



**The Cost of Disaster Unpreparedness:  
A SPECIAL REPORT ON IMPLIATIONS OF  
THE NATIONAL RESPONSE PLAN,  
THE NATIONAL INCIDENT MANAGEMENT SYSTEM,  
THE NIMS INTEGRATION PLAN FOR HOSPITALS AND HEALTHCARE,  
THE FEDERAL FALSE CLAIMS ACT and  
THE SARBANES-OXLEY ACT  
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UNIQUE WORK PRODUCT:

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INTRODUCTION:

The Homeland Security Act of 2002 provided the authority for the creation of the Department of Homeland Security (DHS). It also directed the Director of DHS to create a National Incident Management System (NIMS). Published in 2004, NIMS formed the framework for detection, mitigation, response and recovery from manmade and natural occurring disasters, events and incidents of national significance within the United States, its territories, protectorates and Indian Tribal nations. NIMS provided the framework for the creation of the National Response Plan (NRP), also published in 2004. The National Response Plan is an all-hazards, all-agencies approach to the detection, mitigation, response and recovery from disasters, whether natural or manmade events and incidents of national significance. A little known provision of NIMS created a classification system for all disaster-related resources. This classification system, the National Resource Typing System (NRTS) provides a unified cross-agency, cross-jurisdictional means of classifying all resources that are or could be used in response to a NRP/NIMS event, whether these resources are equipment or personnel.

A critical review of history shows that advancements in the general atmosphere and safety of healthcare delivery have occurred primarily as a result of legislation, regulation and litigation. Beginning as early as the Flexner report of 1910, healthcare has required the threat of legal intervention or financial penalty to make substantial changes education, operations, medication safety and self governance. As a result there now exist multiple state, federal and private sector agencies dedicated to the regulation and safe provision of healthcare services in the United States. DHS through NRP/NIMS and the NRTS have become the newest of these agencies.



### SIGNATORY STATUS FOR RESPONSIBILITIES:

All federal agencies, all 50 states, all U.S. protectorates and territories and all Tribal Nations within the scope and authority of the federal government have now become signatories to NRP/NIMS. Among these signatories are the Health Resource and Services Administration (HRSA) and the Department of Health and Human Services (DHHS), the parent agency for Medicare, Medicaid and Veteran Healthcare funding. This signatory status places certain responsibilities upon these agencies and governments, as well as providing them certain rights and privileges. These rights and responsibilities are incumbent upon all agencies that derive their funding or authority from a signatory to NRP/NIMS.

### RESPONSIBILITIES OF A SIGNATORY:

In addition to an irrevocable agreement to participate fully in any disaster, whether manmade or natural, event or incident of national significance within the region of that signatory or the authority of that signatory's office, department or agency, all signatories to the NIMS/NRP have **pre-agreed** to all changes, classifications, modifications and regulations that may be promulgated by the director of DHS or the NIMS Integration Center or the NRP Implementation Center. Such changes, classifications, modifications and regulations must be implemented **without modification**.

The Director of DHS has ultimate authority, "with the advice and counsel of the signatories, as well as **stake holder organizations**," to make those changes that are deemed necessary by the Director of the DHS. Interim changes, modifications and updates to NIMS are handled through the NIMS Integration Center; similarly NRP is updated and modified through the NRP Implementation Center. Thus, any change in regulation, qualification, credentialing, certification or classification (typing) of a resource becomes "fruit of the tree" and it is immediately incumbent upon all signatories to NIMS/NRP to implement such changes, qualifications, credentials, certifications and/or typing upon implementation by the respective agency of authority.

### PRIVILEGES OF SIGNATORIES:

Signatories to NIMS/NRP have the right and responsibility by virtue of their status as a signatory to provide agency representation at the NIMS Integration Center, the NRP Implementation Center, and the Inter-Agency Incident Command Center (IICC). The IICC is the head office that oversees multi-jurisdictional responses to disaster, particularly when multiple incident command centers must be set up to deal with multiple regional or local disasters.



## NIMS REQUIREMENTS UPON DHS OF SIGNIFICANCE:

Within NIMS, there are several clauses that are of significance to establishing a new industry in the area of Disaster Preparedness, Planning, Training and Evaluation within the United States. Recurrent through the document is the phrase “**establish qualifications, credentials and certification for hospitals and healthcare facilities in cooperation with ... and stake holder organizations**”. This phrase appears in every reference to hospitals and healthcare facilities in all levels of the response – administrative, financial, logistical and most notably operational. When hospitals are specifically noted, this phrase occurs with increased regularity. To date, there has been no classification, credentialing or certification system for hospital-based healthcare professionals implemented by the DHS, NIMS, or NRP. The NRTS provides no guidance, as of the writing of this report, for the qualification, certification, credentialing, or typing of medical providers and, more specifically, physicians. However, the NIMS Integration Center, on September 12, 2006, quietly published a Hospital and Healthcare Facility NIMS Implementation Plan.

It is the position of High Alert, LLC, based upon our review of these documents, that this provides an opportunity to successfully dominate the nascent Disaster Preparedness, Planning, Training and Evaluation industry within the United States.

### ***“Personnel Qualification and Certification***

*Qualification and certification activities are undertaken to identify and publish national-level standards and measure performance against these standards to ensure that incident management and emergency responder personnel are appropriately qualified and certified to perform NIMS-related functions.” (NIMS page 4)*

### ***“Ongoing Management and Maintenance***

*This component establishes an activity to provide strategic direction for and oversight of the NIMS, supporting both routine review and the continuous refinement of the system and its components over the long term.” (NIMS page 5)*

*“Review and approve (with the assistance of national professional organizations and with input from Federal, State, local, tribal, private-sector, and nongovernmental entities) discipline-specific requirements and training courses.” (NIMS page 38)*

### ***“Personnel Qualification and Certification***

*Under the NIMS, preparedness is based on national standards for the qualification and certification of emergency response personnel. Standards will help ensure that participating agencies and organizations field personnel who possess the minimum knowledge skills and experience necessary to execute incident management and emergency response activities safely and effectively. Standards typically include training, experience, credentialing, currency, and physical and medical fitness. Personnel that are certified for employment in support of an incident that transcends interstate jurisdictions through the Emergency Management Assistance Compacts System will be required to meet national qualification and certification standards. Federal, State, local, and tribal certifying agencies; professional organizations; and private organizations should credential personnel for their respective jurisdictions.” (NIMS page 38)*



*“To enable this qualification and certification function at the national level, the NIMS Integration Center, as defined in Chapter VII, will*

*-Facilitate the development and/or dissemination of national standards, guidelines, and protocols for qualification and certification.*

*-Review and approve (with the assistance of national professional organizations and with input from Federal, State, local, tribal, private-sector, and governmental entities) the discipline-specific requirements submitted by functionally oriented incident management organizations and associations.*

*-Facilitate the establishment of a data maintenance system to provide incident managers with the detailed qualification, experience, and training information needed to credential personnel for prescribed incident management positions.” (NIMS pages 38-39)*

#### ***“Categorizing Resources***

*Resources are categorized by size, capacity, capability, skill, and other characteristics. This makes the resource ordering and dispatch process within jurisdictions, across jurisdictions, and between governmental and nongovernmental entities more efficient and ensure that ICs receive resources appropriate to their needs. Facilitating the development and issuance of national standards for ‘typing’ resources and ‘certifying’ personnel will be the responsibility of the NIMS integration Center described in Chapter VII.” (NIMS page 44)*

#### ***“Identification and Typing Resources***

*Resource typing entails categorizing by capability the resource that incident managers commonly request, deploy, and employ. Measurable standards identifying the capabilities and performance levels of resources serve as the basis for categories. Resource users at all levels identify these standards and then type resources on a consensus basis, with a national-level entity taking the coordinating lead. Resource kinds may be divided into subcategories (types) to define more precisely the resource capabilities needed to meet specific requirements. Resource typing is a continuous process designed to be as simple as possible to facilitate frequent use and accuracy in obtaining needed resources. (See Appendix B for a more complete discussion of the NIMS national resource typing protocol.) To allow resources to be deployed and used on a national basis, the NIMS Integration Center defined in Chapter VII is responsible for defining national resource typing standards.” (NIMS pages 45 – 46)*

#### ***“Certifying and Credentialing Personnel***

*Personnel certification entails authoritatively attesting that individuals meet professional standards for the training, experience, and performance required for key incident management functions. Credentialing involves providing documentation that can authenticate and verify the certification and identify of designated incident managers and emergency responders. This system helps ensure that personnel representing various jurisdictional levels and functional disciplines possess a minimum common level of training, currency, experience, physical and medical fitness, and capabilities for the incident management or emergency responder position they are tasked to fill.” (NIMS page 46)*



