



# Development of Standards and Guidelines for Healthcare Surge during Emergencies

## Population Rights

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**NOTE:** This document is the first draft output from the Population Rights work team. It is the culmination of input received from multiple sources which includes ideas generated by stakeholders, reference material gathered through research, documents submitted by stakeholders, and analysis of current regulations and statutes. It is a work in progress and will continue to be refined over the next few weeks. We would like to solicit your feedback on the content of this document. Should you have reference material or ideas, please contribute them via email to [hcsurge@us.pwc.com](mailto:hcsurge@us.pwc.com). The quality and effectiveness of this deliverable is ultimately decided by you, the stakeholder.

### Introduction

Providing healthcare during a large scale public health emergency presents significant challenges for healthcare facilities, licensed healthcare professionals, and communities. During emergency events, healthcare systems must convert quickly from their existing patient capacity to “surge capacity” - a significant increase beyond usual capacity - to rapidly respond to the needs of affected individuals. The demands of the emergency may prevent compliance with the existing healthcare standards. Just as California has healthcare standards for use with a normal operations, it is essential that California provide guidelines that identify the extent to which existing standards can be flexed or waived for healthcare delivery during emergencies.

Surge planning for the healthcare system is a substantial and complex challenge. In a time of significant disaster, a successful plan must provide flexibility to address capacity (volumes of patients) and capabilities (types of illnesses) that emerge above baseline requirements. The issues addressed are diverse and include standards of practice during an emergency, liability of hospitals and licensed healthcare professionals, reimbursement of care provided during an emergency, operating alternate care sites, and planning considerations for surge operations at individual hospitals.

Upon completion of this project, stakeholders will have access to a *Standards and Guidelines Manual* that will serve as a reference manual on existing statutory and regulatory requirements identifying what will be flexed or modified under different emergencies; *Operational Tools* that include forms, checklists and templates to facilitate and guide the adoption and implementation of statutory and regulatory requirements outlined in the Standards and Guidelines Manual; and a *Training Curriculum* outlining intended audience, means of delivery and frequency of training that will enable adherence to the policies and overall readiness of the healthcare delivery system.

The deliverables will serve as the basis for planning and operations of healthcare facilities, providers and communities during an unexpected increase in demand for healthcare services. The deliverable will focus on eight areas: (1) Declaration and Triggers; (2) Existing Facilities; (3) Alternate Care Sites; (4) Personnel; (5) Supplies, Pharmaceuticals and Equipment; (6) Funding Sources; (7) Administrative; and (8) Population Rights.

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While Declaration and Triggers forms the basis for the other areas of focus in terms of defining surge and identifying triggers, Population Rights provides each area of focus with an ethical foundation for delivering healthcare during a surge situation. During surge, reasonable exercise of clinical judgment and common sense should come into play when making decisions. The outputs of the Population Rights work groups are guides and tools that urge and enable healthcare personnel to uphold the long standing principles of ethical practice even when resources are scarce and time is compromised.

This document is divided into two sections. The first section provides a table of contents and the thought leadership behind guidelines regarding the transition from patient-based to population-based outcomes. It begins with four basic ethical principles of healthcare surge and concludes with practice guidelines that provide healthcare personnel with behavioral guidance during the provision of medical care during surge.

The second section identifies generic tools that will assist healthcare facilities, providers and healthcare workers in promoting population-based outcomes. Current statutes, regulations and professional standards of practice relating to the ethical issues of informed consent and advance healthcare directives, special needs populations, and post-mortem care may not be fully adhered to

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during a healthcare surge. The tools set forth create standards of care that healthcare personnel would adopt during a healthcare surge.

### **Guidelines Regarding the Transition from Patient-Based to Population-Based Outcomes**

*This section provides a table of contents and the thought leadership behind guidelines regarding the transition from patient-based to population-based outcomes. Preliminary work was conducted to create these guidelines, including a table of contents and a rough draft of Chapters II and III.*

#### **Chapter I: Introduction**

The introduction of this guideline will identify the guideline's scope and include all issues to be addressed. The difference between patient-based outcomes and population-based outcomes will also be distinguished.

