these protections if provided with countermeasures seized by another government (e.g., a county government using countermeasures seized by a state government).

	granted liability protection under the Federal Tort Claims Act (FTCA) and workers' compensation rights under the Federal Employees Compensation Act (FECA).	Under each declaration to date, liability protections for those prescribing, distributing or administering covered countermeasures to patients for the specified conditions only exist in the event of a declared state of emergency (federal, state or local). Currently, the federal declaration of a public health emergency should be sufficient to trigger the protections afforded to the countermeasures specified in the declarations for pandemic influenza; although the original declaration is due to expire, the expectation is that it will be extended. Even for claims alleging willful misconduct, the Act places onerous restrictions on plaintiffs and provides that there is no willful misconduct as a matter of law if the death or serious injury is reported to the Secretary or a state or local program planner within 7 days of learning of such death or injury. The Secretary of HHS has full control over the content of declarations under the Act (within the confines of the statute) and there are no requirements in the Act regarding prior notice for any	

		such changes. See PREP Act: ftp://ftp.hrsa.gov/countermeasurescomp/Public_Readiness_and_Emergency_Preparedness_Act.pdf	
Hospitals are uncertain as to how to **privilege and credential clinical volunteers** during an emergency. Some hospitals are reluctant to use volunteers at all because of the fear of liability.	HHS requires all states to implement programs for credentialing volunteers consistent with its "Emergency System for the Advanced Registration of Volunteer Health Professionals" (ESAR-VHP) Draft Compliance Requirements. New York State's ServNY program, drawing on MRCs in New York City and around the State, meets the ESAR-VHP requirements and allows hospitals to receive pre-screened and credentialed medical and non-medical volunteers at all levels. The Joint Commission's standard EM.02.02.13 (formerly appearing as MS 4.110) allows hospitals to grant disaster privileges to volunteers eligible to be licensed independent practitioners when the institution's emergency management plan has been activated and the organization is unable to meet immediate patient needs. New York State's Department of Health endorsed the standard in 2004.	See ServNY information: https://apps.nyhealth.gov/vms/appmanager/vms/public Joint Commission Standard MS 4.110, DOH August 6, 2004 Advisory http://www.gnyha.org/345/File.aspx	

Are volunteers acting outside formalized volunteer systems protected by the common law concept of the **"Good Samaritan?"**	**The Good Samaritan Law is not in fact a single statute;** it is a collection of laws that provide protection from civil judgments when a healthcare provider, first responder or lay person provides emergency care to a sick or injured individual, outside of a facility where the caregiver ordinarily provides patient care.	NYS Education Law § 6527(2) provides that any licensed physician who voluntarily and without the expectation of monetary compensation renders first aid or emergency treatment at the scene of an accident or other emergency, outside a hospital, doctor's office or any other place having proper and necessary medical equipment, to a person who is unconscious, ill or injured, shall not be liable for damages for injuries alleged to have been sustained by such person or for damages for the death of such person alleged to have occurred by reason of an act or omission in the rendering of such first aid or emergency treatment unless it is established that such injuries were or such death was caused by gross negligence on the part of such physician. http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS Similar protections are also extended to: ▪ physicians who provide indirect medical control to a voluntary ambulance	Hospitals and individual practicioners should rely on the formalized volunteer programs as much as possible; many hospitals will refuse to accept individual volunteers.

		service or voluntary advanced life support first response service. NYS Public Health Law Section 3013; ▪ a licensed dentist, registered professional nurse or licensed practical nurse, physician's assistant and specialist assistant, podiatrist or physical therapist; ▪ certified first responders, emergency medical technicians, advanced emergency medical technicians or a person acting under their direction (NYS Public Health Law section 3013(1), ▪ any lay person (NYS Public Health Law 3000-A) http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS	

		Each of these statutes attempts to remove the impediment to provision of care by individuals who are willing and able to provide assistance, while continuing to hold healthcare professionals to the standard of care when they are treating patients in their usual practice setting.	

PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER HOSPITAL ACTION
Hospitals expect that **out-of-state physicians will volunteer** their services during an emergency. Though hospitals may need this assistance, they are reluctant to allow doctors not licensed by New York State to work in their hospitals. They are curious if there is any type of **licensing reciprocity between states** for emergencies.	Hospitals' first course of action should be to make a request through their State systems to receive Federal assistance through a Disaster Management Assistance Team (DMAT); there is an extensive Federal structure for supplying a coordinated team of pre-trained and pre-screened medical volunteers. Hospitals are encouraged to work within existing volunteer systems. Any licensed volunteer professionals from out of state who respond to an emergency in NYS through the Emergency Management Assistance Compact ("EMAC") are considered licensed in NYS if they are currently licensed in their home state. During Hurricane Katrina, HHS deployed volunteer healthcare workers who had been through a Federal credentialing process. These employees were considered "non-paid temporary employees" and	Information on Disaster Management Assistance Teams from the U.S. Department of Health and Human Services http://www.hhs.gov/aspr/opeo/ndms/teams/dmat.html Emergency Management Assistance Compact materials http://www.emacweb.org/ (See also Exec Law §29-g regarding EMAC) http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS See also Secretarial authority at 42 USC 1320b-5(b)(2). http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00001320---b005-.html See also HHS guidance on volunteers during Hurricane Katrina https://volunteer.ccrf.hhs.gov/ See also resources from the Center for Law and the Public's Health at Georgetown and Johns	Hospitals should consider how to approach this problem in advance of an emergency situation, and ED personnel should be trained on the hospital's policies.

	were authorized to work in designated regions requiring disaster assistance. In addition, the Secretary of HHS is permitted to waive State licensing requirements in the event of an emergency for health care professionals with equivalent licensing in another State.	Hopkins Universities http://www.publichealthlaw.net/Research/Katrina.htm	

RELATED PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER HOSPITAL ACTION
Hospitals fear institutional **liability for actions taken by their staff or volunteers during an emergency**. They are not certain if **malpractice insurance** would cover such liability.	As of late June 2009, FOJP reports that facilities should have an MOU regarding sharing of personnel with another facility during an emergency that includes a provision about assumption of liability/ insurance coverage. Facilities should each share the MOU with their carrier. Per FOJP, such an MOU should not increase premiums unless the facility assumes completely new obligations, which is unlikely. In addition, registering with a bona fide volunteer network, as discussed above, before an emergency decreases the risk of liability for individuals and their facilities.	See GNYHA Model MOU Regarding Sharing of Personnel During a Disaster http://www.gnyha.org/eprc/general/workforce_volunteer/	Hospitals should consult with their carrier and consider executing the MOU referenced in this chart. Hospitals should prepare in advance for how to utilize any volunteers who may be necessary in an emergency. Hospitals may establish policies for utilizing volunteers that include supervision of volunteers providing patient care by appropriate clinical staff.

What type of **Federal protection is available for nonprofit organizations** like hospitals, as opposed to protections for the individual volunteer?	Federal law offers limited protections to the organizations themselves.	The Volunteer Protection Act of 1997 (VPA), P.L. 105-19, became effective September 16, 1997. It immunizes individuals who do volunteer work for nonprofit organizations or governmental entities from liability for ordinary negligence in the course of their volunteer work. It also limits punitive damages and non-economic damages against volunteers who are held liable. It does not affect the liability of nonprofit organizations or governmental entities. Liability limitation applies to volunteers, not to nonprofit organizations and governmental entities; they may continue to be held vicariously liable, even if volunteers are immune. http://ws1000-555.gnyha.com/cgi-bin/patience.cgi?id=aac203d0-7267-11de-896f-f1fe323829d7	All hospitals, healthcare providers, etc. should still seriously consider the protective benefits of general liability insurance, since the VPA applies exclusively to volunteers, not the vicarious liability of nonprofit organizations ands governmental entities themselves.

In an emergency, hospitals fear that all staff, including residents, will want and need to work extended hours. As a result, they may necessarily violate the State's **resident work hour** requirements. They fear liability for such an infraction yet worry that it will be impossible to monitor staff hours during an emergency.	DOH has stated previously that it cannot waive the resident work hour requirements in advance. However, it would consider extenuating circumstances like a disaster when evaluating residents' schedules or work hours. Hypothetically, if a hospital were to have an IPRO or other review shortly after an emergency, DOH would use "very good judgment" to evaluate any anomalies in work hours. They caution, however, that the hospital would face problems if DOH were to re-evaluate after a few months and find the same violations of resident work hours. Once again, hospitals should bear in mind that neither Federal nor State regulators have an interest in finding violations while hospitals are struggling to serve communities recovering from emergencies. Both hospitals and regulators should rely on professional judgment and common sense.	DOH staff gave this advice over the phone but said it was not able to issue more definitive written guidance. See also 10 NYCRR 405 *et seq* http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm	Hospitals acknowledge that they must assign their staffs appropriately. Some hospitals note that they have required their residents to take a break during emergencies, even though most physicians are unwilling to leave their posts. Hospitals should review this issue and include it in its emergency response plan and staff education.

PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER ACTION
III. ALTERNATE CARE SITE CONSIDERATIONS			
Hospitals anticipate **moving patients to alternative patient care space to accommodate patient surge during a pandemic**. The patients placed in an alternative site may be those already admitted to the hospital (i.e., those who are not victims of the pandemic), or they may be those who come to the hospital for influenza treatment. In either case, such a location shift may be necessary logistically, but hospitals fear they will face **State sanctions for treating patients in an alternative space or outside of the hospital entirely.**	The Joint Commission encourages identification of "latent" space and employing other surge capacity tactics as part of emergency planning. Further, DOH regulations indicate "a hospital may temporarily exceed [the bed capacity specified in the operating certificate] in an emergency." *See* 10 NYCRR §401.2(a). However, DOH has stated previously that if hospitals move patients to alternative spaces and the State does not activate an emergency plan or response, hospitals may not be reimbursed for treating these patients. In addition, the State has noted there would have to be some evaluation of who can be moved and who cannot. DOH cannot provide a definitive answer but encourages hospitals to use	*See* 10 NYCRR §401.2(a). http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm Consult with DOH staff See Joint Commission White Paper on creating emergency preparedness systems. http://www.jointcommission.org/NR/rdonlyres/9C8DE572-5D7A-4F28-AB84-3741EC82AF98/0/emergency_preparedness.pdf See also Joint Commission subsequent paper on "surge hospitals" http://www.jointcommission.org/NR/rdonlyres/802E9DA4-AE80-4584-A205-48989C5BD684/0/surge_hospital.pdf	Hospitals should coordinate with NYCDOHMH and, as appropriate, request situation-specific guidance from DOH, including guidance regarding eventual reimbursements Hospitals should plan for the use of alternative space Hospitals should have documented policies and train staff on use of non-traditional patient space and alternative care sites. Hospitals may review the non-traditional patient care settings created by HHS following Hurricane Katrina, including those created in New York State for evacuees.

Hospitals are also concerned about the implications of moving patients **if the State has not yet or does not activate its emergency plan or response**. They may need to act before they receive any definitive word from the State.	common sense and to call the State if possible for guidance in an emergency.		
In a pandemic, hospitals may have to **discharge the healthiest of its inpatients** in order to accommodate the surge of patients requiring care. Hospitals fear that they may not have the time or staff available **to comply with each element of the NYS safe discharge regulations**.	DOH cannot waive the safe discharge regs or any other hospital requirements in advance. However, DOH states that it would take the emergency into consideration in the event of a concern. DOH is not aware of issuing any citations to any hospitals after 9/11 regarding discharge regs. DOH has indicated support for using home care nurses as support staff if there is a need for unexpected discharge to accommodate surge. Hospitals should bear in mind that neither Federal nor State regulators have an interest in finding violations while hospitals are struggling to serve communities recovering from emergencies. Both hospitals	DOH staff provided this advice by phone but they are unable to issue more definitive written guidance. See also 10 NYCRR 405.9 http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm	Hospitals should incorporate guidelines for patient discharge in its emergency response plan and ensure that staff is familiar with these guidelines. NYCDOHMH has developed tools to assist hospitals. See http://www.nyc.gov/html/doh/html/bhpp/bhpp.shtml Hospitals have proposed a variety of solutions, including: ▪ Establishing discharge prescription stations to help patients with meds; ▪ Employing discharge planners and case managers; ▪ Using nursing homes to house and treat non-emergency patients; ▪ Relying on VNS and other home care and agencies to treat discharged or influenza patients

	and regulators should rely on common sense and professional judgment.		
Can **nursing home and other continuing care facilities** be used as **alternate care sites** in the event of an influenza pandemic? .	Alternate site beds could be preferable to hospitals for those who require convalescent care before returning to the community after the acute stage of the disease has been survived. However, New York State regulations prohibit the admission of anyone with a communicable disease into a nursing home or continuing care facility. Thus, such facilities could only function as alternate care sites for hospital patients that are not infectious or not hospitalized due to the pandemic. During a pandemic, nursing homes may also face increased pressure to keep their own patients within the facility, rather than send them to a hospital if infected due to the potential lack of resources and necessary rationing that will be taking place.	10 NYCRR 415.26(i)(1)(viii)(d) states that a resident suffering from a communicable disease shall not be admitted or retained unless a physician certifies in writing that transmissibility is negligible, and poses no danger to other residents, or the facility is staffed and equipped to manage such cases without endangering the health of other residents; http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm	**The State should consider relaxing nursing home regulations** like10 NYCRR 415.26(i)(1)(viii)(d) both to permit the nursing home to function as an alternate care site as necessary and to allow current nursing home patients to stay at their own facilities, rather than being sent to a hospital. Futher, **we suggest the development of guidelines for what facilities and equipment would be required for use in an alternative, temporary space to handle pandemic flu**. Finally, there should be constant communication between nursing homes and their clients and clients' families prior to and during a pandemic in consideration of these issues.