***“ Responsibilities***

*The NIMS Integration Center will be further responsible for:*

- developing assessment criteria for the various components of the NIMS, as well as compliance requirements and compliance timelines for Federal, State, local, and tribal entities regarding NIMS standards and guidelines;*
- facilitating the definition of general training requirements and the development of national-level training standards and course curricula associated with the NIMS, including the following:*
  - the use of modeling and simulation capabilities for training and exercise programs*
  - field-based training, specification of mission-essential tasks, requirements for specialized instruction and instructor training, and course completion documentation for all NIMS users*
  - the review and recommendation (in coordination with national professional organizations and Federal, State, local, tribal, private-sector, and nongovernmental entities) of discipline-specific NIMS training courses*
- facilitating the development of national standards, guidelines, and protocols for incident management training and exercises, including consideration of existing exercise and training programs at all jurisdictional levels;*
- facilitating the establishment and maintenance of a publication management system for documents supporting the NIMS and other NIMS-related publications and materials, including the development or coordination of general publications for all NIMS users, as well as their issuance via a NIMS publication management system;*
- reviewing (in coordination with appropriate national professional standards-making, certifying, and accrediting organizations and with input from Federal, State, local, tribal, private-sector and nongovernmental entities) of the discipline-specific publication management requirements submitted by professional organizations and associations;*
- facilitating the development and publication of national standards, guidelines, and protocols for the qualification and certification of emergency responder and incident management personnel, as appropriate;*
- reviewing and approving (with the assistance of national professional organizations and with input from Federal, State, local, tribal, private-sector, and nongovernmental entities), as appropriate, the discipline-specific qualification and certification requirements submitted by emergency responder and incident management organizations and associations;*
- facilitating the establishment and maintenance of a documentation and database system related to qualification, certification, and credentialing of incident management personnel and organizations, including reviewing and approving (in coordination with national professional organizations and with input from the Federal, State, local, tribal, private-sector and nongovernmental entities), as appropriate, of the discipline-specific requirements submitted by functionally oriented incident management organizations and associations.*



- establishment of a data maintenance system to provide incident managers with the detailed qualification, experience, and training information needed to credential personnel for prescribed "national" incident management positions;*
- coordination of minimum professional certification standards and facilitation of the design and implementation of a credentialing system that can be used nationwide;*
- facilitating the establishment of standards for the performance, compatibility, and interoperability of incident management equipment and communications systems, including the following:*
  - facilitating, in coordination with appropriate Federal agencies, standards-making, certifying, and accrediting organizations, and appropriate State, local, tribal, private-sector, and nongovernmental organizations, the development and/or publication of national standards, guidelines, and protocols for equipment certification (including the incorporation of standards and certification programs already in existence and used by incident management and emergency response organizations nationwide)*
  - reviewing and approving (in coordination with national professional organizations and with input from Federal, State, local, tribal, private-sector, and nongovernmental entities) lists of equipment that meet these established equipment certification requirements*
  - collaborating with organizations responsible for emergency responder equipment evaluation and testing*
- facilitating the development and issuance of national standards for the typing of resources;" (NIMS pages 60-62)*

## NRTS CLAUSES OF SIGNIFICANCE:

The National Resource Typing System (NRTS) provides for a tiered classification system for all resources, whether equipment or personnel. This includes all levels of healthcare providers, including physicians. Currently there is no system for the classification or “typing” of hospitals and healthcare organizations under the NRTS. Our detailed review of NRTS reveals the system is, with the review of the director of DHS, self-modifying and that any typing system properly presented for inclusion in the NRTS is automatically sent for review to the Director of DHS and it is incumbent upon the Director of DHS at that time to implement some form of typing system. Human nature and governmental nature being what it is, and history being a prime example with regard to DHS, NIMS and NRTS, it is our belief that any typing system presented by a national professional organization would automatically be adopted with minimal modification.

### **“RESPONSIBILITIES**

*The NIMS Integration Center described in Chapter VII has the overall responsibility for ongoing development and refinement of various NIMS activities and programs. Under its auspices, the National Resource Management Working Group, chaired by the Emergency Preparedness and Response Directorate of the Department of Homeland Security, is responsible for establishing a*



*national resource typing protocol. The NIMS resource typing protocol is based on inputs from representatives from various Federal agencies and departments and private organizations, as well as representatives of State and local emergency management; law enforcement; firefighting and emergency medical services; public health; public works; and other entities with assigned responsibilities under the Federal Response Plan and the National Response Plan. Federal, State, local, and tribal authorities should use the national typing protocol when inventorying and managing resources to promote common interoperability and integration.” (NIMS page 121)*

#### *“C. ELEMENTS OF THE NATIONAL TYPING PROTOCOL.*

*The resource typing protocol provided by the NIMS describes resources using category, kind, components, metrics, and type data. The following data definitions will be used” (NIMS page 121)*

##### *“1. Resource*

*For purposes of typing, resources consist of personnel, teams, facilities, supplies, and major items of equipment available for assignment to or use during incidents. Such resources may be used in tactical support or supervisory capacities at an incident site or EOC. Their descriptions include category, kind, components, metrics, and type.” (NIMS page 121)*

##### *“2. Category*

*A category is the function for which a resource would be most useful. Table B-1 briefly describes the categories used in the national resource typing protocol.” (NIMS page 121)*

##### *“Category: Health and Medical*

*Purpose: To provide assistance to supplement local resources in meeting public health and medical care needs following a disaster or emergency or during a potential developing medical situation.” (NIMS page 121-122)*

##### *“3. Kind*

*Kind refers to broad classes that characterize like resources, such as teams, personnel, equipment, supplies, vehicles, and aircraft.” (NIMS page 123)*

##### *“4. Components*

*Resources can comprise multiple components.” (NIMS page 123)*

##### *“5. Metrics*

*Metrics are measurement standards. The metrics used will differ depending on the kind of resource being typed. The mission envisioned determines the specific metric selected. The metric must be useful in describing a resource's capability to support the mission. As an example, one metric for a disaster medical assistance team is the number of patients it can care for per day. Likewise, an appropriate metric for a hose might be the number of gallons of water per hour that can flow through it. Metrics should identify capability and/or capacity.” (NIMS page 123)*

##### *“6. Type*

*Type refers to the level of resource capability. Assigning the Type I label to a resource implies that it has a greater level of capability than a Type II of the same resource (for example, due to its power, size, or capacity), and so on to Type IV. Typing provides managers with additional information to aid the selection and best use of resources. In some cases, a resource may have less than or more than four types; in such cases, either additional types will be identified, or the type will be described as "not applicable." The type assigned to a resource or a component is based on*



*a minimum level of capability described by the identified metric(s) for that resource.”  
(NIMS 123-124)*

*“7. Additional Information*

*The national resource typing protocol will also provide the capability to use additional information that is pertinent to resource decision-making. For example, if a particular set of resources can only be released to support an incident under particular authorities or laws, the protocol should provide the ability for resource managers to understand such limitations.”  
(NIMS page 124)*

*“NIMS INTEGRATION CENTER (NIC)  
NATIONAL EMERGENCY RESPONDER CREDENTIALING SYSTEM – FACT SHEET*

*“The development of a national credentialing system is a fundamental component of the National Incident Management System (NIMS). The NIMS states that “credentialing involves providing documentation that can authenticate and verify the certification and identity of designated incident managers and emergency responders” to ensure that response personnel “possess a minimum common level of training, currency, experience, physical and medical fitness, and capability” for the respective role that they are tasked to fill.” (NIC October, 2005)*

*“The NIMS Integration Center (NIC) initiated development of a national credentialing system in FY 2005 to enhance the ability of Federal, State, Tribal, and local jurisdictions to identify and dispatch appropriately qualified emergency responders from other jurisdictions when needed.” (NIC October, 2005)*

*“A national credentialing system ensures that personnel resources requested to assist another jurisdiction in a response are adequately trained and skilled. A national system to verify the identity and qualifications of emergency responders will not provide automatic access to an incident site. This system can serve to prevent unauthorized (self-dispatched or unqualified personnel) access to an incident site.” (NIC October, 2005)*

*“The NIC will work with existing State, Territory, or discipline-specific credentialing bodies toward national recognition for multi-jurisdictional response under mutual aid agreements.”  
(NIC October, 2005)*

*“The main components of a proposed credentialing system are:  
eligible volunteers;  
certifications and qualifications standards;  
credentialing organizations;  
credentialing information that can easily identify personnel and verify certifications, training, and licenses;  
and a record-keeping system.” (NIC October, 2005)*

*“To support this credentialing initiative, the NIC is using working groups to identify job titles that should be credentialed as well as the minimum qualification, certification, training, education, licensing, and physical fitness requirements for each position. Working groups will represent the following disciplines: Incident Management, Emergency Medical Services, Fire/HazMat, Law Enforcement, Medical and Public Health, Public Works, and Search and Rescue.”  
(NIC October, 2005)*



*“Currently active groups include the Incident Management, Emergency Medical Services, Fire/HazMat, Public Works, and Search & Rescue working groups. The NIC is finalizing working group rosters for the remaining disciplines.” (NIC October, 2005)*

### NIMS RESPONSIBILITIES UPON DHHS OF SIGNIFICANCE:

In addition to an irrevocable agreement to participate fully in any disaster, whether manmade or natural, event or incident of national significance within the region of that signatory or the authority of that signatory’s office, department or agency, all signatories to the NIMS/NRP have **pre-agreed** to all changes, classifications, modifications and regulations that may be promulgated by the director of DHS or the NIMS Integration Center or the NRP Implementation Center. Such changes, classifications, modifications and regulations must be implemented **without modification**.

