

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

September 2009

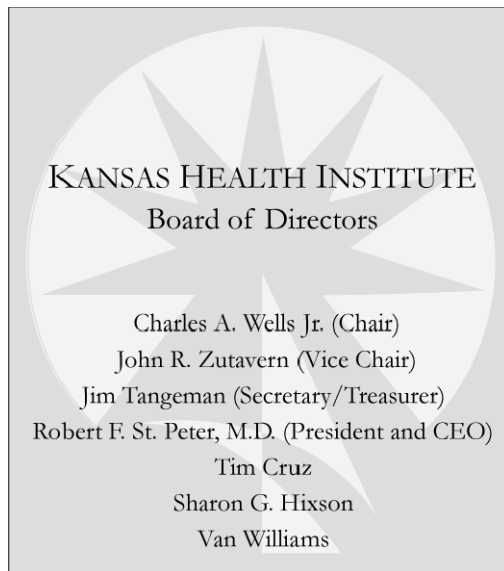
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Gianfranco Pezzino, M.D., M.P.H.
Senior Fellow



KANSAS HEALTH INSTITUTE

212 SW Eighth Avenue, Suite 300
Topeka, Kansas 66603-3936
(785) 233-5443
www.khi.org



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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 This publication presents the results of an extensive review of published and unpublished material on the subject and recommendations on how to develop state and local plans for the use of scarce resources.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

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.

- 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.

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

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

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.

- 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

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.

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.

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.

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.

California Government Code Section 8659

Any physician or surgeon (whether licensed in this state or any other state), hospital, pharmacist, nurse, or dentist who renders services during any state of war emergency, a state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency shall have no liability for any injury sustained by any person by reason of such services, regardless of how or under what circumstances or by what cause such injuries are sustained; provided, however, that the immunity herein granted shall not apply in the event of a willful act or omission.

Wyoming 35-4-114

Immunity from liability. (a) During a public health emergency as defined by W.S. 35-4-115(a)(i), any health care provider or other person who in good faith follows the instructions of the state health officer in responding to the public health emergency is immune from any liability arising from complying with those instructions. This immunity shall apply to health care providers who are retired, who have an inactive license or who are licensed in another state without a valid Wyoming license and while performing as a volunteer during a declared public health emergency as defined by W.S. 35-4-115(a)(i). This immunity shall not apply to acts or omissions constituting gross negligence or willful or wanton misconduct.

Virginia 8.01-225.02

Certain liability protection for health care providers during disasters. A. In the absence of gross negligence or willful misconduct, any health care provider who responds to a disaster shall not be liable for any injury or wrongful death of any person arising from the delivery or withholding of health care when (i) a state or local emergency has been or is subsequently declared in response to such disaster, and (ii) the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency and which resulted in the injury or wrongful death at issue.

OTHER LEGAL ISSUES

Workers' compensation during a declared emergency is generally available to both public and private health care workers in the same way as outside of an emergency. Workers' compensation benefits may or may not be available to volunteers, depending on the circumstances of the emergency and specific state laws. EMAC has some provisions describing workers' compensation during mutual aid operations.

The Emergency Medical Treatment and Active Labor Act (42 U.S.C. § 1395dd, EMTALA) is a United States Act of Congress passed in 1986. It requires hospitals and ambulance services to provide care to anyone needing emergency treatment regardless of citizenship, legal status, or ability to pay. As a result of the act, patients needing emergency treatment can be discharged only under their own informed consent or when their condition requires transfer to a hospital better equipped to administer the treatment. EMTALA applies to "participating hospitals," i.e., those that accept payment from certain federal programs. However, in practical terms, EMTALA applies to virtually all hospitals in the U.S. EMTALA provisions may be difficult to implement during a public health emergency. Since EMTALA is a federal law, governors in general do not have the authority to suspend it.

The circumstances of a public health emergency may make it difficult for providers and institutions to comply with federal and state confidentiality requirements. States laws and regulations addressing privacy and confidentiality may need to be temporarily suspended or modified. The federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule also contains some requirements that may not be practical or realistic during an emergency, but it contains exceptions for disclosures for public health purposes; the rule can be suspended by federal authorities during a declared federal emergency.

LEGAL ENVIRONMENT DURING PUBLIC HEALTH EMERGENCIES IN KANSAS

Declaration of Emergency

Like in most states, the governor of Kansas can issue a proclamation declaring a state of disaster emergency (K.S.A. 48-924). The declaration remains in effect for 15 days and can be extended by 30 days at the time with legislative concurrence. Kansas law gives ample powers to the governor during a declared emergency, including the authority to:

- 1) Issue orders and proclamations with the force of law; and
- 2) Suspend the provisions of any regulatory statute, if strict compliance with those provisions would prevent, hinder, or delay the response to the disaster (K.S.A. 48-925).

