THIRD NATIONAL EMERGENCY MANAGEMENT SUMMIT

POINT-COUNTERPOINT: A "CRISIS STANDARD OF CARE": DOING THE RIGHT THING WHEN YOU MUST DO SOMETHING AND YOU CAN'T DO EVERYTHING

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I. PRACTICAL PREPAREDNESS STEPS

A. Moving From Traditional Standards of Care to a Crisis Standard of Care

1. Traditionally, the standard of care for healthcare professionals focuses on doing whatever is reasonably possible to save *every* life. However, relevant government agencies recognize that an altered standard of care may be necessary in the event of an emergency.

Agency for Healthcare Research and Quality (AHRQ)

- Altered Standards of Care and Mass Casualty Events: "A shift to providing care and allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in contrast to the traditional focus on saving individuals." *See* U.S. Department of Health and Human Services, Agency for Healthcare Research & Quality, Altered Standards of Care in Mass Casualty Events: Bioterrorism and Other Public Health Emergencies, AHRQ Pub. No. 0-0043 (2005), *available at* www.ahrq.gov/research/altstand/altstand.pdf.

Homeland Security Council

- Implementation Plan for the National Strategy for Pandemic Influenza: "The standard of care will be met [during a pandemic] if resources are fairly distributed and are utilized to achieve the greatest benefit." See Homeland Security Council, National Strategy for Influenza Pandemic: Implementation Plan (2006), *available at* www.whitehouse.gov/homeland/pandemic-influenza-implemenation.html.

Department of Defense

- Policy for Prioritizing Delivery of Medical Care during Pandemics and Other Public Health Emergencies of National Significance: This policy articulates the framework that the Military Health System (MHS) will adopt for the delivery of medical care during pandemics and other public health emergencies. "Under emergency conditions, the allocation of resources may not be based solely on medical necessity or risk, but also may be based on operational or other national security requirements, as directed by the President or Secretary of Defense." *See* Department of Defense Policy for Prioritizing Delivery of Medical Care during Pandemics and Other Public Health Emergencies of National Significance, HA Policy 08-010 (September 1, 2008), *available at* www.health.mil/Content/docs/pdfs/policies/2008/08-010pdf.

2. Healthcare providers, however, cannot afford to wait for national or state legislative or regulatory developments to address standards of care issues. The time horizon for any such government intervention is simply too long and too uncertain. Thus, healthcare providers should begin to engage in planning *now* to determine the functional requirements of a comprehensive system to manage an emergency or other mass casualty events. This is a challenging undertaking for healthcare providers given the wide range of provider entities and organizations that exist in this country -- from public to private and with widely varying organizational structures and missions.

3. An excellent resource for provider planning is the Medical and Health Incident Management ("MaHIM") System developed by the Institute for Crisis, Disaster, and Risk Management at George Washington University. The MaHIM System is intended to provide a comprehensive *functional* system description for mass casualty medical and health incident management with the goal of limiting morbidity and mortality in a population exposed to a major hazard like a pandemic. The MaHIM System does not seek to define the technical requirements of how to address a mass casualty event, but rather describes the *functional* requirements -- "what needs to be done". Moreover, MaHIM, in recognition of the understandable inability of government to address all areas of provider preparedness, focuses on a framework for provider preparedness based upon authority generated by *responsibility* rather than exclusively upon *statutory* or *regulatory* power. As the authors note, past provider planning efforts have often begun with the question "who's in charge?" and commonly stalled on this question. *See* Medical and Health Incident Management System Final Report (December 2002), *available at* www.gwu.edu/~icdrm/publications/MaHIM.

4. Expert commentators are beginning to conclude that there should be a "crisis standard of care" for emergencies such as pandemics where healthcare demands exceed available resources. These commentators also contend that evidence-based research is needed to develop a crisis standard of care. *See, e.g.,* Emile Chang, Howard Backer, Tareg Bey & Kristi Koenig, *Maximizing*

Medical and Health Outcomes after a Catastrophic Disaster: Defining a New "Crisis Standard of Care," Journal of Emergency Medicine, 2008 (abstract); Kristi Koenig, David Cone, Jonathan Burstein and Carlos Camargo, Jr., *Surging to the Right Standard of Care*, Academic Emergency Medicine, 2006, at 195.

B. Implementation Challenges and Potential Solutions

1. Potential Malpractice Claims. An emergency presents treatment challenges that inevitably will cause providers to modify their normal treatment protocols. This increases a provider's risk for malpractice claims.

a. What actions can be taken by healthcare providers to minimize the risk of such claims?

