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**Guide for Planning the Use of
Scarce Resources During a
Public Health Emergency in Kansas**

September 2009

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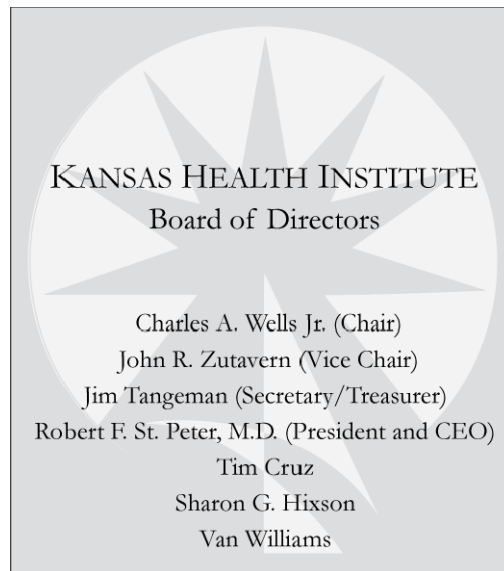
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EXECUTIVE SUMMARY

In 2009, the Kansas Department of Health and Environment (KDHE) contracted with the Kansas Health Institute (KHI) to provide guidance regarding how to plan for the use of scarce resources during a public health emergency. This publication presents the results of an extensive review of published and unpublished material on the subject and recommendations on how to develop state and local plans for the use of scarce resources. During this process, KHI also convened a work group consisting of physicians, nurses, other health care workers, and KDHE staff to review a draft of the document and provide advice and validation of the recommendations and guidelines to be incorporated into the final report.

While there is no single, universally accepted model to approach the complex issues that arise when health care resources may not be sufficient to treat patients by following standard protocols of care, there are some principles and practices that have been used by agencies and organizations in other states that could be helpful in Kansas. Most experts in this field point out that before any planning begins, an ethical framework should be decided upon which plans can be built. The most common ethical principles that have been used for this purpose are:

1. Duty to care. This is the fundamental obligation of health care professionals to care for patients.
2. Duty to steward resources. This is the obligation for government and health care providers to steward resources during a period of true scarcity.
3. Duty to plan. A failure to produce acceptable guidelines for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers.
4. Distributive justice. A just system is one in which allocation of resources is accomplished in a fair way, broadly and consistently.
5. Transparency. Any just system of allocating scarce resources requires robust efforts to promote transparency and must seek broad input.

Other principles used during the planning process are reciprocity (the fairness-based obligations of gratitude owed to groups that accept unusual risks and burdens in the service of others) and key worker status (priority given to groups of workers that have key functions in health care and other critical infrastructures). The role of age in the resource allocation process is

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controversial, but in general is de-emphasized in favor of the use of objective clinical signs and symptoms that serve as indicators of the probability of survival of patients for whom resources are allocated.

A situation in which resources to treat sick people are scarce requires a shift from a model aimed at doing everything possible to save every life to a model aimed at maximizing the number of lives saved. Because of this shift, many standard protocols of care will need to be revised and temporarily altered until sufficient resources are in place again. There is universal support in the field for the role of state and federal agencies in providing guidance to health care providers and institutions about when and how to make modifications to standard protocols of care.

In most states the trigger to signal that standard protocols of care may need to be temporarily altered is a declaration from the governor that a public health emergency exists. In Kansas the governor has broad powers during a declared emergency, including the authority to issue orders and proclamations with the force of law and to suspend or modify the provisions of any state law or regulation.

The modification of standard protocols of care during an emergency would present complex legal issues. There are important liability concerns among those who would be involved in the response to a public health emergency. Provisions are in place to protect emergency responders and health care workers from liability if they comply with directives issued by public health agencies. However, in Kansas, hospitals and private health care providers do not have such liability protection.

Recommendations included in this document are:

- Convene a scarce resource allocation task force including a broad representation of stakeholders, with the goal to prepare detailed recommendations for KDHE about principles and practices to adopt for the allocation of scarce resources and the development of altered standard protocols of care.

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- Create an advisory committee on public health emergencies with the role of advising the governor and the state health officer about health emergency issues.
- Strengthen laws that provide liability protection during a public health emergency for hospitals and private health care providers.

Given the urgency represented by the current influenza pandemic and the possibility that some shortage of resources may occur if the pandemic becomes more severe, this document also contains recommendations for some quick actions to address in a timely manner concerns raised by the pandemic. The “*fast track*” actions recommended are:

- Prepare drafts of executive orders that cover situations that could arise during the pandemic and review those drafts with the parties that would be affected if the orders are issued.
- Develop technical protocols describing how to allocate certain resources that may become scarce during a pandemic.
- Develop protocols describing how hospitals can implement altered protocols of care during an emergency.
- Develop options to address liability concerns for hospitals and private health care providers.