Through executive order, the governor can delegate part of the emergency powers to other state officials, for example to the state health officer to decide how to distribute vaccine during an influenza pandemic.

The governor's ability to delegate his or her authority during an emergency in Kansas can be used to establish standard procedures recommended for health care workers and institutions. For example, upon delegation from the governor the state health officer could issue standard procedures for the triage of patients in need of a ventilator when the demand exceeds the number of available units. The same health officer could issue standard procedures allowing hospitals to use and reuse common supplies and equipment, such as gloves, gowns, and masks, or advising them how to allocate scarce clinical resources of a general nature, such as beds, surgery capability, and laboratory and other diagnostic services.

Licensing and Credentialing

Health care professionals in Kansas are required to be licensed through the Board of Healing Arts (BOHA). The board issues rules that describe the licensing requirements for each professional category. Hospitals are licensed by the Kansas Department of Health and Environment, and nursing homes by the Kansas Department on Aging. After declaring an emergency the governor has the power to temporarily suspend or modify through executive order licensing requirements for health care providers and facilities. This could include, for example, expanding the role of certain licensed professions (e.g., allowing physician assistants to prescribe certain medications), or lifting some staffing level requirements for hospitals. It could also include using professionals-in-training who have a sufficiently strong medical background to perform certain services, or empowering health care facilities to employ unlicensed providers to execute certain tasks.

The BOHA does not have jurisdiction over unpaid volunteers engaged in the response to a public health emergency, who are not required to be licensed.

Health care facilities also have standard requirements that they need to meet to participate in some federal programs (e.g., Medicare and Medicaid); like all federal rules, these are beyond the authority of the state governor.

Mutual Aid

K.S.A. 48-9a01 describes the use of the interstate emergency management assistance compact and implements the provision in the federal EMAC. In particular, the statute provides to officers and employees from another state the same liability protection afforded to their counterparts in Kansas and provides a reciprocity mechanism of recognition of licenses issued in other participating states (although the governor may limit the extent of the reciprocal recognition). The reciprocity does not exempt the state requesting aid from verifying the licensing status of an out-of-state worker. Currently no automated system exists to verify the credentials and licensure status of out-of-state workers and volunteers who come to Kansas as a result of the EMAC compact.

Liability Protection

Like in most states, when a declaration of emergency is issued health care workers in Kansas may be protected from legal liability to different degrees depending on their qualification and role in the response activities. When protection is granted, it does not include damages resulting from gross negligence or intentional harm.

K.S.A. 48-915 provides immunity from liability to state and local government entities and their agents and representatives, as well as volunteer workers (usually defined as unpaid volunteers), when they are engaged in activities complying with the emergency declaration or any order issued as a result of the declaration. In addition, government workers are protected also by the Kansas Tort Claims Act (K.S.A. 75-6101 *et seq.*). It should be noted that while the Kansas tort claims act provides immunity for government employees and officials, but holds government entities liable for damages caused by the negligent or wrongful act or omission of their employees, K.S.A. 48-915 (in effect only during a declared emergency) provides immunity also to government agencies, in addition to their employees, representatives and agents.

Government employees from other states deployed to Kansas through the compact agreement (EMAC) are considered agents of the state of Kansas and as such are protected from liability under K.S.A. 48-9a01.

Members of regional medical emergency response teams are deemed state employees (K.S.A. 48-915) and therefore are also protected from liability. Developing regional emergency medical response teams is listed in K.S.A. 48-928 as one of the duties of the state division of emergency management, but their definition, composition, and roles are not specified.

“Good Samaritan” provisions in K.S.A. 65-2891 protect any health care provider who in good faith renders emergency care or assistance at the scene of an emergency or accident from liability for any civil damages.

Finally, if a federal declaration of public health emergency is issued, health care providers who use any of the countermeasures ordered by the federal government (e.g., a vaccine) are protected from liability for the use of the countermeasures under federal law.

Two noticeable omissions exist in the laws that protect from liability individuals and entities that respond to a declared public health emergency in Kansas: private sector employees and workers (such as private physicians), and non-governmental entities such as hospitals. In fact, in at least one case (the Good Samaritan law, K.S.A. 65-2891), there is a specific exclusion from liability protection when the care is rendered in a physician’s office, clinic, or hospital. This situation is similar to the one found in several other states. As Hoffman notes in her review of liability during a public health emergency, “These exclusions are startling because health care entities and paid workers are likely to bear the brunt of the burden during a public health emergency, as hundreds or thousands of patients seek medical care.”