#### **Chapter II: Basic Ethical Principles of Healthcare Surge**

Principle #1: (Adapted from Public Health Principle #7): The local health officer has an ethical obligation to utilize all readily accessible information in a responsible way and in a timely manner in making a determination that a healthcare surge situation exists.

Principle #2: (Adapted from Public Health Principle #6): To the fullest extent possible under the circumstances of a healthcare surge, local health officers and those working under their direction and authority should provide those in the community with accurate information pertaining to the nature of the healthcare surge and the responses to it with reasonable frequency.

Principle #3: (Adapted from AHRQ's *Altered Standards of Care in Mass Casualty Events* Principles #1 and #2): Those persons involved in formulating and implementing the response to a healthcare surge should pursue the goal of preserving as many lives as possible. In pursuit of this goal, those persons should strive, to the fullest extent possible, to respect individual rights and community norms.

Principle #4: Reasonable accommodations should be made for the personal needs and commitments of those healthcare and other personnel responding to the healthcare surge.

#### **Chapter III: Behavioral Principles of Optimal Care in a Low Resources Environment**

##### **Sections Included:**

- A. Introduction and Overview
- B. Basic Behavioral Principles during a Healthcare Surge
- C. Recommendations for Action
- D. References

##### **A. Introduction and Overview**

Much planning has been undertaken at the federal, state, and local levels to enhance surge capacity in response to a large-scale emergency resulting in mass casualties. Such an event involving thousands or tens of thousands of victims may require alterations in health and medical care standards. To address this issue, the Agency for Healthcare Research and Quality (AHRQ) convened in August 2004 a panel of 39 experts drawn from the fields of bioethics, emergency medicine, disaster management, health administration, law, and public health. The deliberations of this panel led to a report, *Altered Standards of Care in Mass Casualty Events (Altered Standards)*, which outlines a number of important issues and policy recommendations.

Some of the selected, key findings of this report include the following:

1. The goal of an organized and coordinated response to a healthcare surge should be to maximize the number of lives saved.
2. 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 healthcare surge. 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.

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3. Many health system preparedness efforts do not provide sufficient planning and guidance concerning the altered standards of care (which we will henceforth term 'standards of care during a healthcare surge') that would be required to respond to a healthcare surge.
4. The basis for allocating health and medical resources in a healthcare surge must be fair and clinically sound. The process for making these decisions should be transparent and judged by the public to be fair.
5. Protocols for triage (i.e., the sorting of victims into groups according to their need and resources available) need to be flexible enough to change as the size of a healthcare surge grows. Triage protocols must depend on both the nature of the healthcare surge and the speed with which it occurs.
6. A number of important non-medical issues that affect the delivery of health and medical care need to be addressed to ensure an effective response to a healthcare surge. They include:
  - a. The authority to activate or sanction the use of 'standards of care during a healthcare surge' under certain conditions;
  - b. Issues related to effective communication with the public
  - c. Issues related to populations with special needs

Some of the above points are discussed in more detail in subsequent sections of this chapter.

### B. Basic Behavioral Principles during a Healthcare Surge

The following guiding principles (adapted from the report *Altered Standards*) should be used in developing altered standards of care in response to a healthcare surge:

**Principle 1:** In planning for a healthcare surge, healthcare personnel should aim to maintain functionality of the healthcare system and to deliver a quality of care that is optimal under current circumstances. Most importantly, healthcare personnel should aim to preserve as many lives as possible. Adhering to this principle will involve:

- The allocation of scarce resources in order to save the most lives
- The development of a basis for the allocation of resources that is fair, open, transparent, accountable, and well understood by both professionals and the public

**Principle 2:** The rights of individuals must be protected to the extent possible and reasonable, including but not limited to the following circumstances:

- In establishing and operationalizing an adequate legal framework for the delivery of care;
- In determining the basis on which scarce resources will be allocated;
- When considering limiting personal freedom through quarantine or isolation as well as the conditions for release;
- When privacy and confidentiality may have to be breached.