If patients need to be cared for at home during an influenza pandemic, **can home care agencies assist in their treatment**?	Certified Home Health Agencies (CHHAs) and Long Term Home Health Care Programs (LTHHCPs) work under very specific regulatory requirements that may prove to create a barrier to rapid utilization of needed services.	10 NYCRR 763.1 *et seq* regulates home care programs. These requirements cover patients' rights, patient care, policies and procedures, patient assessment and plan of care, and patient records. http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/11fb5c7998a73bcc852565a1004e9f87/8525652c00680c3e8525652b0061dd90?OpenDocument	It may be advisable for the State to create guidance so that patients who can be cared for at home safely and legally. This could involve relaxation of relevant regulations, including 10 NYCRR 763.1 *et seq.* The City should also consider utilizing social service agencies to provide support and connection to individuals restricted to their homes.
How will our existing systems handle the **increased need for hospice or palliative care services**?	Trained personnel will be needed to assist in palliative care for dying patients regardless of care setting. Hospice and palliative care providers will be in high demand.	10 NYCRR 790 *et seq* establishes requirements for hospice programs. These requirements include patient and family rights, plan of care, and medical record requirements. http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm	Health care providers should invest in preemptive cross training to allow more health care professionals and other individuals capable of being appropriately trained to address expanded palliative care needs. There will be a particular need for counseling and support beyond writing prescriptions and other clinical services.

IV. INDIVIDUAL AND CIVIL RIGHTS

PERCEIVED OBSTACLE	CONSIDERATIONS FOR ANALYSIS	AVAILABLE AUTHORITY	SUGGESTED GUIDELINES FOR FURTHER ACTION
Are there specific steps hospitals should take to **protect patients' civil rights** in case of an influenza pandemic?	Per the United States Department of Justice, it is important to remain vigilant in ensuring civil rights compliance. Access to accurate emergency and health information is critical to providing all people with the ability to make informed decisions and protect themselves, their families, and the community at large. In addition, we must ensure that unfounded fear and/or prejudice do not limit access to housing, education, benefits, services, employment, and information on account of race, color, national origin, disability, or other protected status.	Federal authorities relating to civil rights and pandemic can be found through the Department of Health and Human Services and the Department of Justice at: http://www.hhs.gov/ocr/ and http://www.usdoj.gov/crt/h1n1_response.php	Department of Justice guidelines emphasize the following steps in response to H1N1: 1. ***Provide information in languages other than English.*** More information about ensuring language access can be found at www.lep.gov. Multi-lingual brochures on language access rights can be found at http://www.lep.gov/dojbrochures.html. 2. ***Ensure that there is no harassment or other discrimination directed at people based on national origin, ethnicity, or immigration status.*** For multi-lingual information on national origin discrimination, please see http://www.lep.gov/dojbrochures.html. 3. ***Provide access to information and health services to people with disabilities.*** For more information on access for individuals with

			disabilities, please see www.ADA.gov. Attention must also be paid to state regulations, including requirement that hospitals implement Language Assistance Program to ensure meaningful access to the hospital's services and reasonable accommodation for all patients who require language assistance 10 NYCRR 405.7(a)(7) http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/0/8525652c00680c3e8525652c00631b38?OpenDocument
Hospitals worry that HIPAA may limit the medical and social information that can be released in an emergency.	**Existing HIPAA allowances:** Under HIPAA, health care providers may share patient information as necessary to identify, locate, and notify family members, guardians, or anyone else responsible for the individual's care. It should be noted that HIPAA permits the sharing of patient PHI as relates to public health activities, HIPAA should not be a barrier to appropriate sharing of information during the crisis. The health care provider should get verbal permission from individuals, when possible; but if the individual is incapacitated	45 CFR164.510(b) http://edocket.access.gpo.gov/cfr_2002/octqtr/pdf/45cfr164.510.pdf HHS OCR has established an emergency planning tool to determine if disclosures are permissible: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/emergencyprepdisclose.pdf See also HHS FAQs http://www.hhs.gov/hipaafaq/permitted/emergency/960.html http://www.hhs.gov/ocr/privacy/hipaa/faq/providers/hipaa-1068.html	Hospitals should plan to comply with HIPAA requirements even in a pandemic. Staff, employees, and providers should be educated, and hospitals may consider having a separate set of HIPAA policies that take into account any exemptions or pandemic-related changes. Note that there are also State confidentiality requirements for each provider class, including: Hospitals: 10 NYCRR 405.7(b)(13) http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm Nursing Homes: 10 NYCRR 415.3(d) http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm Adult Day Health Care: 10 NYCRR 425.21 http://www.health.state.ny.us/nysdoh/phforum/nyc