RECOMMENDATIONS

PROCESS TO DEVELOP PLANNING DOCUMENTS

The purpose of this section is to describe options for a process for developing planning documents on how to use scarce resources during a public health emergency. The importance of the development of a thorough plan cannot be over-emphasized. In the event of a catastrophic event, the lack of a plan to address critical issues such as triage and allocation procedures for ventilators could result in the unjust allocation of resources or the perception that the allocation was unjust.

Based on the experiences of other states it can be anticipated that a successful planning process will need to involve multiple partners and stakeholders and could take several months. Some of the issues addressed through that process are urgent, particularly in relation to the current influenza pandemic that has the potential to affect large numbers of people in the fall and winter, resulting in scarce resources and a need for alternative standard procedures. This report also will include some options for an expedited planning process that would enable the state to become quickly prepared to respond to a public health emergency created by the pandemic. This expedited process will be referred to in the rest of the document as “*fast track*.”

There is consensus that government agencies have an essential role in providing guidance to health care professionals and institutions on how to operate during an emergency when resources are scarce and standard protocols of care may need to be modified. In doing that, one of the challenges is how to strike a balance between the need to provide useful, standardized protocols that can assure effective, consistent, uniform, and equitable use of the resources available and the need to respect the autonomy and professional independence of health care providers and institutions.

Some states that have started the process of planning for the allocation of scarce resources and altered standard protocols of care have produced detailed guidelines that cover specific potential emergency situations and list meticulously how providers and hospitals are expected to handle them. As an example, the Bureau of Emergency Medical Services in Utah has a triage and treatment guideline supplement that contains flow charts with triage decision algorithms and

treatment guidelines for radiological emergencies, burn injury emergencies, and other emergencies. Some of the protocols include recommended pharmaceutical treatments with the dosage of each medication.

Most states stop short of producing such detailed guidelines and focus more on the process to assist hospitals and providers in the development of contingency plans that share common criteria. This approach has been proposed or used in various forms in Colorado, Indiana, Missouri, Washington, South Carolina, and other states. Based on the experience and results in those states, we suggest that the following steps be considered for implementation in Kansas.

SCARCE RESOURCES ALLOCATION TASK FORCE

We suggest that KDHE convene a task force and authorize it to prepare recommendations to KDHE on principles and practices to adopt for the allocation of scarce resources and the development of altered standard protocols of care. The task force should be as inclusive as possible, with representatives from professional organizations, hospitals, government agencies, special needs groups, private organizations with subject-matter expertise, academic institutions, and consumers.⁵ Similar task forces have been used successfully in other states. Convening a task force before a state plan is issued presents several advantages: it can generate good ideas from the people most directly involved in the issues that the task force addresses; it can spread the planning work across more people, making it more manageable; and it can assure better support for the plan. The task force would conduct most of its work through work groups covering the following areas:

1. Ethical principles that should guide the planning process and the allocation of scarce resources.
2. Legal issues created by planning for the allocation of scarce resources and modified standard procedures.

⁵ The Agency for HealthCare Research and Quality recommends the involvement of the following groups: emergency management agencies, police and fire departments, emergency medical services, ambulance and other transport providers, health departments and community health centers, hospitals, ambulatory care centers, private physician offices, medical examiners, nursing homes, health centers, mental health services, and morticians. Additional groups that might be considered are schools, churches, hotels, businesses, and other organizations that can provide space for alternate care facilities and cooperate in the preplanning required to activate such sites.

3. Technical aspects for the major emergency areas (e.g., allocation of ventilators, vaccines, or intensive care beds).

The task force should be guided by a high-level state official, preferably the state health officer, and should receive adequate staffing support through KDHE.

Examples of issues that the task force could address are:

- a) General ethical principles to follow in the allocation of scarce resources in Kansas;
- b) How to ensure and protect an adequate supply of trained providers and support staff, including cross-credentialing for out-of-state responders;
- c) How to triage patients into groups by the nature of their condition, probability of success of interventions/treatment, and consideration of resources available;
- d) How to maintain infection control and a safe care environment;
- e) How to use and reuse common supplies and equipment, such as gloves, gowns, and masks;
- f) How to allocate scarce clinical resources of a general nature, such as beds, surgery capability, and laboratory and other diagnostic services;
- g) How to allocate scarce and highly specialized clinical resources, such as decontamination units, isolation units, ventilators, burn beds, and intensive and critical care units;
- h) How to treat specific conditions, including how to make best use of available pharmaceuticals;
- i) How to protect health care providers and support staff and their families;
- j) How to handle non-compliance when altered standards of care are decided;
- k) How to modify documentation standards to ensure enough information to support care and obtain reimbursement without posing an undue administrative burden; and
- l) How to manage excessive fatalities.