**Principle 3:** *This principle provides behavioral-based guidance in relation to ethical principle #2 in Chapter II, above.*

To manage expectations and educate the public about the impact of an event, whom to call for information, where to go for care, and what to expect, the following points should be kept in mind:

- The public should be brought into the discussion during the early stages of planning so that citizens develop clear understanding of concepts such as rationing of resources;
- Public understanding and acceptance of plans are essential to success;
- Messages should be consistent and timely at all stages;
- Official health and medical care messages should be delivered through public media by the local physician health officer (or other local physician (e.g., hospital or medical group chief of staff) whom the public perceives to have knowledge of the event and the area), the California state health officer, a representative of the Centers for Disease Control and Prevention, or the Surgeon General depending on the level of communication necessary.
- Spokespersons at all levels—local, State, regional, and Federal—should coordinate their messages;
- It may be necessary to vary the modes of communication according to the type of information to be communicated, the target audience for which it is intended, and the operating condition of media outlets, which may be directly affected. Attention to the need to use languages other

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than English and the use of alternative communication channels outside of usual media outlets are examples of specific concerns. Also, specificity and details within messages would vary by target population (affected area vs. neighboring areas vs. the rest of the state).

### D. Recommendations for Action

Several recommendations (adapted from *Altered Standards*) for action related to planning a health and medical care response to a healthcare surge are identified below. The list of recommendations is not meant to be comprehensive, but it provides a starting point for discussion related to standards of care during a healthcare surge.

These ideas suggest that a collaborative approach should be taken when developing next steps; both government and private organizations have unique roles and important contributions to make in moving forward.

#### **Recommendation 1: Develop general and event-specific guidance for allocating scarce health and medical care resources during a healthcare surge.**

Public and private organizations, including professional societies, should develop guidance in specific areas related to the allocation of scarce clinical resources. Examples include but are not limited to the following:

- Triage guidelines and measures for specific types of events.
- Allocation guidelines for scarce resources, such as ventilators, burn beds, or surgical suites.
- Guidance for the triaging and treatment of children, specifically the ways in which altered standards of care might differ for a pediatric population.

#### **Recommendation 2: Develop and implement a process to address non-clinical issues related to the delivery of health and medical care during a health care surge.**

Examples of non-clinical issues include but are not limited to the following:

- Alternative ways to establish authority to move to standards of care during surge
- Alternative ways to ensure an adequate legal framework, including liability, certification and licensing, and mutual aid agreements for the provision of health and medical care in a healthcare surge.
- Alternative ways to resolve issues of fiancé and reimbursement issues related to the provision of health and medical care in a healthcare surge.

#### **Recommendation 3: Develop a comprehensive strategy for risk communication with the public before, during, and after a healthcare surge.**

Experts agreed that a unified strategy and tools for public communication around mass casualty risk and health medical care response are indicated. Part of the challenge is to craft credible messages that the public will perceive as immediately relevant and important to their daily lives without causing undo alarm. Such a strategy should take the form of anticipatory guidance. Messages should be developed collaboratively with various stakeholders (such as the American Hospital Association, the Joint Commission of the Accreditation of Health Care Organizations, and others), that should also participate in their dissemination.

Specific ideas and suggestions made regarding public communication include but are not limited to the following:

- Train California journalists to cover health events as a means to partner effectively with the media in reaching the public.
- Find effective ways to communicate clinical information to lay audiences.
- Utilize primary care providers and local public health departments, especially nurses, in getting out agreed-upon messages in local communities on a one to one basis.
- Provide a communications capability at the level of the individual facility as well as through joint information centers.

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- Include communications internal to health care facilities and among system components, such as hospitals and alternate care sites, in communications strategies.