The Center for Medical Services (CMS) is the DHHS agency specifically empowered and charged with the responsibility of overseeing all operations for Medicare, Medicaid and Tricare. These responsibilities include the certification of participating Hospitals and Healthcare facilities whether directly through a network of Regional Offices (RO’s) and State Agencies (SA’s) or through approved private organizations including the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the Healthcare Facility Accreditation Program (HFAP) of the American Osteopathic Association (AOA). CMS draws its authority directly from the secretary of DHHS and is responsible for performing all the duties and responsibilities of the secretary of DHHS as applied to Medicare, Medicaid and Tricare, including but not limited to promulgating regulations and regulatory guidance towards this end.

- *“The Social Security Act (the Act) mandates the establishment of minimum health and safety and CLIA standards that must be met by providers and suppliers participating in the Medicare and Medicaid programs. The Secretary of the Department of Health and Human Services (DHHS) has designated CMS to administer the standards compliance aspects of these programs.”*
- *“Section 1864(a) of the Act directs the Secretary to use the help of State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards.”*
- *“Section 1902(a)(9)(A) of the Act requires that a State use this same agency to set and maintain additional standards for the State Medicaid program.”*
- *“Section 1902(a)(33)(B) requires that the State use the agency utilized for Medicare... to determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary.”*
- *“CMS also may, under 42 CFR Part 442.30, invalidate a Medicaid provider agreement after determining that the agreement does not constitute valid evidence of the provider's compliance with the Federal regulatory requirements.”*
- *“A hospital accredited by JCAHO or AOA is deemed to meet all CoPs for hospitals”*



- *“The authority of the Secretary of DHHS to approve, disapprove, or terminate the Medicare participation of certified providers and suppliers is delegated to CMS...”*
- *“If termination is on the grounds of fraud, program abuse, or noncompliance with peer review requirements, the authority to terminate or to establish eligibility for reinstatement reposes with the Office of Inspector General (OIG), DHHS.”*
- *“The Secretary has authority under §§1902(a)(33), 1919(g)(3), and 1910(b)(1) of the Act to cancel approval of all Medicaid facilities... that do not meet Federal health or safety requirements. Such a determination is in lieu of, or overrides, a determination by the State and is binding...”*

## NIMS IMPLEMENTATION CENTER HOSPITAL AND HEALTHCARE FACILITY PLAN

The NIMS Implementation Center Hospital and Healthcare Facility Plan provides a new landscape for those providing Disaster Planning, Preparedness, Training and Evaluation services as well as for national organizations involved in the certification or accreditation of healthcare facilities, healthcare professionals, planning professionals and emergency management professionals.

The NIMS Implementation Center Hospital and Healthcare Facility Plan sets several requirements for hospital and healthcare facility compliance with NRP/NIMS. These include:

- **“Element 1 - Adoption of NIMS**
  - *“Adopt the National Incident Management System (NIMS) at the organizational level for all appropriate departments and business units, as well as promote and encourage NIMS adoption by associations, utilities, partners and suppliers.”*
- **“Element 2 - Incident Command System (ICS)**
  - *“Manage all emergency incidents, exercises and preplanned (recurring/special) events in accordance with ICS organizational structures, doctrine, and procedures, as defined in NIMS. ICS implementation must include consistent application of Incident Action Planning and Common Communication Plans.”*
  - *“Depending on the size and on-site capabilities of the hospital and healthcare system, the size and scope of ICS will vary. Hospitals and healthcare systems should implement an ICS that allows for the provision of safe and effective patient care and continuity of hospital operations regardless of the size of the hospital, size and type of incident, and/or limitations of resources, personnel and equipment.”*
  - *“The structure of a hospital ICS should be included in the Emergency Operations Plan (EOP) which will identify an Incident Commander and the appropriate departments/personnel to meet the following ICS areas—command staff, operations, planning, logistics, and/or finance needed to have an effective incident command structure. Once the ICS personnel are identified, subsequent training and exercises should be conducted to review the structure and ICS responsibilities designated to the hospital’s and healthcare system’s personnel.”*



- **“Element 3 - Multiagency Coordination System**
  - *“Coordinates and supports emergency incident and event management through the development and use of integrated multiagency coordination systems (MACs). That is, develop and coordinate connectivity capability with Hospital Command Center (HCC) and local Incident Command Posts (ICPs), local 911 centers, local Emergency Operations Centers (EOCs), the state EOC and others as applicable.”*
  - *“MAC relationships should be defined prior to an incident to address the potential emergency needs and areas of priority:*
    - *Personnel staffing, roles, and authority*
    - *Decontamination of patients, personnel, and/or equipment etc.*
    - *Equipment and supplies*
    - *Security*
    - *Ancillary Services”*
  - *“Once MAC relationships have been established, hospitals and healthcare systems should participate in collaborative planning sessions, resulting in exercises and training that should be conducted among the agencies to test and validate facilities, equipment, personnel, procedures and integrated communications.”*
- **“Element 4 - Public Information System**
  - *“Implements processes and/or plans to communicate timely accurate information through a Joint Information System (JIS) and Joint Information Center (JIC).”*
  - *“A hospital should identify at least one PIO or Public Affairs Representative/Spokesperson (dependent on the size of the hospital or healthcare system) that is responsible for media and public information as it pertains to an event that involves the hospital. The designated PIO or Public Affairs Representative/Spokesperson should establish working relationships, prior to an incident occurring, with local media outlets, emergency management, law enforcement, public health, emergency medical services, etc.”*
- **“Element 5 – NIMS Implementation Tracking**
  - *“Hospitals and healthcare systems will track NIMS implementation annually as part of the organization’s emergency management program.”*
  - *“It is the sole responsibility of the hospital and healthcare system to self-certify that it is NIMS compliant. Hospital and healthcare systems should designate a NIMS implementation designee to implement annual activities and track NIMS implementation. This designee should have a working knowledge of the emergency management life cycle (i.e. Preparedness, Prevention, Mitigation, Response, and Recovery) as well as the daily and emergency operations procedures and protocols of the hospital or healthcare system.”*



- **“Element 6 – Preparedness Funding**
  - *“Develop and implement a system to coordinate appropriate hospital preparedness funding to employ NIMS across the organization.”*
  - *“Hospitals and healthcare systems should establish a working relationship with their state Department of Health and state hospital associations to identify activities to obtain and appropriately allocate preparedness funding. Hospitals and healthcare systems should also develop a proactive process to seek other federal funding to support preparedness that takes advantage of developing interoperability training with their local and regional multi-disciplinary partners that enhances the Unified Command aspects of NIMS. Assistance with developing such funding should be coordinated with the assistance of each state’s Hospital Association and Emergency Management Authority.”*
- **“Element 7 – Revise and Update Plans**
  - *“Revise and update plans [i.e. Emergency Operations Plan (EOPs)] and standard operating procedures (SOPs) to incorporate NIMS components, principles and policies, to include planning, training, response, exercises, equipment, evaluation, and corrective actions.”*
  - *“Hospitals and healthcare systems should update emergency plans to establish the necessary policies and procedures to achieve preparedness and respond to and recovery from an incident. Once updated, plans should be exercised and reviewed to determine and measure functional capability. Plan reviews should be conducted annually and/or after every event or incident to identify future updates that may be needed.”*
- **“Element 8 – Mutual-Aid Agreements**
  - *“Participate in and promote interagency mutual-aid agreements, to include agreements with public and private sector and/or nongovernmental organizations.”*
  - *“Hospitals and healthcare systems should establish mutual-aid agreements with neighboring hospitals and/or healthcare systems, public health departments, hazardous materials response teams, local fire department, local law enforcement, area pharmacies, and/or medical supply vendors. Established mutual-aid agreements should be shared with local emergency management prior to an incident occurring.”*
- **“Element 9 – IS-700 NIMS**
  - *“Complete IS-700: NIMS: An Introduction”*
  - *“IS-700 NIMS: An Introduction should be completed by the hospital personnel that would have a leadership role in emergency preparedness, incident management, and/or emergency response during an incident. Personnel designated to fulfill ICS roles (i.e. hospital emergency manager, hospital administration, department heads) should complete IS-700 or equivalent, though additional participants may include the following hospital and healthcare systems staff:*
    - *physicians;*
    - *nursing;*
    - *ancillary,*
    - *materials/resource management;*
    - *security/safety;*
    - *laboratory;*
    - *radiology; and/or*