The task force would produce recommendations to KDHE, and KDHE would prepare a plan based on a review of those recommendations.

The task force will conduct its activities building upon the work already done in other states and in Kansas. KDHE should prepare for the task force members copies of this report and of

some of the key documents developed in other states and encourage the use of these documents as a starting point for the discussion.

It is anticipated that this process could take between six and 12 months, depending on the level of commitment of task force members and the level of detail contained in the recommendations.

ADVISORY COMMITTEE ON PUBLIC HEALTH EMERGENCIES

The same group of stakeholders involved in the development of the recommendations for KDHE planning could appoint a smaller standing committee with the role of advising the governor and the state health officer on health emergency issues and possible measures to implement during an emergency. A similar model is adopted in Colorado through the Governor's Expert Emergency Epidemic Response Committee (GEEERC).

LEGAL ISSUES

The most important gap in the legal landscape during a public health emergency in Kansas is the lack of protection from professional liability and malpractice for private health care workers and hospitals. This lack of protection is a reason for concern. Even when providers follow guidelines published by KDHE or other professional organizations, liability could arise from triaging decisions, choices concerning how to ration scarce resources, confidentiality breaches, providing medical services without appropriate licensure, or providing negligent care. Health care providers are well aware of these possibilities and have indicated in various surveys that the potential for litigation might influence their willingness to participate in response activities. It is unlikely that this legislative gap could be addressed during an emergency through executive order of the governor.

In her review of liability issues during public health emergencies, Hoffman, the Case Western Reserve University School of Law professor, proposes the enactment of a comprehensive immunity provision that would extend to all health care providers who respond to a public health emergency. This is an ambitious proposal that should be studied and assessed by legal experts. A simpler solution that would remove most of the liability concerns in Kansas

could be the adoption of a new statute that would provide protection to health care providers and hospitals from civil liability when they follow in good faith the directions of state officials in charge of coordinating the emergency response. This approach has been adopted by a growing number of states. Examples of the legislative language used in some of those states were presented earlier in this document. Although there would likely be some opposition to such legislation, it would likely have the support of organizations representing medical professionals and hospitals, as well as constituents and legislators concerned about the potential for litigation and its effects on the provision and cost of health care during a public health emergency.

OTHER ACTIONS

If out-of-state workers or volunteers are deployed to Kansas to assist in the response to a health emergency it will be necessary to verify their credentials and licensure status in their state of residence. This is important both to assure that only individuals with the appropriate skills and credentials be deployed and to avoid potential liability exposures. Currently no system is in place to perform this verification across state border lines, except through personal contact with the state of residence of each responder. Options for a quicker, automated verification system should be explored.

Some workers' compensation issues also need to be clarified. This is a complex area in which state and federal rules affect both the private and the public sectors. It is likely that most workers involved in the response to a public health emergency would be covered through their regular workers' compensation mechanism. However, concerns have been expressed repeatedly by workers about potential gaps in their protection, and sometime it is not immediately clear who is expected to provide workers' compensation during an emergency (for example, if a hospital worker suffers an injury while on duty in a different hospital). In addition, responsibilities for protection for volunteers also are not clear. It is recommended that further research be conducted on this issue through legal experts in workers' compensation laws, and that the results be widely shared with the employers and employees that could be affected.

Involving the general public in decisions on the allocation of scarce resources is extremely important. Transparency is one of the key ethical principles commonly listed by experts in this

field and was strongly recommended by some members of the stakeholders panel. Without an early engagement of the public in this process it will be difficult for ordinary people to understand the rationale of the allocation decisions and to support them. We recommend that KDHE develop a carefully orchestrated and targeted public information campaign to explain the principles and methods used in the development of these plans.

Finally, hospitals must meet certain federal requirements to participate in federal programs such as Medicare and Medicaid, and it is unlikely that governor would have authority to suspend those requirements. It is recommended that federal and state officials, as well as hospital representatives, review these issues together and explore options to minimize the liability exposure for hospitals that may not be able to meet those federal requirements during a public health emergency.