	or not available, providers may share information for these purposes if, in their professional judgment, doing so is in the patient's interest. A patient locator system should be established to assist in location of patients and notification of family members. **Waiver of HIPAA sanctions:** In addition, if the President declares an emergency or disaster *and* the Secretary declares a public health emergency, the Secretary may waive sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule: 1. the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care (45 CFR 164.510(b)) 2. the requirement to honor a request to opt out of the facility directory (45 CFR 164.510(a)) 3. the requirement to	See also GNYHA HIPAA Guidance http://www.gnyha.org/publications/PDF/2003_HIPAA_Brochure.pdf	rr10.htm

	distribute a notice of privacy practices (45 CFR 164.520) 4. the patient's right to request privacy restrictions (45 CFR 164.522(a)) 5. the patient's right to request confidential communications (45 CFR 164.522(b)) These waivers would be for all patients being treated by a facility overrun by pandemic and not simply for those individuals directly afflicted by influenza.		
Decisions about end of life care are traditionally predicated on patient autonomy and surrogate decision-making, as well as shared decision-making with clinical team. In a pandemic situation, **the individual's preferences may have to be sacrificed to accommodate more urgent patient needs.**	As discussed in the companion Ethics grid, a pandemic will likely move us to a public health paradigm. Though existing State law governs end of life decision making, this standard may need to be relaxed during a pandemic. Hospitals are advised to consider the ethical and legal implications of such a change, and to incorporate end of life decision making into their pandemic response planning. Hospitals should spend	**Relevant legal issues and resources include:** <u>NYS Do Not Resuscitate Law, Pub Health Law § 2960 et seq</u>. Relevant sections set forth requirements for DNR decision-making under various scenarios: when the patient has capacity (2964), when decision making is done by a surrogate (2965), when the patient is without capacity (2966), and when a dispute needs to be mediated (2972), among other specifics.	The State may wish to consider **appropriate relaxation of laws and requirements in this area**, depending on the life cycle of the pandemic. Such changes might include: <u>Do Not Resuscitate Law</u> ▪ Establish clear prognostic thresholds for when resuscitation is beneficial or futile. ▪ Provide more flexibility for a decision-making agent with true knowledge of the patient's prior wishes, perhaps allowing a designated health care agent to act instead of a DNR surrogate. ▪ Incorporate provisions to address a

	appropriate resources attempting to get health care proxies and other tools for decision-making for patients. In addition, public health messaging should include the fact that there will be a necessary contextualization in standards of practice due to diminishing resources, which may affect end of life care. Patients and their families should be prepared for this reality.	http://public.leginfo.state.ny.us/menugetf.cgi NYS Advance Directive Law, Pub Health Law §2981 State law currently requires an advance directive for withdrawal of life support. http://public.leginfo.state.ny.us/menugetf.cgi Brain Death : NYS Regulations and Guidance from DOH sets forth the process for determining brain death, including requirements for two examinations at six hour intervals and providing reasonable accommodation of an individual's religious or moral views, among other steps. 10 NYCRR §400.16 http://www.health.state.ny.us/nysdoh/phforum/nycrr10.htm NYS DOH Guidance: http://www.health.state.ny.us/professionals/hospital_administrator/determination_of_brain_death/ http://www.health.state.ny.us/professionals/doctors/guidelines/determination_of_brain_death/docs/determination_of_brain_death.pdf	potential fear of discrimination for the isolated patient, one without an advocate or agent. (This category likely to increase due to the social dislocation borne of a pandemic.) ▪ Eliminate the 72 hour hold and the necessary referral to dispute mediation streamlined process for necessary dialogue. ▪ Ensure that there will not be impact on insurance coverage for cases when a pandemic yields "mandated" or systemic DNR orders, akin to the existing provision of the DNR law at §2975. ▪ Allow DNRs based on a hospital's diminished ability to provide treatment due to dwindling resources. Advance Directive Law: ▪ Allow family members to make decisions to withdrawal life support, as is permitted in most other states. ▪ Establish standards permitting the withdrawal treatment after a time interval, depending on the gravity of the pandemic. Brain Death: ▪ Current law requires two examinations at six hour intervals. Shorten this interval or limit the requirement to a single examination.

			▪ NYS currently calls for provision of reasonable accommodations of an individual's religious or moral views. Consider waiving this requirement in a pandemic.