- *inter-facility transport.*”
- *“... include IS-700 in semi-annual or yearly competencies or as part of employee evaluation to achieve training for all identified hospital personnel. IS-700 can be taken on-line ... or in the classroom setting when taught by a qualified instructor.”*
- *“A hospital or healthcare system should maintain one overall record of completion for employees as well as documentation in the employee’s personal file.”*
- **“Element 10 – IS-800.A: NRP**
  - *“Complete IS-800.A: NRP: An Introduction”*
  - *“IS-800.A: National Response Plan (NRP): An Introduction should be completed by personnel whose primary responsibility is emergency management within a hospital or healthcare system.”*
  - *“... incorporate IS-800 into semi-annual or annual competencies or a part of employee evaluation to achieve training for identified hospital personnel whose primary responsibility is emergency management. IS-800 can be completed on-line... or in the classroom setting when taught by a qualified instructor.”*
  - *“A hospital or healthcare system should maintain one overall record of training completion for all identified ICS employees.”*
- **“Element 11 – ICS 100 and 200**
  - *“Complete ICS 100 and ICS 200 Training or equivalent courses”*
  - *“ICS-100 Introduction to ICS or equivalent should be completed by the hospital personnel that would have a direct role in emergency preparedness, incident management, and/or emergency response during an incident. Personnel designated to fulfill ICS roles (i.e. hospital emergency manager, hospital administration, department heads) should complete IS-100 or equivalent, though additional participants may include the following hospital and healthcare systems staffs:*
    - *physicians;*
    - *nursing;*
    - *ancillary,*
    - *materials/resource management;*
    - *security/safety;*
    - *laboratory;*
    - *radiology; and/or*
    - *inter-facility transport.”*
  - *“ICS-200 ICS for Single Resources and Initial Action Incidents or equivalent should be completed by personnel whose primary responsibility is emergency management, to include (at a minimum) middle management within a hospital or healthcare system. Middle management may refer to physicians, department managers, unit leaders, charge nurses, and any staff (i.e. hospital administration) that would have a role in an emergency operations center (hospital, local, or state).”*
  - *“... incorporate ICS-100 and ICS-200 or equivalent courses into semi-annual or annual competencies, or as part of employee evaluation to achieve training for all hospital personnel. IS-*



*100 and 200 can be taken on-line ... or in the classroom setting when taught by a qualified instructor.”*

- *“A hospital or healthcare system should maintain one overall record of completion for all employees as well as documentation in the employee’s personal file.”*
  
- **“Element 12 – Training and Exercises**
  - *“Incorporate NIMS/ICS into internal and external local, regional, and state emergency management training and exercises.”*
  
  - *“Hospitals and healthcare systems should include NIMS and ICS policies and practices into internal and external training and exercises. During trainings and exercises, plans should be reviewed to ensure hospital and healthcare systems staff competency and proper execution of roles and responsibilities during an event.”*
  
- **“Element 13 – All-Hazard Exercise Program**
  - *“Participate in an all-hazard exercise program based on NIMS that involves responders from multiple disciplines, multiple agencies and organizations.”*
  
  - *“Hospitals and healthcare systems should participate in local, regional, and/or state multi-discipline and multi-agency exercises twice per year to every 2 years (dependent on the type of drill or exercise to be held). Exercise activities should address internal and external communications, receiving, triage, treatment, and transfer of mass casualties, progression of casualties through the hospital system, resource management, security procedures, specialty lab testing, and/or site/facility safety. Exercises can be conducted through drills, tabletop, functional, and/or full-scale exercises.”*
  
  - *“It is strongly encouraged that personnel conducting drills or helping to plan exercises should have the experience and documented training to facilitate these events. Such exercise design and evaluation training is available from federal and state emergency management agencies. Additionally, a system to provide a critical evaluation process for use in every exercise, drill and actual event in which the hospital or healthcare system would participate is strongly encouraged. Such evaluations should provide both quantitative and qualitative data / information upon which to define a process for improvement in future drills, exercises or actual events. The ability to identify both strengths and areas for improvement is critical to effective drill and exercise management over time and helps to strengthen Element 14– Corrective Actions.”*
  
- **“Element 14 – Corrective Actions**
  - *“Hospitals and healthcare systems will incorporate corrective actions into preparedness and response plans and procedures.”*
  
  - *“After a hospital or healthcare system has participated in a drill or exercise, a corrective action report should be created. In the corrective action report, the following points should be addressed for each identified issue:*
    - *The identified action to correct the issue or deficiency,*
    - *The responsible person or group of people to implement the action,*
    - *The due date for completion of the action, and*
    - *The resulting corrective action should be incorporated into plans and procedures once completed.”*



- **“Element 15 – Response Inventory**
  - *“Maintain an inventory of organizational response assets.”*
  - *“Supplies and equipment (i.e., personal protective equipment (PPE), patient care supplies, generator) that will be used in excess during an incident response should be determined (based on amount of staff, potential patients, usage time, etc.), ordered, and stocked on-site or elsewhere prior to an incident. Healthcare systems should stock additional supplies at a warehouse and/or throughout their hospitals to maintain necessary supplies that during an incident that will exceed normal par levels. These supplies or response assets should be maintained in a record of inventory whether on paper or in a database.”*
  - *“For items whose usage would exceed par levels as a result of a large scale incident or items that for which expiration would be an issue (i.e., additional antibiotics, vaccines, PPE, etc.), an MOU or MOA should be developed to expedite receipt of items when needed. Plans should reference the MOU or MOA information to include the following:*
    - *Contact information of who the agreement is with;*
    - *Types or actual supplies or equipment to be provided;*
    - *Mobilization method and receipt of resources;*
    - *Tracking and reporting of resources;*
    - *Recovery of resources; and*
    - *Reimbursement of resources.”*
- **“Element 16 – Resource Acquisition**
  - *“To the extent permissible by law, ensure that relevant national standards and guidance to achieve equipment, communication, and data interoperability are incorporated into acquisition programs.”*
  - *“To the extent possible, hospital and healthcare systems should work to establish common equipment, communications, and data interoperability resources with other local hospitals, emergency medical services (EMS), public health, and emergency management that will be used during incident response.”*
- **“Element 17 – Standard and Consistent Terminology**
  - *“Apply standardized and consistent terminology, including the establishment of plain English communication standards across the public safety sector.”*
  - *“Hospitals and healthcare systems should establish common language that is consistent with language to be used by local emergency management, law enforcement, emergency medical services, fire department, and public health personnel. Plain language should be addressed in plans as well as written into training and tested during drills and exercises.”*
  - *“The use of plain English does not prohibit the use of in-house hospital emergency codes to communicate within the facility. When communicating with entities outside the hospital, plain language should be used in place of internal specific emergency codes (e.g. Dr. Red is internal to a hospital, if a hospital was reporting a fire to the incident commander they would simply state that they have a fire or if a hospital is establishing lock down they would not use there internal emergency code terminology to notify outside resources but simply state that they are on lock down.)”*



## JCAHO ACCREDITATION STANDARDS and DISASTER PREPAREDNESS:

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has become the *de facto* standard for hospital and healthcare facility accreditation. The American Osteopathic Association (AOA) has a parallel Healthcare Facility Accreditation Program (HFAP). For the purposes of this discussion, there is no practical difference in the standards set forth by JCAHO and AOA. As JCAHO is the more common accreditation, the discussion will center on the JCAHO standards.