- Providers should develop triage protocols to prioritize emergency cases by level of acuity.

- Providers should develop emergency treatment algorithms similar to, for example, algorithms for treatment of myocardial infarctions.

- Providers should develop treatment protocols focused on processing large numbers of similar cases in order to make patient care more efficient during an emergency. For example, a protocol could be developed for a modified H&P limited to visual inspection, vital signs, and cultures.

- Providers should develop "short form" documentation requirements focused solely on emergency treatment issues, including a short form consent to treatment.

- Providers should develop policies related to the dispensing of scarce medications and lifesaving equipment such as ventilators. Such policies can address significant rationing of care and other ethical issues.

- Providers should discuss the potential malpractice risks presented by an emergency with both their malpractice defense counsel and their emergency preparedness counsel. Both counsel should be included in the consideration of modified treatment protocols and other proposed "shortcuts."

b. Will there likely be insurance coverage for such malpractice claims? If not, what steps should providers take to improve their coverage position?

- Providers should have candid discussions with their insurance carrier about the potential malpractice risks presented by an

emergency and discuss possible approaches to minimize such claims.

2. Insufficient Staff. In an emergency, there may be a critical shortage of hospital workers due to the particular circumstances of the emergency situation (*e.g.,* inability to commute to work, ill or injured employees, family caregiving responsibilities).

a. What are the most significant staffing issues that healthcare providers likely will face?

- Providers should develop emergency staffing contingency plans, identifying essential staff for medical services and other staff for non-medical essential services. For example, non-emergency related hospital services such as obstetrics and cardiac care must still be provided or referred to other facilities (if possible during an emergency). In addition to physicians and nurses, other critical clinical personnel include respiratory therapists, pharmacists, laboratory employees, blood bank and morgue staff. Providers also will need to identify crucial administrative, food services, housekeeping, security and facilities staff.

- Clinical personnel should be cross-trained to assist in providing care during an emergency. Administrative staff should also be cross-trained to provide basic nursing services.

- Providers should identify possible sources of temporary personnel in the community for assignment during an emergency. For example, physicians and nurses in the community with special expertise in infectious diseases, pulmonary medicine and critical care medicine should be identified and call rosters developed for possible temporary assignment. Other possible sources of emergency staffing include retired personnel, medical and nursing students, the local Red Cross, and state and federal public health agencies.

3. Insufficient Facilities Capacity. Provider facilities likely will be strained beyond their capacity limits during an emergency which could result in critical shortages of beds, supplies and equipment.

a. What are the most significant facility-capacity issues that providers likely will face?

- Providers should develop policies setting forth admission and discharge priorities by patient condition and acuity during an emergency. The policies should address triggers for the

cancellation of elective procedures, prioritization guidelines for early discharge of current inpatients, and criteria on transfers to other treatment settings.

- Visitors will need to be restricted and mechanisms should be established for enforcing such restrictions, including the use of hospital security services. Hospitals should meet with local law enforcement officials to determine ways in which they can assist in this area.

- Provider facilities should begin developing plans for facility surge capacity, including the use of alternate care sites. For facilities, potential "surge hospitals" include shuttered hospitals or closed wards, mobile medical facilities (*e.g.*, trucks fitted with surgical and intensive care units), portable facilities (commonly referred to as "hospitals in a box") and "facilities of opportunity" (*e.g*., veterinary hospitals, convention centers, exhibition halls, empty warehouses, airport hangars, schools, hotels). See, *e.g*., Joint Commission for the Accreditation of Healthcare Organizations, *Surge Hospitals: Providing Safe Care in Emergencies* (2006), available at www.jointcommission.org/publicpolicy/surge_hospitals.htm.

- Providers should identify areas of their facilities that could be vacated for use as surge capacity.

- Hospitals should consult with their state hospital licensing and certificate-of-need (where applicable) agencies on plans and processes to expand bed capacity during an emergency.

- Providers should develop criteria for reduction in the routine use of laboratory, radiology and other diagnostic ancillary services.

- Providers should stockpile sufficient quantities of consumable supplies that will be needed in an emergency (*e.g*., masks).

- Providers should identify reserve morgue capacity.