Examples and reference documents from other states to assist in the implementation of the “*fast track*” actions are provided in this document.

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INTRODUCTION

SCOPE AND GOALS OF THIS REPORT

In early 2009, the Kansas Department of Health and Environment (KDHE) entered into a contract with the Kansas Health Institute (KHI) to provide services for the development of recommendations and planning guidance in the area of allocation of scarce resources, specifically related to public health emergencies and other emergencies with health consequences. KDHE also asked KHI to conduct research and analysis of Kansas emergency statutes, especially related to the governor's emergency authority to waive existing statutes and regulatory requirements during a public health emergency. This report represents the main deliverable for that contract. The document is meant to be used by KDHE as the basis for the development of allocation of scarce resource planning documents at the state, regional, and local levels that the agency intends to provide.

During the course of this project KHI staff conducted an extensive review of the information available on this subject. The review included articles published in peer-reviewed journals, documents available on the World Wide Web, and other unpublished documents obtained from various government and private agencies that have conducted or are in the process of conducting similar activities. A review of pertinent laws and regulations in Kansas and some other states also was done. The report's main author also attended a workshop in New York City in April 2009 titled "*Standards of Care During a Mass Casualty Event*," organized by the Institute of Medicine. A list of published material that was identified during the project is contained at the end of the report.

During this process, KHI also convened an advisory panel consisting of physicians, nurses, other health care workers, and KDHE staff to review the draft document and provide advice and validation of the recommendations and guidelines to be incorporated into the final report.

CONCEPTS OF SCARCE RESOURCES AND ALTERED STANDARDS OF CARE

It has been widely recognized that a public health emergency, such as an influenza pandemic or a bioterrorism act, could easily push the health care system beyond its capacity to deliver optimal care for all the individuals affected. Under those circumstances, there is a need for plans

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that can provide directions on how to maximize the efficient use of the available resources and make the necessary adjustments in the current health and medical care standard protocols.

The concepts of scarce resources and altered standards of care are two different, but closely related concepts. The term “*scarce resources*” refers to a situation in which resources are not available to treat all patients that need to be treated following standard protocols of care.

The term “*standards of care*” has been defined in different ways, including:

- The type and level of medical care required in specific circumstances via professional norms, accreditation, or other requirements;
- Authoritative statements by which a profession describes the responsibilities for which its practitioners are accountable; and
- General medical practices considered to meet the norms of medical professionalism.

As discussed in the section on legal issues, the term “*standards of care*” also has a specific legal meaning, which may not exactly overlap these definitions. For this reason, in this document we will avoid the use of the term “*standards of care*” and use instead the term “*standard protocols of care*.”

“*Standard protocols of care*” are usually the result of consensus among members of a profession on how to treat patients with certain diseases or symptoms, and are often released by professional organizations. Government and regulatory agencies may also have a role in promoting, developing, and endorsing standard protocols of care. Standard protocols address not only what care is given, but to whom, when, by whom, and under what circumstances and in what places. Under normal circumstances, these standards usually call for the allocation of all appropriate medical resources to improve the health status or save the life of each individual patient. However, should a mass casualty event occur, the demand for care provided in accordance with current standard protocols would exceed system resources; that is, a situation of scarce resources would occur, and standard protocols would have to be modified to match the resources that are available.

Although there is not a universally accepted definition of *altered standard protocols of care* (or “*altered standards of care*”), this term is generally assumed to mean a shift to providing care and allocating scarce equipment, supplies, and personnel in ways that save the largest number of lives, in contrast to the traditional focus on saving individuals. This important concept is further described in the section of this report that discusses ethical principles.

The questions raised about how to provide medical care during emergencies when resources may be insufficient have resulted in several states implementing processes to develop specific plans for such situations, and task forces have been created to study one or multiple aspects of the problem. Some national organizations also have taken an interest and produced documents on this topic. A full list of the documents that have been identified and considered in the preparation of this report is included at the end of the publication. In the following pages we will examine some fundamental issues and summarize the content of the publications that we found most helpful.

PRINCIPLES AND PRACTICES FOR THE ALLOCATION OF SCARCE RESOURCES

PLANNING PROCESS

The Agency for Healthcare Research and Quality published in 2005 a document titled “*Altered Standards of Care in Mass Casualty Events.*” The document is the result of deliberations from a panel of experts convened in 2004. Some of the key findings in the report are listed below.