Participating hospitals and healthcare facilities renounce “self-certification” in favor of external accreditation by JCAHO. The DHHS through CMS uses JCAHO accreditation *in lieu* of CMS certification for the purposes of CMS provider eligibility. Loss of JCAHO accreditation is synonymous with loss of CMS provider eligibility. JCAHO published a special compliance manual entitled *Standing Together* which outlines the JCAHO standards for disaster preparedness in the post-9/11 era and provides guidance on meeting these standards.

- *“The Joint Commission discourages the development of separate plans for each contingency because these would be impractical to use and difficult to keep updated.”*
- *“Emergency Management... Planning Strategies:*
  - *Use an ‘all-hazards approach.’*
  - *Acknowledge the potential for a catastrophic event.*
  - *Compile a list of potential hazards.*
  - *Recognize the problems inherent in hazard lists.*
  - *Assess and prioritize the listed hazards.*
  - *Fine-tune the list by conducting a ‘gap analysis.’ ”*
- *“... the emergency management planning team’s first task is to conduct a hazard vulnerability analysis.”*
- *“Preparedness and Response... Planning Strategies:*
  - *Ensure that planning covers basic societal functions.*
  - *Make the planning process as doable as possible.*
  - *Address the four phases of emergency management.*
  - *Address human resources requirements.*
  - *Plan for convergent responders.*
  - *Involve the public in community preparedness efforts.*
  - *Enable people to care for themselves.*
  - *Plan for layered preparedness and response.*
  - *Ensure compatibility with unified command functions and the incident command system.*
  - *Link the community’s plan to the NIMS and the NRP.*
  - *Consider linking to the Joint Field Office.*
  - *Link to county and state plans and planning initiatives.*
  - *Establish mutual aid agreements.”*
- *“address each of the four phases of emergency management, which are prevention, preparation, response, and recovery.”*



The JCAHO standards have specifically adopted the START/JumpSTART Disaster Triage System. JCAHO guidance also specifically addresses Disaster Preparedness and Training through Immersion Simulation Drills, referred to as “community wide” and “influx drills (influx of simulated patients).” The JCAHO guidance allows tabletop exercises, but this type of drill does **not** fulfill the need for influx drills. JCAHO specifies that an accredited hospital **must** conduct at least one community wide drill every year and at least two influx drills every two years.

- *“Emergency Drills must include a "community wide" practice drill component in at least one of the required drills.”*
- *“... at least one drill must also include an ‘influx of simulated patients’.”*
- *“Tabletop drills are not acceptable by the Joint Commission to satisfy the ‘influx of patients’ component of a drill.”*
- *“For an "influx" drill to be acceptable, it must be an active process that is conducted throughout the facility, involve personnel from the organization, and simulate the movement of patients. A tabletop drill does not meet this requirement.”*
- *“Any accredited organization that provides emergency services or is designated as a disaster receiving station needs at least one external drill per year that includes an influx from outside the organization of volunteer or simulated patients.”*
- *“Enough "victims" should be used for the mass-casualty exercise to adequately test the system, with the number of victims necessary to test the organization's resources and reactions under stress.”*

#### CENTER FOR MEDICAL SERVICES (CMS):

The Department of Health and Human Services (DHHS), a signatory to NRP/NIMS, is the supervisory agency for Medicare, Medicaid and Tricare (Veteran’s Administration) funding through the Center for Medical Services (CMS). This regulatory agency provides certification for hospitals and other healthcare facilities either through JCAHO/HFAP or directly through its own system of state inspection offices/teams. CMS regulations carry the force of federal law under various aspects of the Social Security Act Title XVIII and XIV. The specific Federal Register sections applicable to this discussion include 42CFR482.1 and its applicable regulatory guidance. The CMS State Operations Manual provides the clearest guidance on the current interpretation of 42CFR482.1 and CMS regulations.

As an office of a NRP/NIMS signatory agency, it is incumbent on CMS to comply with the full implementation of NRP/NIMS. This compliance includes requiring NRP/NIMS compliance of all vendors (Hospitals and Healthcare Facilities) receiving funding through CMS. CMS regulations create a regulatory requirement for full NRP/NIMS compliance by all Medicare,



Medicaid and Tricare certified Hospitals and Healthcare facilities. As an office of a NRP/NIMS signatory (DHHS) these requirements are no more than a restatement of NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan.

- *“Assuring the safety and well being of patients would include developing and implementing appropriate **emergency preparedness** plans and capabilities. The hospital must develop and implement a comprehensive plan to ensure that the safety and well being of patients are assured during emergency situations. The hospital must coordinate with Federal, State, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and well being of patients. The following issues should be considered when developing the comprehensive emergency plans(s):*
  - *The differing needs of each location where the certified hospital operates;*
  - *The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);*
  - *Security of patients and walk-in patients;*
  - *Security of supplies from misappropriation;*
  - *Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;*
  - *Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);*
  - *Communication among staff within the hospital itself;*
  - *Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures*
  - *Identification, availability and notification of personnel that are needed to implement and carry out the hospital’s emergency plans;*
  - *Identification of community resources, including lines of communication and names and contact information for community emergency preparedness coordinators and responders;*
    - *Transfer or discharge of patients to home, other healthcare settings, or other hospitals;*
    - *Transfer of patients with hospital equipment to another hospital or healthcare setting;*
    - *Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.”*
- *“The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.”*
- *“...the hospital must comply with all the requirements of this Condition of Participation (CoP) and provide those services in accordance with acceptable standards of practice. ‘Acceptable standards of practice’ includes maintaining compliance with applicable Federal and State laws, regulations, and guidelines regarding hospital emergency services, as well as any standards or recommendations promoted by or established by nationally recognized professional organizations...”*
- *“...hospital staff should follow current standards of practice for patient environmental safety, infection control, and security.”*
- *“The chief executive officer, the medical staff, and the director of nursing must*



- *Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and*
- *Be responsible for the implementation of successful corrective action plans in affected problem areas.”*

CMS provides for both enforcement of these safety and preparedness regulations.

- *“The SA evaluates each general hospital **as a whole** for compliance with the CoPs and certify it as a single provider institution including all components:*
  - *Under the legal control of the hospital governing body and part of the same corporation or governmental administrative entity; and*
  - *Subject to the direction of the hospital administrator and medical staff organization.*
  - *...even when the components are separately housed... It is not permissible to certify only part of a general hospital.”*
- *“The LSC is applied to hospitals under authority of §1861(e)(9) of the Act and by 42 CFR 482.41(b).”*
- *“The CoPs/Requirements apply to the entire certified provider/supplier and to all patients... being served by the certified entity, regardless of payment source...”*
- *“A participating provider cannot participate in a program, and a supplier’s service cannot be covered, unless it is in compliance with each of the applicable CoPs...”*

Further, CMS has elevated non-compliance with safety and preparedness to the level of an “immediate jeopardy” and thus immediate suspension of a hospital or healthcare facility’s status as a CMS (Medicare, Medicaid & Tricare) participating provider.

- *“When immediate jeopardy to patient health and safety is found, whether in the course of a scheduled Federal monitoring survey, in response to a complaint, or as part of sample validation efforts of an accredited entity, the RO initiates termination procedures.”*
- *“Immediate Jeopardy - “A situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death...”*
- *“**Harm** does **NOT** have to occur before considering Immediate Jeopardy. Consider both potential and actual harm when reviewing the triggers...”*



## CORRELATION OF THE NIMS-IC PLAN, CMS REGULATIONS & JCAHO STANDARDS:

### Correlation 1:

The NRP/NIMS signatory agreement signed by DHHS and thus incumbent upon CMS to implement combined with the applicable policies, regulations and accreditation requirements of CMS, HRSA and JCAHO create a mandate for full and unmodified compliance with NRP/NIMS/NRTS and the NIMS Implementation Center Hospital and Healthcare Facility Plan is incumbent upon all hospitals and healthcare facilities.

(Element 1)

### Correlation 2:

CMS regulations and JCAHO standards both call for the use of an Incident Command structure and attention to the four phases of disaster. This paraphrases the NIMS Implementation Center Hospital and Healthcare Facility Plan requirements for the use of the Incident Command System structure and ICS education.

(Elements 2, 4, 9, 10 and 11)

### Correlation 3:

CMS regulations and JCAHO standards require hospitals and healthcare facilities to cooperate with community-based multi-agency disaster responses as well as to participate in community wide multi-agency drills. This parallels the NIMS Implementation Center Hospital and Healthcare Facility Plan and effectively implements this portion of this plan.