FAST TRACK

While the task force conducts its activities, it is imperative that KDHE lead the process to meet the immediate needs posed by the influenza pandemic. To this purpose, we recommend that the following activities be implemented:

1. Prepare Drafts of Executive Orders;
2. Adopt Technical Protocols; and,
3. Address Open Legal Issues.

Each activity is described with more detail below.

Prepare Drafts of Executive Orders

As explained throughout this report, executive orders issued by the governor or a designee during a declared emergency have an important role in facilitating response activities. Executive orders can cover a wide variety of situations. It is important that KDHE, in conjunction with the Division of Emergency Management, prepare drafts that address issues that could arise during the pandemic. Some of these drafts have already been developed. This effort should continue and be expanded to cover additional potential issues, so that executive orders can be released timely,

if needed, and their content is appropriate and meets the approval of the parties touched by the order. Examples include, but are not limited to:

- Allowing hospitals to employ unlicensed volunteers for simple tasks (e.g., blood pressure check in non-acute patients, assisted ambulation, administration of oral medications);
- Allowing hospitals to cease admission and transfer of patients and determine on their own whether they have reached their capacity. This could preempt some provision in the federal EMTALA law requiring hospitals to provide care to everyone who presents to their emergency rooms, although the effect of such an order on the federal law should be further studied by legal experts;
- Modifying or lifting minimum staffing requirements for acute and long-term care institutions;
- Allowing hospitals to use space for acute care that ordinarily would not meet state standards;
- Allowing long-term care institutions to perform certain acute care functions;
- Allowing hospitals to modify or suspend their procedures to provide credentials to staff;
- Expanding the roles of some professional categories beyond their routine scope of practice (e.g., allowing veterinarians to administer human vaccines; allowing physician assistants to practice under the supervision of any licensed physician, or to write certain drug prescriptions; allowing pharmacists to administer vaccine to children);
- Modifying licensing requirements for certain tasks (e.g., allowing unlicensed nursing and pharmacy students to perform certain simple tasks under the supervision of a licensed professional); and
- Allowing health professionals holding an out-of-state or an inactive license to provide care under proper supervision from another fully licensed provider.

The list above only includes the issues that may be likely to appear during the influenza pandemic. Additional drafts may be needed in other types of public health emergencies. The state of Colorado has published a description of the draft executive orders that have been prepared to address a variety of legal issues during public health emergencies. The document can be found at <http://www.cdphe.state.co.us/epr/Public/InternalResponsePlan/Attachment3.pdf>.

Adopt Technical Protocols

The development of protocols describing how to allocate scarce resources during a public health emergency is a key function of state officials. While some protocols can be developed after the work of the task force is completed, there is an urgent need for protocols that can be used to address the current influenza pandemic. These protocols can be adapted from documents and procedures already developed in other states or by national organizations, after the necessary revisions to make them suitable for use in Kansas. It is highly recommended that input from a restricted group of experts be gathered during the development of these protocols. Given that the current documents already available are fairly detailed, we estimate that this fast track process could be completed in a few weeks.

Below is a list of some important issues that may need to be addressed through a fast track mechanism, as well as some possible sources for the urgent protocols.

Allocation of Scarce Resources and Modified Standard Protocols of Care in Hospitals

The Minnesota Department of Health has prepared some charts that describe how to allocate scarce resources in a hospital during an emergency. The document uses easy-to-read, color-coded charts and describes strategies for the allocation of some important resources: oxygen, medications, hemodynamic support and IV fluids, mechanical ventilators, and staffing. An example of the tables in the document is shown below. The document is aimed primarily to responding to the influenza pandemic, but could also be used in other emergencies that cause similar shortages of resources. Strategies described in the document include:

1. Prepare. Pre-event actions taken to minimize resource scarcity;
2. Substitute. Use an essentially equivalent device, drug, or personnel for one that would usually be available (e.g., morphine for fentanyl);
3. Adapt. Use a device, drug, or personnel that are not equivalent but that will provide sufficient care (e.g., anesthesia machine for mechanical ventilation);
4. Conserve. Use less of a resource by lowering dosage or changing utilization practices (e.g., minimizing use of oxygen-driven nebulizers to conserve oxygen);

5. Reuse. Reuse (after appropriate disinfection or sterilization) items that would normally be single-use items; and
6. Reallocate. Take a resource from one patient and giving it to a patient with a better prognosis or greater need.

The document is available at <http://www.health.state.mn.us/oep/healthcare/index.html>.