- The goal of an organized and coordinated response to a mass casualty event should be to maximize the number of lives saved. Adhering to this principle will involve allocating scarce resources in order to save the most lives and developing a basis for the allocation of resources that is fair, open, transparent, accountable, and well-understood by both professionals and the public.
- Changes in the usual standards of health and medical care in the affected locality or region will be required to achieve the goal of saving the most lives in a mass casualty event. Rather than doing everything possible to save every life, it will be necessary to allocate scarce resources in a different manner to save as many lives as possible. Triage

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efforts will need to focus on maximizing the number of lives saved. Instead of treating the sickest or the most injured first, triage would focus on identifying and reserving immediate treatment for individuals who have a critical need for treatment and are likely to survive. This fundamental shift of focus from individual to mass health care is critical to achieve the goal of maximizing the number of lives saved.

- Many health system preparedness efforts do not provide sufficient planning and guidance concerning the altered standards of care that would be required to respond to a mass casualty event. Effective planning for implementation should be done at the facility level. However, facility-level planning alone is not sufficient and needs to be integrated into a regional systems approach, involving in the process a broad array of public and private stakeholders.
- The basis for allocating health and medical resources in a mass casualty event must be fair and clinically sound. The process for making these decisions should be transparent and judged by the public to be fair. The public should be brought into the discussion during the early stages of planning so that citizens develop a clear understanding of concepts such as rationing of resources.
- Protocols for triage need to be flexible enough to change as the size of a mass casualty event grows and will depend on both the nature of the event and the speed with which it occurs.
- An effective plan for delivering health and medical care in a mass casualty event should take into account factors common to all hazards (e.g., the need to have an adequate supply of qualified providers available), as well as factors that are hazard-specific (e.g., guidelines for making isolation and quarantine decisions to contain an infectious disease).
- A number of important nonmedical issues that affect the delivery of health and medical care need to be addressed to ensure an effective response to a mass casualty event. They include:
 - The authority to activate or sanction the use of altered standards of care under certain conditions.
 - Legal issues related to liability, licensing, and intergovernmental or regional mutual aid agreements.

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- Financial issues related to reimbursement and other ways of covering medical care costs.
- Issues related to effective communication with the public.
- Issues related to populations with special needs.
- Issues related to transportation of patients.
- Guidelines and companion tools related to the development of altered standards of care in a mass casualty event are needed by, and would be extremely useful to, preparedness planners.

CAPACITY STAGES

In an article published in 2009 in the journal “*Disaster Medicine and Public Health Preparedness*,” John Hick and colleagues propose a taxonomy that can help understand how surge capacity and scarce resources could be handled during an emergency. The authors classify resources into the three broad groups of patient care space, staffing, and supply. These resources can be used in three capacity stages:

1. Conventional capacity — The spaces, staff, and supplies used are consistent with daily practices within the institution. These spaces and practices are used during a major mass casualty incident that triggers activation of the facility emergency operations plan.
2. Contingency capacity — The spaces, staff, and supplies used are not consistent with daily practices but maintain or have minimal impact on usual patient care practices. These spaces or practices may be used temporarily during a major mass casualty incident or on a more sustained basis during a disaster (when the demands of the incident exceed community resources). Examples include managing ventilated patients on monitored step-down units when no intensive care beds are available; having a floor nurse providing basic nursing care for a burn patient, whereas a burn unit nurse and physician provide oversight and perform dressing changes; and reuse after disinfection and cleaning of certain disposable patient care items (e.g., cervical collars, basins). This stage is comparable to what other authors call “surge capacity.”
3. Crisis capacity—Adaptive spaces, staff, and supplies are not consistent with usual standards of care but provide sufficiency of care in the setting of a catastrophic disaster (i.e., provide the best possible care to patients given the circumstances and resources

available). This stage of an emergency is when standard protocols of care would be significantly modified. Examples include placing patients in hallways or lobby areas on pre-staged cots; lay volunteers assisting with basic patient hygiene and nonmedical aspects of care and monitoring; reusing invasive line; and re-allocating ventilators.

ETHICAL PRINCIPLES AND STRATEGIES

Minnesota Pandemic Ethics Project

In 2007 the Minnesota Department of Health (MDH) contracted with ethicists from the Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics to develop and lead the Minnesota Pandemic Ethics Project. This project's purpose was to propose ethical frameworks and procedures for rationing scarce health care resources in a severe pandemic. The project team convened a community-based resource allocation panel, expert work groups, and an implementation protocol committee, together comprising more than 100 people. The preliminary report published in January 2009 contains the proposed ethical frameworks and procedures for rationing the following resources:

- Antiviral medications,
- N95 respirators,
- Surgical masks,
- Vaccines, and
- Mechanical ventilators.

The panel chose as its overarching guiding principle to pursue Minnesotans' common good in ways that are accountable, transparent, and worthy of trust; promote solidarity and mutual responsibility; and respond to needs fairly, effectively, and efficiently.