(Elements 3 and 8)

### Correlation 4:

The combination of the CMS use of JCAHO accreditation as CMS certification and the deferment of certification by hospitals to JCAHO makes JCAHO accreditation the *de facto* certification to fulfill the NIMS Implementation Center mandate for “self-certification.” Thus JCAHO accreditation also has become the *de facto* certification of compliance with the NIMS Implementation Center Hospital and Healthcare Facility Plan for each individual Hospital or Healthcare Facility.

(Element 5)



#### Correlation 5:

CMS regulations and JCAHO standards prescribe that an accredited hospital or healthcare facility must develop and publish for CMS/JCAHO review an operational budget including the provision of capital for **all** aspects of business operation. This echoes the NIMS Implementation Center Hospital and Healthcare Facility Plan provisions regarding Preparedness Funding. (Element 6)

#### Correlation 6:

CMS regulations and JCAHO standards require revision of existing plans as well as regular updating of plans in light of both pre-event Vulnerability Analysis and Post Event Review (After Action Review). These clauses validate the NRP/NIMS and NIMS Implementation Center Hospital and Healthcare Facility Plan requirements for plan revision and regular reevaluation. (Elements 7 and 14)

#### Correlation 7:

CMS regulations and JCAHO standards detail requirements for both Community Wide and Surge (Influx) disaster drills. Further, both organizations discourage Tabletop Exercises in favor of Live Patient and Simulator Environment Drills. The detailed and recurrent reference to these drills emphasizes the weight and importance placed on this phase by these regulatory and accrediting agencies. This emphasis reflects the same importance given to disaster drills by NRP/NIMS and NIMS Implementation Center Hospital and Healthcare Facility Plan. (Elements 12, 13 and 14)

#### Correlation 8:

CMS regulations and JCAHO standards specify that hospitals and healthcare facilities must maintain sufficient supplies and resources including generators, potable water, medications and oxygen to ensure the safety of all staff, patients and residents. These requirements are included in multiple key sections of the regulations including Life Safety, Facility Operations, Patient Safety and Human Resources/Personnel. The JCAHO and CMS sections are actually more stringent and specific than the comparable NIMS Implementation Center Hospital and Healthcare Facility Plan portions. (Elements 15 and 16)



### Correlation 9:

CMS regulations and JCAHO standards specify the use of plain English and a common nomenclature in all communications without allowance for a different language or nomenclature in event of disaster. This common language requirement is far more stringently worded than the associated NIMS Implementation Center Hospital and Healthcare Facility Plan sections in large part owing to the high priority placed by both CMS and JCAHO on the 1999 *To Err is Human* report published by the Institute of Medicine.  
(Element 17)

### IMPLICATION OF THE NIMS-IC PLAN, CMS REGULATIONS & JCAHO STANDARDS:

#### Implication 1:

Whether by design or serendipity, recently published CMS regulatory changes and progressive refinement of JCAHO standards have resulted in accreditation criteria that now closely approximate those put forth in NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan. This has the effect of creating a **regulatory mandate for hospitals and healthcare facilities to fully implement NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan.**

#### Implication 2:

Owing largely to the National Patient Safety Program initiated by JCAHO and CMS in response to the Institutes of Medicine *To Err is Human* report, recently published CMS regulatory changes and progressive refinement of JCAHO standards have resulted in **accreditation criteria for resource acquisition/inventory and common communication nomenclature that exceed those put forth in NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan. Further, both agencies have tied these criteria to the facility safety/Life Safety criteria for accreditation.**

#### Implication 3:

Following the catastrophic events of the 2004 and 2005 hurricane season and the recent National Academies of Science reports regarding Hospital and Community Disaster Preparedness, recently published CMS regulatory changes and progressive refinement of JCAHO standards have resulted in **accreditation criteria for disaster planning, education and drills that exceed those put forth in NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan. Further, both agencies have tied these criteria to the facility safety/Life Safety criteria for accreditation.**



#### Implication 4:

Because certification by CMS and indirectly JCAHO accreditation are required for Medicare, Medicaid and Tricare insurance participation and because CMS and JCAHO have tied much of their disaster preparedness criteria to the facility safety and Life Safety certification criteria, violation of these criteria would immediately suspend CMS certification and thus immediately suspend Medicare, Medicaid and Tricare insurance participation by the violating hospital or healthcare facility. Further, all private insurance suspends program participation in the event of a CMS suspension. **Thus violation of the CMS and/or JCAHO disaster preparedness criteria and by extension the NIMS Implementation Center Hospital and Healthcare Facility Plan holds significant financial penalties for any hospital or healthcare facility.**

#### NEW and OMINOUS SIGNS FROM FEDERAL REGULATORS

When High Alert first raised the specter of NRP/NIMS compliance being linked to CMS (Medicare, Medicaid and Tricare) billing, the discussion above had been strictly theoretical. Several federally funded training programs have now brought to the table a new and ominous implication of the NIMS Integration Center Implementation Plan for Hospitals and Healthcare. Additionally, hospitals have reported being informed that disaster preparedness will be linked to CMS reimbursement (Medicare, Medicaid and Tricare payments). This is the first step in a progression that, if followed by CMS, Department of Health and Human Services (DHHS), Department of Homeland Security (DHS) and Department of Justice (DoJ), will put the full weight and power of the federal government behind a mandate for hospital preparedness. An appreciation how CMS and DoJ have handled dealt with healthcare providers who have run afoul of these agencies in the past 18 months may portend the future.

In early 2006, DoJ instituted a change in how it dealt with Medicare, Medicaid and Tricare fraud. In prior years, these issues were typically dealt with as civil issues with civil penalties and restitution. Most offenders plead "guilty" or "no contest" to the charges, paid a fine and went home. Beginning in early 2006, DoJ began using the "guilty" plea from the civil cases as evidence to prosecute these individuals criminally. The type of insurance fraud spanned the gambit from billing for nonexistent patients to billing more than the documentation would support. It is this latter prosecution that is the cause of concern.

Since NRP and NIMS regulations are promulgated upon all signatories to NRP/NIMS, including DHHS, this would include CMS (Medicare, Medicaid, Tricare). Since all healthcare providers who bill CMS directly or indirectly are regulated by CMS and have independent contractor status with CMS, the requirements and regulations promulgated upon CMS by NRP/NIMS through DHHS are passed down to those contractors. This is affirmed by every healthcare provider every time they bill CMS on a UB92, CMS1500 or electronic equivalent because these forms include



the attestation that the healthcare provider is in compliance with all regulations and requirements of CMS and the program billed.

It is this last fact that opens the door for DoJ to involve itself in hospital preparedness. Through their actions in 2006, DoJ has shown the willingness to criminally prosecute healthcare providers for overt insurance fraud, including signing a false attestation. Signing the CMS attestation when not in compliance with NRP/NIMS is the same as signing the attestation when medical record documentation is not in compliance with CMS documentation standards. In short, the failure to be all hazards prepared may have just been raised to the level of a federal felony; enter Qui Tam.

Basically, a Qui Tam (*"He who sues on behalf of the king as well as for himself"*) is a provision of the Federal Civil False Claims Act that allows a private citizen to file a suit in the name of the U.S. Government charging fraud by government contractors and other entities who receive or use government funds. In healthcare, the whistleblower has information that a Medicare/Medicaid provider has knowingly submitted or caused the submission of false or fraudulent claims. The False Claims Act provides incentive to whistleblowers by granting them between 15% and 30% of any award or settlement amount. In addition, the statute provides an award of the whistleblower's attorney's fees.

A private citizen, called a relator, can file a complaint in the U.S. District Court with jurisdiction over the case. The complaint is filed "under seal," that is, confidentially. Once a complaint is filed, the Department of Justice (DoJ) has 60 days to investigate the information disclosed and determine whether it will join in the lawsuit. The DoJ can, and often does, request the court grant extensions to give it more time to investigate. It is not unusual for a complaint to remain under seal for as long as two to three years before the DoJ makes a decision. However, a relator does have the right to challenge extension requests and to have the seal lifted. Once a complaint is filed, the DoJ will assign the case to an investigative agency that has jurisdiction over the allegations. During the period of time the complaint is under seal, the Government investigators will conduct a preliminary investigation based on the information disclosed by the relator. This usually includes a comprehensive interview of the relator and review of relator's records if any exists. It also will include interview of any corroborative witnesses, review of appropriate government records and interviews of government officials. The investigation can also be expanded to include obtaining and reviewing the records of the defendant through the subpoena process. Once the preliminary investigation is completed, the results are analyzed by the DoJ in order to determine whether it will join in the lawsuit.