4. Use of Non-Employee Personnel (*e.g.*, non-employed volunteers or out-of-state forces). Due to staffing inadequacies, providers may need to bring in additional staff who will not be familiar with the facility's policies or treatment protocols, and any out-of-state volunteer professionals are unlikely to be properly licensed by the provider's licensing authority.

a. Providers should develop "quick study" kits for non-employee personnel that succinctly describe key hospital policies, treatment protocols and key contact information (*e.g*., telephone

numbers, pager numbers, e-mail addresses) necessary to render care at the provider's facility.

b. Providers should develop plans on how to house and feed an out-of-town work force.

c. Providers should consider discussing with their insurance carriers how insurance coverage may be affected by the use of non-employee personnel, including the use of unlicensed personnel (*e.g.*, health care professionals coming from other jurisdictions).

5. Protection and Safety of Staff. Depending upon the particular set of circumstances, an emergency situation often will present new risks for staff.

a. Providers will need to balance the protection and safety of its staff with treating a large volume of seriously ill or injured patients during an emergency.

b. Providers should establish guidelines for rapidly vaccinating or providing antiviral medications to health care personnel, including a priority list for essential clinical personnel for scarce vaccines and antivirals.

c. Providers should assess their potential need for personal protective equipment and begin stockpiling sufficient numbers.

d. Providers should develop policies to cohort essential clinical personnel such that personnel working in more critical areas do not contaminate less critical areas and vice versa in the event of a pandemic.

e. Providers should identify mental health and psycho-social counseling resources for counseling of staff during an emergency to address issues of grief, stress and fear that inevitably will arise.

f. Providers should develop plans for reassignment of high-risk personnel (*e.g.*, pregnant and immunocompromised persons).

6. Patient Rights. Patients enjoy certain rights in provider settings (*e.g.*, the right to confidentiality) that inevitably will be curtailed during an emergency. One of the key challenges presented by an emergency will be the way facilities balance such individual patient rights against the need to accommodate the needs of all patients.

a. Providers should identify the primary conflicts between the protection of patient rights and the medical needs of treating

large numbers of seriously ill or injured individuals during an emergency.

b. Providers should develop easy to read, one-page handouts for patients and their families relating to those patient rights that in normal operations are observed, but that may not be fully complied with during an emergency.

II. LEGISLATIVE, REGULATORY AND POLICY ISSUES

A. Liability Concerns

1. The most significant legal impediment to the implementation of alternative clinical pathways during an emergency is the risk that healthcare providers will face civil, and possibly even criminal, liability for deviating from the traditional standards of care. This is true for both individual and institutional providers. Liability potentially exists for medical malpractice, criminal negligence, and for acting beyond the scope of or without a professional license.

2. A medical malpractice claim consists of an allegation that a healthcare provider has breached the provider's duty to provide services at a certain level of care and skill, resulting in damage to the plaintiff. The applicable standard of care for a malpractice action is determined by each state as a matter of state law.

3. Most states also have criminal negligence statutes. Many of these statutes define criminal negligence as the failure by a person to be aware of a substantial and unjustifiable risk that a result will occur or that a circumstance exists. The risk must be of such a nature and degree that the failure to be aware of it constitutes a gross deviation from the standard of care that a reasonable person would observe in the situation. Other states define criminal negligence as a failure to act which demonstrates a willful, wanton or reckless disregard for the safety of others who might reasonably be expected to be injured thereby. *See, e.g.*, 17-A ME. REV. STAT. ANN. §34; OR. REV. STAT. § 161.085 (2003). The types of charges that may be brought for criminal negligence include homicide, assault and battery, and child or elder abuse.

4. The professional licensing of physicians, nurses and other individual healthcare providers is also a matter of state law. The necessity to act beyond the scope of one's license during an emergency, or the use of volunteer professionals from other jurisdictions who are therefore not licensed by the state in which the services are provided, create potentially significant legal impediments to altered clinical pathways.

5. While various forms of statutory immunity for healthcare providers are available, there are no comprehensive liability protections in place for healthcare providers for deviations from traditional standards of care or for acting beyond the scope of or without a license. Instead, immunity for actions taken during a

mass casualty event currently depends on a patchwork of state and federal statutes. There are, unfortunately, gaps and limitations in the degree of immunity that is currently available.

B. Sources of State Immunity

1. Model State Emergency Health Powers Act ("MSEHPA"). Approximately 40 states have adopted various provisions of this Model Act. The Act provides immunity following a declaration of an emergency by the state's governor or public health authority for personnel who render assistance at the request of a state or its political subdivisions. Gross negligence and willful misconduct are excluded from immunity. *See* Model State Emergency Health Powers Act *available at* www.turningpointprogram.org/Pages/pdfs/statute_mod/phsm_emergency_law.pdf.