From the report it appears clear that the members of the panel struggled with some key ethical and strategic issues related to the allocation of scarce resources. Here is an example:

“Deciding how best to ration health-related resources from a statewide perspective during a global public health disaster raises novel ethical issues. Should some individuals and some groups have prioritized access to certain resources? If so, why? Should resources like vaccines

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go to those at greatest risk of dying from the flu even if they may not respond as well to vaccines as others? Should resources be used to protect persons who are taking risks to help others, because they are contributing to everyone's survival — whether they are irreplaceable workers at a power plant, health care workers caring for flu victims, or volunteers delivering “Meals on Wheels?” Should resources be given first to children, because they cannot fend for themselves, they are society's future, and society is responsible for their welfare? Should patients be removed from ventilators so that others more likely to benefit can be given a chance at survival?”

Rationing strategies were developed based on clinical considerations (prioritizing groups at highest clinical risk so long as they are likely to respond well to the resource) and non-clinical considerations. The non-clinical considerations generated the highest level of discussion among panel members. The panel endorsed the use of the following factors in recommending the strategies:

1. Reciprocity. The fairness-based obligations of gratitude owed to groups that accept unusual risks and burdens in the service of others.
2. Key worker status. These are groups of workers that have key functions in health care and other critical infrastructures. Groups of key workers that are recommended by the panel to be at highest priority must have additional characteristics as well, such as disproportionately high occupational exposure or be at high risk of flu-related mortality or serious morbidity. The panel recommends against prioritizing key workers for ventilators for two reasons. First, patients ill enough to require mechanical ventilation are not expected to recover and return to work for many weeks, and some substantial number might never be well enough to return to their jobs. It is unlikely that prioritizing key workers to receive ventilators could accomplish the goal of getting ill workers quickly back on the job to help others during the pandemic. Second, if key workers were prioritized to receive ventilators for reciprocity reasons alone, it is possible that they would use most, if not all, of the short supply of ventilators; other groups systematically would be deprived access. The panel concluded this would be unfair to those who do not work outside the home, who are students, young children, retired, or have jobs not considered key to preserving Minnesota's critical infrastructures.

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3. Age. The panel, with some reservation, agreed to propose age-based rationing for some resources, as a way of prioritizing groups after clinical criteria had been considered but before resorting to random selection.

Non-clinical factors that were rejected by the panel included factors like ability to pay, social or economic status, political power, social worth, and gender. The panel also specifically recommended against considering quality of life or duration of extended life. These considerations do not promote the ethical principles of protecting the population's health, protecting public safety and social order, or respecting the moral equality of all citizens.

Based on these factors, some of the general strategies recommended by the panel were:

- Do not resort to random processes prematurely.
- Do not ration based on:
 - Social value (gender, socioeconomic status, race, citizenship, etc.),
 - Quality of life,
 - Duration of extended life, or
 - First-come, first-served.
- Generally, de-prioritize persons who have alternative protection or who are imminently and irreversibly dying.

The report states that the notion of age-based rationing was particularly controversial and merits broad public consideration. Similar statements about the role of age in the allocation of scarce resources also were found in reports from groups in other states.

Except for ventilators, the panel recommends a two-track approach that simultaneously prioritizes two groups of Minnesotans. One track prioritizes groups of key workers within critical public health, health care, and public safety infrastructures. The other track simultaneously prioritizes groups of the general public, regardless of where or whether they work. The ventilator prioritization strategy is a single-track strategy geared to the general public, including workers of all kinds.

The following table copied from the report shows an example of how the panel recommended to allocate a scarce resource, namely antiviral drugs for treatment.