Once a whistleblower brings suit on behalf of the government, the United States Attorney for the district has the option to take over the case. If the US Attorney does so, the government will usually notify the Medicare/Medicaid provider being sued that a claim has been filed. Since Qui Tam actions are filed under seal, the seal must be partially lifted by the court to allow this type of disclosure. The seal prohibits the defendant from disclosing even the mere existence of the case



to anyone, including its shareholders. The government may then, without disclosing the identity of the whistleblower or any of the facts, begin taking discovery from the defendant.

The relator has the right to share in any award granted under the Qui Tam action. The 1986 Amendment to the False Claims Act increased the relator's share of the award in qui tam actions. Prior to 1986, relators were not guaranteed any more than 10 percent of the award. The 1986 Amendment raised the relator's share to a minimum of 15 percent and a maximum of 30 percent.

Claims that are falsely presented to the Government for payment are actionable under the False Claims Act. The False Claims Act covers a Medicare/Medicaid provider who:

- Knowingly presented or caused to be presented a false or fraudulent claim for payment or approval to an officer or employee of the government;
- Knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid by the government;
- Conspired to defraud the government by getting a false or fraudulent claim allowed or paid;
- Knowingly made, used or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government, ("reverse false claim").

A hospital or healthcare facility which fails to fully implement an NRP/NIMS Compliant "All Hazards" Disaster Preparedness program and continues to submit Medicare/Medicaid claims including the attestation that the provider is in compliance with all regulations and requirements of CMS and the program billed presents or causes to be presented a false claim. A claim is considered "knowingly" made if:

- There is actual knowledge of a false claim
- Deliberate indifference to the truth or falsity of a claim
- Reckless disregard of the truth or falsity of a claim

The implications for the corporate officers of a hospital go beyond just CMS fraud, civil penalties and imprisonment. Hospitals are now largely operated by public entities and thus file financial reports and financial statements. These reports are based on projected CMS reimbursements. If a facility is not NRP/NIMS compliant and "All Hazards" disaster prepared, the corporate officers are not only in danger of CMS fraud, but of projecting CMS reimbursements they know are not collectable. Further, the seal on a Qui Tam claim prohibits the defendant from disclosing even the mere existence of the case to anyone, including its shareholders, a fact which is in conflict with the provider's obligation under Security and Exchange Commission regulations that require disclosure of lawsuits that could materially affect stock prices; enter Sarbanes-Oxley.



The Sarbanes-Oxley (SOX) Act of 2002 represents landmark legislation in the world of corporate compliance, securities and capital markets, and overall organization governance and responsibility.

The perceived epidemic nature of corporate scandals illustrated in Enron, WorldCom and others, provided the impetus for Congress to act quickly. The wide spread support was clear in that SOX was approved by a near unanimous vote in Congress (vote of 99-0 in the Senate and 423-3 in the House). The fast pace of approval resulted in need for numerous interpretations, explanations and general confusion.

There is far reaching impact on Corporate Governance and Conduct, Financial Reporting and the Public Accounting Profession and also impacts the medical community, the legal community and investment banking analysts.

Broadly speaking the Act's provisions are built around the following principles:

- Integrity
- Independence
- Proper Oversight
- Accountability
- Strong Internal Controls
- Transparency
- Deterrence

The Sarbanes-Oxley Act came into force in July 2002 and introduced major changes to the regulation of corporate governance and financial practice. Among its many statutory requirements, Sarbanes-Oxley mandates periodic financial reports including certifications that:

- The signing officers have reviewed the report
- The report does not contain any material untrue statements or material omission or be considered misleading
- The financial statements and related information fairly present the financial condition and the results in all material respects
- The signing officers are responsible for internal controls and have evaluated these internal controls within the previous ninety days and have reported on their findings
- A list of all deficiencies in the internal controls and information on any fraud that involves employees who are involved with internal activities
- Any significant changes in internal controls or related factors that could have a negative impact on the internal controls

Public companies are required to comply with SOX and not-for profits are highly encouraged to voluntarily comply. Voluntary compliance with the legislation for not-for-profits would require



- Established formal governance over financial reporting and interaction with the Board of Directors, Audit Committee, and external financial auditors.
- CEOs and CFOs certify whether the company's financial statements are true, complete, and fairly stated.
- CEOs and CFOs evaluate the effectiveness of the company's disclosure controls and procedures and present their conclusions about the effectiveness in the annual filing.
- Management annually assesses and asserts to the effectiveness of the company's internal controls and procedures for financial reporting.

For public companies, SOX contains many requirements that affect senior executives and individual directors. Among those are:

- CEO/CFO Certifications to assure accuracy, completeness and timeliness (separate civil, criminal certifications)
- Establish and assess disclosure controls and procedures for collecting, processing and disclosing information required to be disclosed in periodic reports (10K, 10Q, 8-K) (current requirement); internal control reports in annual reports (fiscal years post 9/15/03)
- Accelerated reporting by Executive Officers and Directors (2 days)
- Code of Ethics, Senior Financial Officers (Disclose in 10K)
- Clawbacks for CEO/CFO bonus, stock sales profits if company's financial statements are restated due to misconduct (12 months from 1st disclosure)

Sarbanes-Oxley establishes an independent commission which is required to study and report on the extent of off-balance transactions. The commission is also required to determine whether generally accepted accounting principals or other regulations result in open and meaningful reporting.

Financial statements published by regulated companies are required to be accurate and presented in a manner that does not contain incorrect statements. These financial statements must include all material off-balance sheet liabilities, obligations or transactions. Regulated companies are required to publish information in their annual reports concerning the scope and adequacy of the internal control structure and procedures for financial reporting. This statement must assess the effectiveness of such internal controls and procedures. A registered accounting firm must, in the same report, attest to and report on the assessment on the effectiveness of the internal control structure and procedures for financial reporting. Regulated companies are required to disclose to the public, on an urgent basis, information on material changes in their financial condition or



operations. These disclosures are to be presented in terms that are easy to understand supported by trend and qualitative information of graphic presentations as appropriate.

This last requirement, known as Section 404, has had one of the largest impacts on corporations in America. Companies impacted have initiated projects to document, assess the gaps over, remediate, and test the internal controls over financial reporting (ICOFR). In addition, each company must assert as to its findings resulting from this process and that the ICOFR are adequate within the parameters established by the Public Company Accounting Oversight Board (PCAOB) and the Securities and Exchange Commission (SEC).

Audit Committee Requirements under SOX affect the full Board of Directors, Board Committees and executive officers of the company. Audit Committee oversight would include:

- Directly responsible for “appointment, compensation and oversight” of independent Auditors (SOA);) Have sole authority to appoint, compensate and oversee outside Auditor (NASDAQ)
- Approve, in advance, the provision by the Auditor of all permissible non-audit services
- Authority to engage and determine funding for independent counsel and other advisors; company must provide funding

Additional duties of the Audit Committee:

- At least annually, obtain and review a report by the independent Auditor describing the firm’s internal quality control procedures; any material issues raised by the most recent internal quality control review, peer review or any inquiry or investigation within the preceding five years and assess the Auditor’s independence with respect to all relationships between the independent Auditor and the company (NYSE)
- Discuss annual and quarterly financial statements with management and independent Auditor, including MD&A (NYSE)
- Establish complaint reporting procedures/mechanism
- Audit Committee must review and approve all related-party transactions (NASDAQ)
- Additional NYSE requirements (e.g., discussing risk assessment and risk management)

Audit Committee Composition

- Independence
  - Audit Committee member not to receive any compensation other than for board or committee service
  - Audit Committee member may not be affiliate of the company or its subsidiary (NASDAQ= own/control >20% voting stock )



- Limit time non-independent Audit Committee members can serve to 2 years; prohibited from serving as chair. Cannot be company employee/family member; affirmative board determination required that in best company interests; disclosure requirements
- Financial Expertise
  - Audit Committee must include at least one “financial expert.”(SOA-disclosure requirement in 10K)(NYSE/NASD require)
  - All Audit Committee members must be able to read and understand financial statements (NYSE/NASDAQ- at time of appointment)
  - At least one member of the Audit Committee must have accounting or related financial management expertise (NYSE); consider education and experience as public accountant or Auditor or public company CFO, Controller, and sufficient financial expertise in the accounting and auditing areas specified in SOA (NASDAQ)

#### Audit Committee Reporting Mechanisms:

- Complaint Procedures:
  - Must establish procedures for receipt, retention and treatment of complaints regarding accounting, internal accounting controls and auditing issues.
  - Implies reporting mechanism, record-keeping and responsive actions
  - Provide mechanism for employees to submit concerns on a confidential, anonymous basis regarding questionable auditing or accounting matters.