OXYGEN USE STRATEGIES FOR SCARCE RESOURCE SITUATIONS			MINNESOTA HEALTHCARE SYSTEM PREPAREDNESS PROGRAM														
POTENTIAL TRIGGER EVENTS	STRATEGY*	RECOMMENDATIONS															
Oxygen Administration	INTERNAL DISRUPTION OF HOSPITAL MEDICAL GAS SYSTEMS	SUBSTITUTE	1. Oxygen Conservation Devices <ul style="list-style-type: none"> Use Oxymizer™ type cannulas at 1/2 the flow setting of standard cannulas. Replace simple & partial rebreather mask use with Oxymizer™ cannulas at flowrates of 6-10 LPM. 														
	INTERNAL SURGE TO HOSPITAL CAPACITY		2. Inhaled Medications <ul style="list-style-type: none"> Restrict the use of Small Volume Nebulizers when inhaler substitutes are available. Restrict continuous nebulization therapy. Minimize frequency through medication substitution that result in fewer treatments (6h-12h instead of 4h-6h applications). 														
Hemodynamic Support and IV	EXTERNAL NOTIFICATION BY GAS SUPPLIER OF DELAYS OR SHORTAGES	SUBSTITUTE & CONSERVE	3. Oxygen Concentrators if Electrical Power Is Present <ul style="list-style-type: none"> Use hospital-based or independent home medical equipment supplier oxygen concentrators if available; use to supplement low-flow cannula use, and preserve the primary oxygen supply for more critical applications. 														
	EXTERNAL NOTIFICATION BY THE MINNESOTA DEPARTMENT OF HEALTH		4. Monitor Use and Revise Clinical Targets <ul style="list-style-type: none"> Employ oxygen titration protocols to optimize flow or % to match targets for SpO₂ or PaO₂. Minimize overall oxygen use by optimization of flow. Discontinue oxygen at earliest possible time. <table border="1"> <tr> <td>Starting Example</td> <td>Initiate O₂</td> <td>O₂ Target</td> <td>Note: Targets may be adjusted further downward depending on resources available, the patient's clinical presentation, or measured PaO₂ determination.</td> </tr> <tr> <td>Normal Lung Adults</td> <td>SpO₂ <89%</td> <td>SpO₂ 90%</td> <td></td> </tr> <tr> <td>Infants & Peds</td> <td>SpO₂ <90%</td> <td>SpO₂ 91-94%</td> <td></td> </tr> <tr> <td>COPD History</td> <td>SpO₂ <88%</td> <td>SpO₂ 90%</td> <td></td> </tr> </table>	Starting Example	Initiate O₂	O₂ Target	Note: Targets may be adjusted further downward depending on resources available, the patient's clinical presentation, or measured PaO ₂ determination.	Normal Lung Adults	SpO ₂ <89%	SpO ₂ 90%		Infants & Peds	SpO ₂ <90%	SpO ₂ 91-94%		COPD History	SpO ₂ <88%
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COPD History	SpO ₂ <88%	SpO ₂ 90%															
Mechanical Ventilation			5. High-Flow Applications <ul style="list-style-type: none"> Restrict the use of high-flow adult cannula systems (Vapotherm™ type) as these can demand 12 to 40 LPM flows. Restrict the use of simple and partial rebreathing masks to 10 LPM maximum. Restrict use of Gas Injection Nebulizers as they generally require oxygen flows between 10 LPM and 75 LPM. Eliminate the use of oxygen-powered venturi suction systems as they may consume 15 to 50 LPM. 														
			6. Air-Oxygen Blenders <ul style="list-style-type: none"> Eliminate the low-flow reference bleed occurring with any low-flow metered oxygen blender use. This can amount to an additional 12 LPM. Reserve air-oxygen blender use for mechanical ventilators using high-flow non-metered outlets. (These do not utilize reference bleeds). Disconnect blenders when not in use. 														
Nutrition Staffing		RE-USE	7. Expendable Oxygen Appliances <ul style="list-style-type: none"> Use terminal sterilization or high-level disinfection procedures for oxygen appliances, small & large-bore tubing, and ventilator circuits. Bleach concentrations of 1:10, high-level chemical disinfection, or irradiation may be suitable. Ethylene oxide gas sterilization is optimal, but requires a 12-hour aeration cycle to prevent ethylene chlorhydrin formation with polyvinyl chloride plastics. 														
	Oxygen (page 1 of 1)	RE-ALLOCATE	8. Oxygen Re-Allocation Implementation <ul style="list-style-type: none"> Prioritize patients for oxygen administration during severe resource limitations. 														

