

Balancing Compliance With Necessity in the Wake of a Bioterrorism Incident

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The events of September 11, 2001, and more recently, the aftermath of Hurricane Katrina have made health care providers and others keenly aware of the importance of proper disaster planning at national, state, local and institutional levels. One of the most challenging aspects of disaster planning is developing a plan that also complies with the myriad of regulatory laws that govern professionals in their normal course of business. As members of one of our nation's most heavily regulated industries, health care providers face an especially difficult task when attempting to develop an efficient and effective disaster plan, while maintaining compliance with various healthcare regulations.

A major bioterrorism attack, in particular, would create problems for the healthcare industry unlike any experienced before. Bioterrorism generally refers to the intentional release of biologic agents into the population as part of a terrorist attack. Such an attack could result in large influxes of patients beyond the capability of a single hospital or the risk of contamination of other patients. Thus, it is important that hospitals develop plans in advance whereby they agree to work in cooperation with each other and their local emergency management systems to approach the disaster in the best possible manner. Such plans are often memorialized in the form of a mutual aid agreement or a memorandum of understanding, whereby hospitals agree to help each other by sharing staff, equipment, and other resources for the common good. In certain situations, the mere sharing of resources may not be enough. For example, the great influx of patients or the fear of infecting the hospital's unaffected patients may necessitate the opening of temporary off-site facilities for triage, acute treatment, or palliative care of infected individuals. The staffing and management of such off-site centers should also be addressed in mutual aid agreements. When negotiating such agreements, hospitals are faced with many unique challenges, such as: hospitals not wanting to take contaminated patients, the need for quarantine of infected individuals, and the need for coordination in staffing off-site facilities.

Health care regulatory laws sometimes pose additional barriers to the development of effective planning and the negotiation of mutual aid agreements. This article addresses some of the common compliance issues

that health care providers face when engaging in bioterrorism preparedness planning and offers guidance for dealing with these issues.

HIPAA Privacy Issues

In the wake of a bioterrorism incident, it is imperative for health care providers, first responders and public health officials to communicate with each other regarding the identification of potential victims, as well as the triage and transfer of patients to hospitals or off-site treatment or triage centers. Some health care providers have voiced concern that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule will create barriers to sharing patient information as necessary to implement bioterrorism plans.

The HIPAA Privacy Rule generally allows disclosures of protected health information without a patient's authorization for the purposes of treatment, payment, or health care operations. Because the disclosures of patient information for those patients transferred to an offsite facility would be considered disclosures for "treatment" purposes, they would be permissible disclosures.

The HIPAA Privacy Rule also contains several exceptions that will allow disclosures of patient information to help control the spread of disease and to notify family members in the event of a bioterrorism incident. Specifically, disclosures are permissible if they are made to a "public health authority" that is authorized by law to collect or receive such information for the purpose of "preventing or controlling disease." 45 CFR 164.512. Section 164.512 also allows disclosure of protected health information to "avert an imminent threat to health or safety." The HIPAA Privacy Rule also allows disclosures to government agencies and disaster relief organizations for the purpose of notifying family members of an individual's location. 45 CFR 164.510.

OSHA/MIOSHA Issues

In many instances, a mutual aid agreement may require hospitals to dispatch employees to another hospital or to an offsite temporary facility. In these situations, employers have the additional concern that they will be sending health care workers into a situation with conditions that present workforce hazards that may violate the Occupational Safety and Health Administration (OSHA) standards.

To plan for OSHA compliance, hospitals should address such OSHA standards when entering into mutual aid agreements. Such agreements should provide assurances that any hospital or off-site temporary facility to which health care workers are deployed will be operated in a manner that will comply with the “OSHA Best Practices for the Protection of Hospital-Based First Receivers of Victims from Mass Casualty Incidents Involving the Release of Hazardous Substances”. The OSHA “Best Practices” address the appropriate assessment of the hazard, the use of appropriate personal protective equipment (PPE), proper procedures for decontamination of victims, as well as appropriate training of personnel who will be first receivers. The “Best Practices” can be found on the OSHA website, at <http://www.osha.gov/SLTC/emergencypreparedness/responder.html>.

Credentialing Issues

Hospitals may also have concerns regarding the use of physicians and other providers who have not been properly credentialed through the hospital’s formal credentialing process.

To address this concern, JCAHO has issued proposed language for two new standards to address emergency credentialing of “disaster privileges” for volunteer practitioners.

Proposed standard HR 1.25 addresses the assignment of disaster job responsibilities to volunteer practitioners, while proposed standard HR 4.35 addresses the assignment of disaster privileges to such volunteer practitioners. Specifically, HR 4.35 requires hospital leaders to assign an individual who will be responsible for granting disaster privileges, to document this individual’s responsibilities and the mechanism for overseeing such volunteers. Further, the proposed standard would allow for the granting of disaster privileges upon presentment of a valid picture ID and any of the following:

- A current picture hospital or health care organization ID card.
- A current license to practice.
- Identification indicating that the individual is a member of a Disaster Medical Assistance Team (DMAT) or Medical Reserve Corps (MRC) or other recognized State or Federal organizations or groups.
- Identification indicating that the individual has been granted authority to render patient care, treatment, and services in disaster circumstances (such authority having been granted by a federal, state, or municipal entity).