#### Requirements Affecting Outside Auditors

- New Auditor Independence Requirements
- Registered public accounting firms will be prohibited from providing eight types of non-audit services to audit clients:
  - Bookkeeping or other services related to company’s accounting records or financial statements
  - Financial information systems design and implementation
  - Appraisal or valuation services, fairness opinions
  - Actuarial services
  - Internal audit outsourcing services
  - Management functions or human resources
  - Broker or dealer, investment adviser or investment banking services
  - Legal services and expert services unrelated to the audit
  - Any other service determined to be impermissible by the future Public Company Accounting Oversight Board



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- Mandatory Auditor rotation: Partner cannot be lead or review partner for more than 5 consecutive years
- Outside Auditor must timely report to Audit Committee:
  - All critical accounting policies and practices to be used in financial reports
  - All alternative treatments of financial information within GAAP that have been discussed with management, ramifications of their use, and treatment preferred by the Auditor
  - Other material written communications with management

There are many recommended actions to enhance compliance. Some specific steps would include:

- Assess/document P&P, processes already in place; determine gaps requiring new standards
- Develop and implement new standards
- Communicate to and train appropriate individuals
  - Board of Directors
  - Senior Management
  - Compliance Officer
  - Other Employees
- Enhance reporting mechanism (ensure Audit Committee link)
- Consider/clarify relationship of Internal Audit/Public Reporting Compliance Coordinator, Compliance Officer, Compliance Committee, Board and Board Committee Oversight
- Consider/incorporate auditing, monitoring approaches in compliance program
- Opportunity to consider/incorporate overall risk assessment and risk management
- Incorporate responsive actions in compliance program
- Financial and Disclosure controls
  - Prepare Disclosure Guidelines (continued)
  - Identify appropriate individuals to involve in process- principal accounting officer/controller, risk management, investor relations, compliance officer, in-house counsel, business unit heads, subsidiary parallel positions, CEO/CFO review
  - Assign responsibility to appropriate specific individuals
  - Consider appropriate oversight and disclosure mechanisms- e.g., checklists, form Disclosure Committee
  - Back-up certifications by key individuals
  - Consider parallel clawbacks in event of material restatement
  - Legal Counsel review of reports
  - Outside Auditor/Audit Committee roles, including review
  - Document meetings, reviews, approvals/pre-approvals



- Review/revise Audit Committee charter

Sarbanes-Oxley imposes penalties of fines and/or up to 20 years imprisonment for altering, destroying, mutilating, concealing, falsifying records, documents or tangible objects with the intent to obstruct, impede or influence a legal investigation. The legislation also imposes penalties of fines and/or imprisonment up to 10 years on any accountant who knowingly and willfully violates the requirements of maintenance of all audit or review papers for a period of 5 years. Organizations may not attempt to avoid these requirements by reincorporating their activities or transferring their activities outside of the United States.

#### WILLFUL BLINDNESS:

The concept of willful blindness Board of Directors and Senior Management can not simply turn a blind eye to violations of the above referenced statutes with impunity. The doctrine of “willful blindness” is alive in well in the realm of corporate accountability. Willful blindness first appeared as a substitute for actual knowledge in English case law over a century ago. “The willful blindness doctrine permits a jury to find that a defendant, in this case our director or senior manager, has knowledge of the material facts because he has deliberately chosen to remain ignorant of illegal activity that would have been disclosed by further investigation.” United States v. Jewell, 532 F.2d 697, 704 (9th Cir. 1976)).

The willful blindness doctrine is primarily recognized by English authorities. Id. 532 F.2d at 705. "A classic illustration of this doctrine is the connivance of an innkeeper who deliberately arranges not to go into his back room and thus avoids visual confirmation of the gambling he believes is taking place." Id. The willful blindness doctrine requires the government to establish that the actor had a conscious purpose to avoid enlightenment. United States v. Barnhart, 979 F.2d 647, 651 (8th Cir.1992).

“Additionally, willful blindness requires proof that the actor took deliberate actions to prevent the obtaining of actual knowledge of the facts.” Id. (Cited by In re Conduct of Albrecht, 42 P.3d 887, 904 (Or. 2002).

The cost to a hospital or healthcare facility for initial immersion simulation training and a full “Crawl-Walk-Run” community disaster drill is \$120,000 to \$180,000. The corporate officers of a hospitals or healthcare facility cannot reasonable claim the inability to know that their facility had not spent the money required to be NRP/NIMS compliant. This willful blindness constitutes the requisite knowledge of guilt for a successful Qui Tam and Sarbanes-Oxley claim.

In addition, SOX creates additional protections for whistleblowers and new federal criminal codes provide additional protections. 18 U.S.C. § 1513: “Whoever knowingly, with the intent to retaliate, takes any action harmful to any person . . . for providing to a law enforcement officer



any truthful information relating to the commission or possible commission of any Federal offense . . .” Elements added to 18 U.S.C. § 1513(e):

- Knowing and intentional action to retaliate
- Against any person (not just an employee)
- Providing truthful information relating to commission or possible commission
- A law enforcement official (not just a Federal agent)
- Regarding any Federal offense

Further, Elements of 18 U.S.C. § 1514A:

- Prohibits a company from sanctioning an employee because of any lawful act to provide information about “fraud against shareholders” to (1) a Federal agency, (2) Congress, or (3) employee’s supervisor.
- Authorizes civil action for damages and equitable relief, including reinstatement, back pay, attorneys’ fees, etc.
- 90-day statute of limitations: employee must file claim within 90 days of retaliation.
- Provision construed narrowly: applies only to information provided in connection with an ongoing proceeding.

### CONCLUSION:

Based on the comprehensive review of CMS regulations, JCAHO standards, NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan, it is the position of High Alert that this creates a market pressure towards Comprehensive Immersion Simulation Training that includes a “Crawl – Walk – Run” Disaster Exercise program for staff and ICS training for administration. This program can be delivered in 5 to 6 days and provides all required education and drills to meet all patient safety, disaster preparedness/response and community/multi-agency drills required under CMS regulations, JCAHO standards, NRP/NIMS and the NIMS Implementation Center Hospital and Healthcare Facility Plan. Such a program provides client hospitals and healthcare facilities with comprehensive disaster planning, preparation and response training, significant patient safety improvement through the use of simulation-based training and demonstrable cost savings compared to the present market approach to these processes while protecting these clients from potential financial harm.

The fortuitous convergence of CMS regulations, JCAHO standards, NRP/NIMS/NIMS Implementation Center Hospital and Healthcare Facility Plan revisions, National Academies of Sciences Reports on Hospital and Community Preparedness and the Institutes of Medicine *To Err is Human* report create an unexpected environment that yields *de facto* mandates for full and unmodified implementation of the NIMS Implementation Center Hospital and Healthcare Facility Plan. Further, the market is ripe for the introduction of the next evolution disaster preparedness training.



Immersion Simulation Training will extend disaster training to the inpatient bedside environment and include high fidelity human patient simulators to train not only disaster and terrorism response/treatment, but also patient safety and other issues raised in the Institute of Medicine report *To Err is Human*. This model creates a training environment akin to that used to train airline pilots and fighter pilots. Teams trained in this model employ techniques patterned after those used to train NASCAR Pit Crews to work quickly and accurately in a high risk, high stress and fast paced environment.

The shift in federal priorities, CMS regulations and private accreditation criteria creates an opportunity as well as a responsibility. Hospital and health care institutions are now held to the highest of preparedness standards with significant penalties in place for those reticent to comply. For those institutions who choose to be “first to market” and become the Immersion Simulation Training Centers for their region a new vista of opportunity is opening. Those hospitals and health care institutions that become the Immersion Simulation Training Center will quickly find that their competitors become their customers as those facilities slower to respond to this new regulatory world come to rely on the new regional training centers to maintain regulatory compliance as well as institutional accreditation.

It can be argued that under Sarbanes-Oxley, a hospital or healthcare facility corporate officer who signs the mandated financial report for the hospital despite the fact that the hospital is not fully NRP/NIMS compliant is guilty of violating the statute because the financial statement is based on false attestations of compliance to CMS at the time the insurance claim is billed. Further, if the false attestation linked to NRP/NIMS compliance results in a Qui Tam action, the corporate officers may face additional jeopardy under both Sarbanes-Oxley and the False Claims Act.

Finally, disaster preparedness is no longer just an accreditation issue. “All Hazards” disaster planning is no longer just a requirement to qualify for federal grants. Education is no longer a last priority. These activities are being linked to civil and criminal statutes with increasing frequency both in open interviews and printed discussion. Disaster planning, preparation and education are becoming the newest legal shield for the healthcare corporate officer.

The Unprepared Beware.