Table 8: Antiviral Treatment Strategies

IV. Strategies for rationing treatment antivirals to the sick (e.g., Tamiflu)			
<ul style="list-style-type: none"> • Attend to the general recommendations for rationing antivirals above (pages 22 – 23). • Various combinations of characteristics warrant prioritizing some groups to receive treatment antivirals before others: <ul style="list-style-type: none"> ○ risk of flu-related mortality and serious morbidity; ○ risk of occupational exposure to flu (for key workers); and possibly ○ age (among ill groups within general population at similar risk of flu-related mortality, children before adults or younger before older more generally). • De-prioritize persons: <ul style="list-style-type: none"> ○ presenting with influenza-like illness > 48 hours;⁶⁴ ○ known to be imminently and irreversibly dying (unless the antivirals serve a unique palliative function). ○ having satisfactory alternative treatment (should such a treatment become available). • When there is a shortage of treatment antivirals (which might not occur until the second wave), ration treatment antivirals for key workers and the general population as outlined below. When the shortage is severe, focus on the highest treatment priorities; when the shortage is less, expand the treatment priorities as follows. 			
Supply	Treatment Priorities	Track A – Ill Key Workers ⁶⁵	Track B – Ill in General Population
Adequate supply	Tier 1	Key workers with high risk of flu-related mortality/morbidity.	Groups, if any, at <i>disproportionately high</i> ⁶⁶ risk of flu-related mortality/morbidity (e.g., pregnant women ⁶⁷).
	Tier 2	<ul style="list-style-type: none"> • Key workers with high occupational exposure,⁶⁸ or • Irreplaceable key workers.⁶⁹ 	Groups at <i>high risk</i> of flu-related mortality/morbidity; If supply is insufficient to meet the needs of these groups either: <ul style="list-style-type: none"> • straightaway apply a fair random process to select individuals to receive treatment; or • first prioritize ill high risk younger groups before older groups, as many groups as the supply can accommodate, for example: <ul style="list-style-type: none"> ○ groups of children (< age of majority); ○ groups < X years of age (e.g., 55); or ○ groups < Y years of age (e.g., 85).
	Tier 3	Key workers.	Groups with \geq moderate risk of flu-related mortality/morbidity.
	Tier 4		All eligible patients.

A similar process was used to develop recommendations for the other resources examined in the report.

Allocation of Ventilators

New York State Guidelines for Ventilators

The state of New York was among the first to convene a task force and issue guidelines for allocating ventilators during an influenza pandemic. The New York State Workgroup on

Ventilator Allocation in an Influenza Pandemic, co-chaired by Tia Powell, M.D., and Guthrie Birkhead, M.D., M.P.H., published the guidelines in March 2007 to address alterations in the standard of care in an emergency. The guidelines document aims at removing subjective assessments from the decision-making process. While focused on the issue of allocation of ventilators, the document includes helpful and thoughtful analyses that refer to the allocation of any scarce health resource during a public health emergency. This document has generated widespread interest and has been used in several other states as a guide to develop similar, state-specific protocols, becoming almost a de-facto standard protocol often referenced in other documents.¹

After some background information on influenza and some planning assumptions on the impact of a pandemic in the state of New York, the document sets the ground for the recommendations by establishing an ethical framework. The report notes that, “An ethical framework must serve as the starting point for a plan that proposes to allocate ventilators fairly. A just rationing plan cannot evolve from technical considerations alone, such as survival probabilities and resource estimates, then have ethics applied as an afterthought, and hope to withstand ethical scrutiny.” This concept of the primacy of ethical principles was echoed in several other documents published on this issue elsewhere.

The ethical principles supported by the New York work group are as follows:

1. Duty to care. This is the fundamental obligation of health care professionals to care for patients. Physicians must not abandon, and patients should not fear abandonment, in a just system of allocation. Patients who are not eligible to receive mechanical ventilation will receive other forms of curative and/or palliative treatment.
2. Duty to steward resources. This is the obligation for government and health care providers to steward resources during a period of true scarcity. The effort to balance this obligation to the community of patients against the primary duty to care for each patient generates the ethical tension in devising a rationing system. Clinicians will need to balance the obligation to save the greatest possible number of lives against the obligation

¹ The document developed by the work group in New York state was published on March 15, 2007, as a draft for public comments. As of July 2009 the document has not been updated.

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to care for each single patient. As the number of affected patients increases, accommodating these two goals will require more and more difficult decisions.

3. Duty to plan. A motivating force in designing a triage system is the knowledge that planning is an obligation. An absence of guidelines leaves allocation decisions to exhausted, over-taxed, front-line providers, who already bear a disproportionate burden in a disaster. A failure to produce acceptable guidelines for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers.
4. Distributive justice. A just system is one in which allocation of resources is accomplished in a fair way, broadly and consistently. Disparities in access to care and outcomes based on differences in ethnicity and income already exist and it is unlikely that they can be totally eliminated in a situation of scarce resources. The goal of a just allocation system in those circumstances should be to not make worse the existing disparities.
5. Transparency. Any just system of allocating ventilators will require robust efforts to promote transparency, by seeking broad input in the design of the system, and educating the public about the evolving plan.

Based on these principles, the group proposed an allocation protocol based primarily on objective clinical evaluation. The patient's access to a ventilator would depend on the patient's own clinical status, as objectively measured, rather than on a direct competition with other patients presenting for care. If incoming patients are determined to be candidates for ventilators, they are categorized on the basis of the "*Ontario Health Plan for an Influenza Pandemic*" protocol and the sequential organ failure assessment score (SOFA scale), which reflects function in the lungs, liver, brain, and kidneys, as well as blood clotting and blood pressure. Based on their SOFA score, patients are assigned to one of four color-coded groups and priority is given to patients for whom treatment would most likely be lifesaving. Patients with a high probability and those with a low probability of mortality are not admitted to critical care. Patients who would likely die without the use of a ventilator, but have a high probability of survival with the use of a ventilator, are admitted to critical care. More details on the clinical protocol for allocation of patients are described later in the section on "*Fast Track*."