2. The Model Intrastate Mutual Aid Legislation ("MIMAL"). This Model Act addresses voluntary health professional responders providing services within a state. Such responders under the operational control of a unit of government are considered employees of that government unit, therefore creating the possibility of sovereign immunity. *See* Model Intrastate Mutual Aid Legislation *available at* http://www.emacweb.org?76.

3. Emergency Management Assistance Compact ("EMAC"). This Model Act, adopted in all 50 states, provides civil immunity for officers and employees of a responding state. Gross negligence and willful misconduct are excluded from immunity. General information relating to EMAC is *available at* http://www.emacweb.org.

4. Uniform Emergency Volunteer Health Professionals Act ("UEVHPA"). This Model Act is being developed by the National Conference of Commissioners on Uniform State laws. The 2007 interim draft provisions on civil liability for voluntary health professionals provide comprehensive immunity for civil liability. *See* Uniform Emergency Volunteer Health Professionals Act *available at* http://www.uevhpa.org/DesktopDefault.aspx?tabindex=1&tabid=55.

5. Good Samaritan Statutes. Theses state statutes vary widely and typically immunize services at the scene of an emergency by a non-compensated volunteer. (*See, e.g.*, 14 ME. REV. STAT. ANN. §164).

C. Sources of Potential Federal Immunity

1. Volunteer Protection Act (42 U.S.C. §§ 14501, et seq.). This federal statute provides immunity for non-compensated volunteers at a nonprofit facility.

2. National Disaster Medical System (42 U.S.C. § 30hh-11(d)). This emergency system, enacted as part of the Pandemic and All Hazards Preparedness Act of 2006 and the Homeland Security Act of 2002, enables

various federal agencies to recruit private persons to assist during a pandemic or other disaster and receive federal employee immunity.

3. Public Readiness and Emergency Preparedness Act (42 U.S.C. § 247d-6d). This federal statute provides broad immunity during a declared public health emergency where the Secretary of HHS also declares the use of a "counter measure," (*i.e*., a drug or biological product or device).

D. Key Limitations of Immunity

1. As a result of this patchwork of state and federal immunity provisions, various gaps and limitations currently exist in immunity protection for healthcare providers seeking to apply altered standards of care during an emergency. These gaps and limitations include the following:

- Some immunity statutes apply only to volunteers who are donating their services free of charge.
- Some immunity statutes apply only following formal declarations of emergency by a state's governor or the local public health authority.
- Many statutes protect only officially designated government personnel and do not offer protection to private volunteers.
- There is little existing protection for institutional providers, and in some cases immunity for individuals providing services on behalf of an institutional provider can vary based on whether the institution is nonprofit or private.
- Gross negligence and willful misconduct are typically excluded from immunity protection, and criminal liability, which in some states could theoretically result simply from providing services without a license, also is typically excluded.

E. Key Issues

1. Should there be a national standard providing for an altered standard of care during an emergency? Why?

2. Should any national standard be set by specific legislation or by regulation pursuant to enabling legislation? If the standard should be set by regulation, which federal agency should be authorized to adopt the regulations?

3. Is the judicial system a better or worse choice for assuming the responsibility of articulating an altered standard of care for an emergency?

4. Is there a role for the states? If so, what?

5. Should there be immunity for providers delivering healthcare services during an emergency?

6. Should the immunity be broad in scope? Civil only? Negligence only?

7. Are the current state statutes adequate? Why not?

8. Should there be federal legislation creating national immunity standards?

9. Should there be both entity and individual protection?

10. Should immunity for individuals apply only to licensed personnel? If so, which ones?

11. Should immunity for individuals apply only to volunteers who are donating their services?

III. CONCLUSION

Minimizing potential liability involves adequate planning in advance to address a public health crisis, terrorist threat, environmental disaster or other emergency situation. Since each healthcare provider is unique, the advance planning will need to be adapted to address the specific needs and capabilities of a particular healthcare professional or entity. Because healthcare organizations and individual providers also are part of the community's healthcare system, organizations should engage in advance emergency planning within the context of a community-wide response in addition to operating as an individual entity.

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Biographical Statement

Elisabeth Belmont, Esq. serves as Corporate Counsel for MaineHealth, a family of healthcare services located in southern, central and western Maine that includes Maine Medical Center, Miles Health Care, Spring Harbor Hospital, St. Andrews Hospital and Healthcare Center, Western Maine Health Care, Waldo County Hospital, NorDx Laboratories, Community Health Services, Practice Partners, Intellicare, SYNERNET, Sisters of Charity Health System, and other affiliated organizations, and has held this position since 1998. Prior to this time, Ms. Belmont was Associate General Counsel for Maine Medical Center, a position she held since 1985.