- Presentation by current organization staff member(s) with personal knowledge regarding practitioner's identity.

The proposed standard further requires the hospital's leaders to initiate primary source verification of licensure and competence as soon as the immediate situation is under control. This verification is not to exceed 72 hours unless communication capabilities are disrupted so as to make verification impossible.

Vaccination/Worker's Compensation Issues

Also of concern for health care employers are issues related to smallpox vaccination. It is expected that individuals who volunteer or are recruited to be part of an emergency bioterrorism response team will be vaccinated for illnesses such as smallpox.

One concern related to vaccination is the potential for work-related injury claims arising from the vaccination. Another concern is the possibility that vaccine recipients might infect immunocompromised patients during the time period after the vaccination. One possible solution is to quarantine health care workers for a period of time following administration of the smallpox vaccination. Besides the obvious concern with staffing shortages, this creates issues related to the payment of the worker during the quarantine time period since this period of time would not likely be considered a "disability" under the workers' compensation laws.

Liability Issues

Health care entities and individual providers are also concerned about liability implications associated with participating in the bioterrorism response plan.

Many states have statutes that protect disaster workers if certain conditions are met. Health care providers should be aware of their state's statutes and ensure that deployment of employees happens under conditions that will trigger statutory immunity.

If health care providers do not feel that their state's statutes provide for adequate immunity, they should consider organizing and lobbying for legislative amendments that will better protect disaster workers from liability.

Due to the inadequacies of some of the current state laws, many hospitals were not able to deploy healthcare workers to assist in Hurricane Katrina because of liability and insurance issues. Obviously, healthcare providers must work together immediately to resolve these problems prior to another disaster.

EMTALA Issues

The diversion of patients to other hospitals or to off-site facilities raised concerns regarding compliance with the Emergency Medical Treatment and Labor Act (EMTALA) which requires all hospitals with emergency departments to provide a medical screening examination and prohibits such hospitals from refusing to examine or treat individuals with an emergency medical condition.

The Centers for Medicare and Medicaid Services (CMS) addresses this issue in the State Operations Manual for Participating Hospitals. Specifically, the manual provides that “. . . in the event of a national emergency or crisis (e.g. bioterrorism) State or local governments may develop community response plans that designate specific entities (hospitals, public health facilities, etc.) with the responsibility of handling certain categories of patients during these catastrophic events.” The manual notes that hospitals would still be responsible for providing a medical screening examination upon request of the patient; however, transfer or diversion of the patient in accordance with the plan would not result in EMTALA sanctions against the transferring hospital.

Suggestions for Disaster Planning

Although compliance with rigid health care regulations may be the furthest thing from the minds of first responders and first receivers of patients during a disaster incident, proper planning can assure that best efforts are made to comply with regulatory laws.

In order to address the compliance issues discussed above, proper planning, whether at the facility, local, state or national level, should include the following:

- Healthcare providers should educate personnel regarding HIPAA exceptions for disaster situations (so that the flow of necessary information is not impeded because of misunderstandings).

- Providers should also educate personnel regarding OSHA Best Practices for First Responders. Additionally, the need for compliance with the “Best Practices” should be included in mutual aid agreements.
- Hospitals should implement policies regarding emergency credentialing in accordance with JCAHO standards.
- Vaccination plans should be put into place that create the least amount of disruption to workforce (*e.g.*, reassign vaccinated individuals to jobs where they can continue to be productive if the hospital determines that there should be a quarantine period for the vaccine recipient).
- Health care providers should be aware of state statutes that will provide immunity during time of disaster. If such statutes are inadequate, elected officials should be called upon to assist with new legislation to address deficiencies.
- Community disaster plans and mutual aid agreements should be reviewed to ensure that EMTALA’s medical screening examination requirement is met by the receiving hospital prior to transfer of patients.

The tendency to become complacent when a disaster or emergency situation seems so distant is nearly unavoidable. Yet, with so many unanswered questions at the local, state, and national levels, healthcare providers are incurring unnecessary risks. The aftermath of a disaster can be progressively worse if proper measures are not taken to plan for such an event. It is imperative that we become aware of the compliance issues, risks, and liabilities involved in disaster response, seek out answers to our questions, and implement solutions now. It is, without a doubt, a difficult and complex matter to prepare for disaster situations.

However, as was demonstrated in the aftermath of Hurricane Katrina, the only thing more difficult than preparing for a disaster is explaining why you did not prepare. Every healthcare provider should be able to answer the question: “When a disaster strikes, will our company and staff be prepared?”

For more information on disaster planning, please contact Lori-Ann Rickard of Rickard & Associates, P.C. at (586)-498-0600 or by email at LARickard@larlegal.com