Just like other groups that produced similar reports, the New York group discussed at length the role of age in decision protocols. In the New York protocols, age is considered indirectly into any criteria that assess overall health, since chronic disease generally increases with age. The protocols do not include age as an exclusion or priority criterion. The work group specifically excluded from the decision process factors that reflect quality of life judgment, rather than estimates of probability of survival. Social worth, such as being the parent of many children or an important community member, was also rejected as a factor in determining access.

Indiana Altered Standards of Care

The Indiana State Department of Health published in 2008 a document titled “*Altered Standards of Care Guidance (with an Emphasis on Pandemic Influenza)*.” The document was developed by the Altered Standards of Care Community Advisory Group and targets specifically hospitals. It presents in a concise way information similar to that contained in documents from other states.

Indiana has chosen to adopt the ethical framework proposed by the New York State Department of Health, which is based on the principles of duty to care, duty to steward resources, duty to plan, distributive justice, and transparency. The triage protocols also are very similar to those proposed in the document published in New York. The report includes in the appendix some helpful charts and diagrams.

LEGAL ISSUES

The occurrence of a public health emergency requiring decisions on the allocation of scarce resources presents multiple challenges of legal nature. This section of the report describes those challenges and presents options to address them.² After a general discussion of legal issues related to public health emergencies, a review of the legal statutory and regulatory environment in Kansas will be presented.

² While an effort was made to prepare a comprehensive and accurate review, legal issues are complex and require a thorough review by legal experts that was beyond the scope of this project. Nothing in this document should be construed as a legal opinion or legal advice. Any questions regarding the application of specific laws should be directed to an official legal counsel. The author recommends consultation with legal counsel before any action described in this report is implemented.

LEGAL DEFINITION OF STANDARD OF CARE

Health care provided in an emergency situation when resources are scarce will be different from health care provided under normal circumstances. The expectations and standard procedures to deliver health care change during an emergency and this change affects legal obligations of health care providers and legal rights of patients.

The legal meaning of the term “*standard of care*” refers to the type and level of medical care expected to be delivered in specific circumstances as described through professional norms, accreditation, or other requirements. Standard of care is defined in reference to what a good, skilled health professional should be reasonably expected to do under a given set of circumstances. There are two components in this definition:

1. The circumstances under which care is provided. A standard of care applicable under routine circumstances (e.g., the provision of mechanical ventilation to an adult patient with seasonal influenza and acute respiratory distress) is not necessarily applicable under different circumstances (e.g., during an influenza pandemic). The standard of care would take into account the particular conditions in which health care is provided.
2. A reference to a professional standard of practice applicable under the circumstances. While professional standards and guidelines issued by professional or government entities do not have, per se, legal value, they often are examined by a court or a jury to determine how a health care provider could be reasonably expected to perform under the circumstances. The law does not generally establish the content of the standard of care and relies on experts to do so.

While, generally speaking, these protocols would not have the force of law (although some could be issued in a way that would require anyone involved in the emergency response to adhere to the protocols), they are a very important element in the management of a public health emergency. In addition to providing essential guidance at times when providers face difficult choices, and maximizing the effectiveness of the response to the emergency, these protocols can establish the ground work to define what standards of care could be reasonably expected during the emergency. As discussed above, the expected standard of care is a critical element in decisions regarding professional liability. Health care workers who follow in good faith the

protocols established by the state health officer are likely to be less exposed to legal liability than workers who act outside of the boundaries described in those protocols.

MODIFICATION OR SUSPENSION OF RULES AND REGULATIONS

While the specific legal standards of care to be applied in the provision of health care usually are not written in law, there are statutes, rules, and regulations that set some parameters and requirements which health care providers and institutions are expected to operate within. During a public health emergency, these legal requirements could potentially delay, impede, and interfere with emergency response activities and may need to be temporarily modified or suspended. Examples include suspension of certain physician and nurse licensure statutes (e.g., allowing out-of-state or inactive license holders to provide care under proper supervision); allowing physician assistants and EMTs to provide care under the supervision of any licensed physician; expansion of staff role to perform duties that they do not usually perform (stretching beyond what is allowed by licensing agencies); providing patient care in a place that usually is not used for care purposes; allowing for less stringent ratios of patients (or beds) to providers; and suspension of certain death and burial statutes.

Most states (including Kansas) allow the modification or suspension of rules and regulations during a declared emergency. Federal statutes and rules can only be modified or suspended by the federal government, usually as a result of a federal declaration of emergency.