Implementation of Altered Standard Protocols in Hospitals

Perhaps the most critical node during a public health emergency in which health care needs to be rationed because of lack of resources is represented by hospitals. This is where altered standard protocols of care will be implemented and decisions will be made that could literally result in life or death for individual patients. It is very important that hospitals follow a uniform system to implement the modified protocols and monitor their results. Lack of uniformity could create confusion among those seeking medical care, potentially leading to migration of patients to hospitals where protocols are perceived as being less stringent, and could also increase the

exposure to legal liability for institutions, since the standard of care could be defined in different ways at different hospitals.

In January 2007 a Task Force for Mass Critical Care prepared several documents with recommendations that describe how to implement the allocation of scarce resources in hospitals. More recently, the Veterans Administration's National Center for Ethics in Health Care prepared recommendations on how to implement triage in veteran hospitals during a public health emergency. The resource allocation mechanism described by both groups is very similar. In summary, each hospital would be expected to put in place the following:

1. A Scarce Resource Allocation Team (SRA). This would be an advisory committee that would work within the Incident Command System structure to oversee and guide rationing, address ethical concerns, and establish mass-care and triage practices at the institution during the emergency. The composition of the team could be different from hospital to hospital, depending in part on the size of the institution, and it would include a team leader (normally a physician with knowledge and experience in critical care), a representative from the ethics committee, a nursing representative, a logistics or management representative, and possibly representatives from the Emergency Department, Legal Department, Infection Control, Palliative Care Service, Social Work Service, Chaplain Service, and Engineering.
2. A Triage Team. This would be a front line team that takes direction from the SRA and implements the triage criteria by reviewing clinical data for triage scoring of individual patients and conducting tertiary triage. The team would include a Triage Officer (ideally a senior specialist in intensive care) who would act as team leader and would have the primary responsibility to conduct the triage in the institution. In addition, in larger institutions membership could also include a nursing representative and a logistics or management representative.
3. A Triage Oversight Team. This would be a committee that would perform a systematic, retrospective review of the decisions of the triage team on a daily basis. This committee may be composed of experienced professionals who typically no longer provide direct care, such as the chief nursing officer, the chief medical officer, the chief respiratory supervisor, the infection control director, and the chief legal counsel. The purpose of the

review committee is to bring to the attention of the triage officer any concerns about the application of the triage algorithm, providing a chance to reflect on these concerns in approaching future decisions. The review committee does not have the authority to change a decision made by the triage officer. It is a widespread belief among experts that an appeals process could create the potential for unworkable delays in the midst of a crisis.

Additional information on the recommendations listed above can be found at:

http://www.chestjournal.org/content/133/5_suppl/1S.full.pdf+html

http://www.ethics.va.gov/activities/pandemic_influenza_preparedness.asp

Mechanical Ventilators

The state of New York issued draft guidelines for allocating ventilators during an influenza pandemic. The document has been extensively discussed earlier in this report. In this section we will provide more details on the triage mechanism and the clinical criteria proposed for allocating ventilators.⁶

The clinical protocol designed by the work group includes the following elements:

1. **Pre-triage Requirements.** Before beginning to ration resources, all health care facilities should create a "surge capacity" by limiting nonessential use of ventilators, canceling or postponing elective procedures, and securing adequately trained staff to operate them.
2. **Patient Categories.** Guidelines for allocating ventilators must be applied to all patients seeking care, not just those with influenza. Priority should be judged on the basis of medical factors alone, and should not be determined by any other factors; for example, preference should not be given to other health care professionals.
3. **Acute Versus Chronic Care Facilities.** Patients on ventilators in chronic care facilities will not be subject to acute care triage guidelines, unless they require transport to an acute care facility. In such a case, they may lose access to continued ventilator use.

⁶ The SOFA protocol proposed in New York and other settings has not been validated among young children. Its use in a pediatric population requires further evidence of validity.

4. Clinical Evaluation. 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. The SOFA scale proposed by New York State is shown in the table below. Patients will then be reassessed at intervals of 48 to 120 hours to determine if they still qualify to use a ventilator, and if they do not, they will be extubated.
5. Triage Decision Makers. There will be a supervising clinician to serve as the triage officer so health care workers providing direct patient care will not have the final say in triage decisions. "Establishing triage officers provides role sequestration that will help sustain clinicians who serve during disasters," the authors wrote. "Without such measures, the secondary effects of the disaster on clinicians, including burnout and stress, may prove more corrosive than the original trauma."
6. Palliative Care. In the event that an extubation is necessary, current facility protocols in regard to removing life-sustaining care and providing palliative care should be followed.
7. Review of Triage Decisions. All triage decisions will be reviewed daily to ensure that all protocols are being followed.
8. Communication. The unique procedures taking place during an emergency must be properly communicated to the public.