### **Recommendation 4: Identify, analyze, and consider modification of Federal, State, and local laws and regulations that may affect the delivery of health and medical care during a healthcare surge.**

As part of an effort to develop a legal framework for providing health and medical care in a mass casualty situation, an effort should be made to create a compendium of laws and regulations at the Federal, State and local levels that affect the delivery of health and medical care. This compendium of laws and regulations would facilitate the creation of an adequate legal framework for moving to altered standards of care when necessary. It would identify the following:

- The responsible parties for each law or regulation (local, State or Federal government).
- Circumstances when each law or regulation can be modified.
- Specific ways each law or regulation could be modified on a temporary basis.

### **Recommendation 5: Develop means for verifying credentials of medical and other health personnel prior to and on-site during a healthcare surge.**

In disaster situations, individuals who claim to be qualified providers and who want to volunteer their services typically approach health care facilities. In order to be able to make use of such resources, facility and incident managers need to have tools and methods, such as searchable databases, for verifying credentials.

Efforts are underway at both the State and Federal levels to address this need. Emergency Systems for Advance Registration of Volunteer Health Care Personnel (ESAR-VHP), as outlined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), as well as the Medical Reserve Corps credentialing efforts, and other State-developed systems are examples of tools that could be useful in this regard.

### **Recommendation 6: Create strategies to ensure health and medical leadership and coordination for the health and medical aspects of system response during a healthcare surge.**

Experience in developing preparedness strategies suggests there is a need to assure high-level health and medical leadership at the system and regional levels. For some systems and regions, this may involve creating a designated Medical Disaster Specialist or a role with comparable responsibilities to coordinate the health and medical aspects of system response. The expertise required ensuring appropriate health and medical leadership in a healthcare surge includes the following:

- Knowledge about how and when to initiate altered standards of care.
- Knowledge and skill to facilitate communication and provide the link between the medical care system and overall incident response.
- Knowledge and skill to provide disaster-related medical leadership in a system of community or region, including all aspects of medical preparedness and response.
- Knowledge and skill to provide leadership for training.
- Knowledge of and the ability to match hospital and system-specific resources to interventions in a crisis.
- Knowledge of surge plans, resources, and techniques for that particular region/city.
- Knowledge and skill in developing resource-sharing agreements, such as regional travel teams and memoranda of understanding, with adjacent areas.

## G. References

Altered Standards of Care in Mass Casualty Events. Prepared by Health Systems Research Inc. under Contract No. 290-04-0010. AHRQ Publication No. 05-0043. Rockville, MD: Agency for Healthcare Research and Quality. April 2005.

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### Chapter IV: Practice Guidelines

During mass casualty events such as epidemics, bioterrorist attacks, and other disasters with large numbers of victims, the demand for medical care may outpace the available resources to deliver that care. Surge capacity planning for such resource poor environments must incorporate a transition from patient based outcomes which utilize a traditional bioethical focus on individual autonomy, to population based outcomes which utilize a utilitarian model aimed at doing “the greatest good for the greatest number” with the limited resources available. The following emergency mass critical care practice guidelines were developed under the premise “that more lives could be saved if a circumscribed set of key critical care interventions were offered to a larger number of patients rather than if maximal critical care interventions with all their incumbent human and material resource requirements could only be provided only to a small number.”<sup>i</sup>

In developing surge capacity plans hospitals should develop tiered criteria for resource allocation as demand for medical care progressively outpaces resources to deliver that care. During a mass casualty event implementation of emergency mass critical care guidelines must be done in conjunction with declarations by the Governor’s office and local public health departments.