LEGAL TRIGGERS FOR A PUBLIC HEALTH EMERGENCY

Since during a public health emergency the legal landscape is considerably different from that which exists outside of an emergency, it is important to have a clear definition of when a public health emergency starts and ends.³

In many states, local authorities may issue a declaration of local emergency. When the nature and scope of the emergency exceeds the local response capacity, a state declaration of emergency takes place. In most states, the governor has the authority to issue a state declaration

³ Although there are some technical and legal differences, for practical purposes in this report the terms “emergency declaration” and “disaster declaration” are used interchangeably.

of emergency. A governor declaration of emergency allows the use of state resources and can be the first step to a federal declaration of emergency, which in turn makes federal resources and funds available to respond to emergencies at the state and local levels.

Some states have specific provisions to declare a public health emergency, while others (including Kansas) address public health emergencies through the same process used for other types of disasters.

Regardless of the specific process adopted by each state to declare the state of emergency during a public health crisis, usually a governor's declaration represents the legal trigger that defines the beginning of the emergency, allowing the implementation of actions necessary to respond to the emergency (e.g., suspension of a state regulation). State laws also address how long a declaration of emergency can remain in place and how it can be extended in time, if necessary.

CREDENTIALING

Federal and state laws require health professionals and facilities to be licensed or accredited. Licensing is a state-based process and there is no automatic reciprocity for individuals licensed in one state to be allowed to practice their profession in another state. Accreditation usually refers to health care institutions and is also regulated by state agencies.⁴ During a public health emergency there may be a need to provide credentialing to out-of-state health care workers who travel to work temporarily at the site of the emergency.

The Emergency Management Assistance Compact (EMAC) is a federal mutual aid agreement that has been enacted by all states and is triggered by a declaration of emergency and request for assistance from a governor. One of the provisions in EMAC is the establishment of license reciprocity, which stipulates that individuals who hold licenses, certificates, or permits issued by one state shall be deemed to have the appropriate credentials for purposes of rendering assistance to another state requesting aid through the compact. This is usually done through

⁴ A voluntary national program for accreditation of hospitals administered by the Joint Commission on Accreditation of Hospitals (JCAH) also exists.

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cross-credentialing registries set up before an emergency declaration that include the names and other relevant information of health workers who are ready to be deployed when an emergency is declared in another state.

It should be noted that EMAC addresses only the issue of licensing, not hospital privileges, for out-of-state workers included in the compact. While holding a license (when required by law) is a prerequisite to practice in a hospital, each hospital administers its own staff credentialing system and reviews and approves applications from health care professionals to assure that they meet the hospital's professional standards. Neither federal nor state laws address the issue of temporary privileges during a declared emergency.

State rules and regulations governing health professional licensure can be modified or suspended in most states through a governor's executive order, if that is necessary to facilitate the response to a public health emergency.

LIABILITY ISSUES

Public health emergencies raise complex and serious liability issues for health care professionals and institutions (e.g., hospitals). Liability concerns during an emergency have been ranked as very important by health care providers in multiple surveys and need to be addressed thoroughly to assure that providers will be ready, willing and able to perform their expected duties during the emergency. Sharona Hoffman (a professor at Case Western Reserve University School of Law) published in 2008 a comprehensive review of liability and immunity in public health emergencies. Some of the information in this section is taken from her article.

Who is Affected?

Numerous parties might be involved in an emergency response, and each of them could be vulnerable to legal liability. Some of the key participants include hospitals, health care professionals (doctors, nurses, physician assistants, pharmacists, and dentists), volunteers, volunteer coordinators (e.g., Red Cross), government entities and their employees (federal, state, and local), and producers of vaccine and other medical supplies. Depending upon the nature of the emergency other categories also could be involved (e.g., veterinarians).

What are the Types of Liability Cases That Could Arise?

In her article, Hoffman lists several causes that could lead to liability suits. The list includes negligence, privacy and confidentiality, the Americans with Disabilities Act and the Rehabilitation Act, constitutional claims, criminal liability, the tort of breach of fiduciary duty, and other violations of federal and state laws. Hoffman notes that, “While the different theories are not equally likely to be asserted or to be successful, in the aggregate, their existence might generate considerable anxiety for providers and constitute a formidable barrier to clinicians’ participation in response activities.” This report will focus only on some aspects of the liability process (primarily civil professional liability from negligence). For a more comprehensive discussion please refer to the article from Hoffman.

Negligence

Litigation due to complaints of negligence represents the most common concern. Individuals who are dissatisfied with the care they received during a public health emergency or who believe they were injured because of inadequate treatment could file negligence cases, particularly medical malpractice suits. The elements of a negligence claim are (1) a duty of care owed by the defendant to the plaintiff, (2) breach of that duty through conduct that fails to meet the applicable standard of care, (3) harm or injury, and (4) a causal link between the injury and the breach of duty.