The document from New York State is available at:

<http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/index.htm>

Variable	0	1	2	3	4
PaO ₂ /FiO ₂ mmHg	>400	< 400	< 300	< 200	< 100
Platelets, x 10 ³ /μL (x 10 ⁶ /L)	> 150 (>150)	< 150 (< 150)	< 100 (< 100)	<50 (<50)	< 20 (< 20)
Bilirubin, mg/dL (μmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop < 5	Dop > 5, Epi < 0.1, Norepi < 0.1	Dop > 15, Epi > 0.1, Norepi >0.1
Glasgow Coma Score	15	13 - 14	10 - 12	6 - 9	<6
Creatinine, mg/dL (μmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	3.5–4.9 (301 – 433)	>5 (> 434)

Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi], doses in ug/kg/min.
SI units in brackets.

Address Open Legal Issues

KDHE can take some steps to mitigate concerns about the lack of liability protection for private providers and hospitals before new legislation is approved.

The first action would be a proactive approach in providing modified standard procedures for health care during the emergency covering a broad gamut of possibilities without infringing on the providers' discretionary authority to make clinical decisions on a case-by-case basis. Although there is no guarantee that a court would accept adherence to the guidelines as a defense against liability should lawsuits arise, such protocols could be invoked by providers in a liability suit to prove that the provider was following the standards of care appropriate under the circumstances — an important element of legal defense in court. Suggestions for some protocols are described in a separate section.

Another option to limit the liability exposure in the short term could be to issue an executive order stating that while the declaration of disaster is in place, private health care providers and hospitals are acting as agents of the state when implementing the protocols that KDHE has issued. This could be dependant upon the commitment from hospitals to accept and implement the technical protocols issued by KDHE. This action would extend to private providers the same liability protection granted to government entities. The disadvantage would be that private providers would be put in a position somewhat subordinate to the state and subject to government orders, something that the providers may object to. Expanding the status of state government agents to private providers would not expose government agencies to additional litigation, since K.S.A. 48-915 provides liability immunity to these agencies and their agents during an emergency declaration.

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DEFINITIONS

Distributive justice — Distributive justice is concerned with the fair allocation of resources among diverse members of a community. Fair allocation typically takes into account the total amount of goods to be distributed, the distributing procedure, and the pattern of distribution that results.

Ethics — The system or code of morals of a particular person, religion, group, profession, etc.

Joint Commission — Oak Brook, Ill.-based organization that accredits the nation's hospitals.

Legal standards of care — The amount of skill that a medical practitioner should exercise in particular circumstances based on reasonable and common practice in medical care. Legally standard of care is defined by reference to a physician using the knowledge, skill, and care ordinarily possessed and employed by members of the profession in good standing, good medical practice within the area of specialty practice, and reasonable, customary, accepted care under the circumstances.

Medical standards of care — The type and level of medical care required in specific circumstances via professional norms, accreditation, or other requirements.

Negligence — A conduct that is culpable because it falls short of what a reasonable person would do to protect another individual from foreseeable risks of harm.

Protocol — The plan for a course of medical treatment or for a scientific experiment.

Reciprocity — The fairness-based obligations of gratitude owed to groups that accept unusual risks and burdens in the service of others.

Standards — Authoritative statements by which a profession describes the responsibilities for which its practitioners are accountable.

Triage — A process of prioritizing patients based on the severity of their condition.

APPENDIX - LIST OF PARTICIPANTS IN THE STAKEHOLDERS PANEL AUGUST 27, 2009

Rose Mary Boyd, St. Francis Medical Center

John Carney, Center for Practical Bioethics

Jack Confer, Kansas Board of Healing Arts

Mary Blubaugh, Kansas State Board of Nursing

Debra Billingsley, Kansas State Board of Pharmacy

Steve Schwarm, hospital legal subject matter expert

Steve Sutton, Kansas Board of EMS

Allison Peterson, Kansas Medical Society

Deborah Stern, Kansas Hospital Association

Cindy Luxem, Kansas Health Care Association

Dan Hinthorn, KU Medical Center & Kansas Clinical Resource Network

Glen White, KU Research and Training Center on Independent Living

Julie Russell, Kansas Health Ethics

Jason Eberhart-Phillips, Kansas Department of Health & Environment

STAFF:

Gianfranco Pezzino, KHI

Tatiana Lin, KHI

Mindee Reece, KDHE

Alicia Parkman, KDHE

Daric Smith, KDHE