As Corporate Counsel, Ms. Belmont is involved in a myriad of complex issues hospitals face on a daily basis including contractual arrangements; hospital-physician relationships, medical staff bylaws and governance; credentialing, peer review and related hearings; corporate organization and governance; corporate and research compliance; patient care and consent issues; regulatory matters such as investigations by licensing or regulatory authorities; risk management and quality assurance initiatives; management of pending and threatened professional and general liability claims prompted by a significant hospital self-insurance program; information technology acquisitions and licensing, and electronic health information networks; HIPAA and health information privacy and security matters; fraud and abuse and Stark issues; tax exemption issues including intermediate sanctions and private inurement; real estate transactions; and employee relations issues.

Ms. Belmont was named by NEW ENGLAND IN-HOUSE/MASSACHUSETTS LAWYERS WEEKLY as one of the 2008 Top 15 In-House Leaders in the Law; by MODERN HEALTHCARE as one of the 2007 Top 25 Most Powerful Women in Healthcare; and by HEALTH LAW 360, the Newswire on Health Law and Policy, as one of the 2007 Outstanding Women in Healthcare.

Ms. Belmont is a member of the American Health Lawyers Association ("Health Lawyers") as well as the Health Law and Electronic Communications and Internet Issues Committees of the Maine State Bar Association. Ms. Belmont currently serves as a member of Health Lawyer's Board of Directors, and is the Immediate Past President. She served as President of Health Lawyers for the period 2007-2008. Ms. Belmont has held a number of leadership positions for Health Lawyers including Chair of the Programs Board Committee for the period 2006-2007, Chair of the Finance Board Committee and Treasurer for the period 2005 – 2006, and Chair of the Public Interest Board Committee for the period 2003 – 2005.

While chairing the Health Lawyers' Public Interest Board Committee, Ms. Belmont initiated the *Public Information Series* and served as a co-author and editor of several publications in this *Series*. The *Public Information Series*, a collection of highly informative, consumer-friendly guidebooks is a category of publications through which Health Lawyers shares its expertise on topics that are of interest both to healthcare attorneys and to the broader healthcare community, including health professionals, healthcare executives, public health agencies, pro bono attorneys, and consumer groups. Ms. Belmont was a principal author of the first publication in the series, *Emergency Preparedness, Response & Recovery Checklist: Beyond the Emergency Management Plan*, and is a co-author of the following publications, *A Guide to*

Legal Issues in Life-Limiting Conditions, *Lessons Learned from the Gulf Coast Hurricanes*, and *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers*. She also developed elder-friendly summaries of the six sections of *A Guide to Legal Issues in Life-Limiting Conditions* at the request of non-profit organizations who wished to co-brand this publication. The *Public Information Series* has been recognized by the American Society of Association Executives and The Center for Association Leadership who named Health Lawyers to the 2007 Associations Advance America Honor Roll, a national awards competition, for this *Series*.

Ms. Belmont previously served as Chair of Health Lawyer's Health Information & Technology ("HIT") Practice Group for the period 1999 –2002, Vice Chair for the period 1997-1999, and the initial Editor of the Practice Group's newsletter, *HIT News*, which she developed in 1997. Ms. Belmont also was a contributing author and editor of the HIT Practice Group's *Health Information Systems & Electronic Medical Records Practice Guide* published in 1997, and both Editor in Chief and a contributing author of the Second Edition of this Practice Guide published in 2003.

Ms. Belmont served as a member of the Editorial Board of the *E-Health Law & Policy Report* published by the Bureau of National Affairs, Inc. and Health Lawyers for the period 2000-2002. She currently is a member of the Editorial Boards of *Medical Malpractice Law & Strategy* published by Law Journal Newsletters and the *Health Law Reporter* published by The Bureau of National Affairs, Inc.

Ms. Belmont also has served as a member of the Confidentiality Task Force for the Maine Community Health Information Network, and currently is a member of the Maine Hospital Association's Telemedicine Advisory Group and HIPAA Task Force.

Ms. Belmont is a frequent lecturer for local, state and national seminars on health law issues and has authored articles on a myriad of health law topics. She is a nationally recognized expert in health informatics law and her specialty practice addresses a broad spectrum of issues arising from the use of information and communications technology in the health industry. Additionally, she is nationally recognized as an expert in the emerging field of legal emergency preparedness.

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