As it was discussed in the section about standards of care, if a law suit is filed against a health professional or institution, the plaintiff will have to demonstrate that the defendant did not follow accepted standards of care that could reasonably be expected to be in place under the circumstances in which the care was provided. The circumstances during a declared emergency are quite different from those outside of an emergency. It could be anticipated that health care professionals and institutions that follow altered standard practices as a result of a declared emergency that are consistent with the recommendations from their professional organizations or from government officials (e.g., the state health officer) would be found not guilty if their actions cause damage to a patient (e.g., a critically ill patient who needs a ventilator and dies because ventilators were allocated to other patients with higher priority based on an accepted decision algorithm). This decision, however, would have to be made by a court and a jury.

Corporate Negligence

According to Hoffman, hospitals, clinics, and other health care organizations involved in emergency response might be liable under a corporate negligence theory for failing to safeguard their patients' safety and welfare.

Hospitals have been found to have the following four duties:

1. A duty to use reasonable care in the maintenance of safe and adequate facilities and equipment;
2. A duty to select and retain only competent physicians;
3. A duty to oversee all persons who practice medicine within its walls as to patient care; and
4. A duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the patients.

In a public health emergency, health care organizations are likely to exceed ordinary capacity. At the height of the crisis, these entities might fail to follow standard procedures for facility maintenance, personnel oversight, treatment protocols, and other matters. Various deficiencies in the care provided by health care organizations could lead to corporate negligence claims.

Legal Immunity During Public Health Emergencies

Numerous sources of immunity are available to different parties involved in the response to public health emergencies. However, as Hoffman notes, "existing immunity scheme is a patchwork that leaves many gaps and unanswered questions." In most cases, when immunity is granted it does not include cases due to gross negligence or intentional harm. The specific legal immunity available in Kansas will be discussed in a separate section of the report.

Government Immunity

Generally speaking, federal, state, and local governmental entities and their employees or agents who respond to a public health emergency within the scope of their official duties are protected against tort lawsuits by state or federal immunity statutes.

Emergency Management Assistance Compact (EMAC)

One of the provisions of EMAC is to grant immunity to “any party state or its officers or employees” offering assistance in another state in accordance with the compact. As Hoffman notes, though, EMAC does not clarify who exactly can be considered officers or employees of a participating state, in particular whether this includes individuals who are deputized by a state for the purpose of responding to a particular emergency.

Immunity for Volunteers

In general, volunteers responding to public health emergencies enjoy extensive liability protection under a variety of state and federal laws. These laws only cover unpaid volunteers. Good Samaritan statutes are laws enacted by many states (including Kansas) that protect health care professionals or other individuals who render aid at the scene of an accident or emergency against civil liability for negligently causing injury while providing assistance. The extent to which Good Samaritan laws could be invoked during a declared emergency lasting for days or weeks is unclear.

Immunity for Health Care Institutions

Most of the liability immunity provided through the mechanisms described in this section only applies to individuals. Usually no provisions exist to provide immunity to facilities (e.g., hospitals). While volunteers can be shielded from liability by Good Samaritan or other laws, these laws usually do not provide protection for non-profit organizations, including non-profit hospitals.

Immunity for Private Sector Actors

Private sector actors benefit from only a limited range of immunity protection during public health emergencies. This represents a serious omission that could undermine the ability and willingness of private health care providers to respond to public health emergencies. Litigation takes a severe financial, emotional, and reputational toll on a health care provider, even if the defendant is ultimately found not liable. Health care providers may be reluctant to be involved in emergency response activities or to adopt altered standard protocols of care because of the

prospect of litigation, as plaintiffs might bring a large number of legal actions against responders in the aftermath of a public health emergency.

One noticeable source of immunity is provided by the federal Public Readiness and Emergency Preparedness Act (PREP Act). Under this act, immunity is available to manufacturers, distributors, program planners, and their officials, agents, or employees, as well as to those qualified to prescribe, administer, or dispense countermeasures (i.e., drugs, vaccines, devices, and other biological products) for emergency use. The liability protection is only provided after the Secretary of Health and Human Services issues a declaration recommending the use of a certain product or device to respond to a public health emergency.

Immunity Arising from State Emergency Response Acts

In most states (including Kansas) legislation governing emergency response activities provides immunity to government entities involved in the response to a declared emergency and to their employees and officers. In most cases the immunity is extended to other representatives or agents of a government entity.

Some states provide liability protection during a public health emergency for broader groups of individuals, including private health care providers. The statutory language used in those statutes is often short and simple. The box on page 21 includes some examples of these laws.