#### Emergency Mass Critical Care: Essential Elements<sup>i</sup>

To ensure the availability of essential critical care interventions during resource poor situations, hospitals should give priority to interventions that fulfill the following criteria:

- interventions that have been shown or are deemed by critical care experts’ best professional judgment to improve survival, and without which death is likely
- interventions that do not require extraordinarily expensive equipment
- interventions that can be implemented without consuming extensive staff or hospital resources

Based on these criteria, at a minimum, hospitals should plan to be able to deliver the following during emergency mass critical care:

- basic modes of mechanical ventilation
- hemodynamic support
- antibiotic or other disease-specific countermeasure therapy
- a small set of prophylactic interventions that are recognized to reduce the serious adverse consequences of critical illness

Mechanical ventilation: “Failure to provide positive pressure ventilation to critically ill patients with severe hypoxemic respiratory failure, acute respiratory distress syndrome, or neuromuscular ventilatory failure will almost certainly result in death. The provision of a basic mode of mechanical ventilation (e.g., assist-controlled or pressure-controlled ventilation) for large numbers of patients should be a priority”<sup>i</sup> when planning for mass casualty events.

Hemodynamic support: “According to national practice guidelines for septic shock, the initial priority of therapy is ‘to maintain a reasonable mean arterial pressure to keep the patient alive.’”<sup>ii</sup> In the event of a need for emergency mass critical care, hospitals should plan to be able to administer intravenous fluid resuscitation and vasopressor therapy to large numbers of hemodynamically unstable victims and should stockpile sufficient equipment to do this without relying on external sources for at least the first 48 hrs of the hospital medical response.”<sup>i</sup>

Prophylactic interventions: during emergency mass critical care hospitals should plan to provide “at least two widely accepted prophylactic interventions that are used everyday in critical care: maintaining the head of a mechanically ventilated patient’s bed at 45° to prevent ventilator-associated pneumonia and thromboembolism prophylaxis.”<sup>iii</sup>

#### Allocation of Critical Care services in resource poor environments

In no area are our resource limitations more concrete and with fatal consequence than in the availability of mechanical ventilation. When strategies to augment capability to deliver mechanical ventilation are insufficient a mechanism for the allocation of this scarce resource must be implemented.

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Previously published clinical guidelines have been developed by a collaborative process using groups of content matter experts including medical specialists, ethicists, and legal experts, and have been reviewed and vetted through an even wider group of experts. Ethical consideration given to the development of emergency mass critical care guidelines has included substantive values (individual liberty, protection of the public from harm, proportionality, privacy, duty to provide care, reciprocity, equity, trust, solidarity and stewardship) and procedural values (reasonable, open and transparent, inclusive, responsive and accountable). “Any restrictions placed on treatment must adhere to the value of proportionality, which requires that restrictions to individual liberties not exceed what is necessary to address the essential needs of the community.”<sup>iv</sup> When the clinical guidelines are implemented they must be used in an open and transparent manner. Hospitals should have plans to revise any guidelines as information becomes available regarding prognostic factors, specifics of the causative agent resulting in illness, and resource availability. Processes for ongoing re-evaluation and for consideration of exceptions must be developed in addition to an appeals mechanism. Aside from being an ethical imperative, a process to evaluate and refine the guidelines prevents undertriage or overtriage.<sup>iv</sup> The following criteria were published originally by Hick, et al.<sup>v</sup>

Attributes of criteria for allocation of mechanical ventilation in resource poor environments<sup>v</sup>:

1. They should assist the individual physician by providing a guideline and policy basis for determining criteria for resource allocation or withdrawal, which will reduce the potential for each physician to have to design and defend individual strategies for individual cases and improve consistency.
2. They should be implemented on a regional, not institutional basis, with a government agency providing policy support for implementation.
3. Appropriate liability protections for providers and institutions cooperating with the public health directives should be assured in advance, or as part of an emergency order.
4. Aside from disease-specific criteria, restrictions should apply equally to all patients (e.g., both those infected and those who are hospitalized for other reasons).
5. Criteria should be implemented in a tiered or stepwise fashion, so that as resources are exhausted, another (stricter) tier of exclusion criteria is implemented in an attempt to provide the best care possible to those with the best chance of survival.
6. Whenever possible, tiers should be based on objective determinations of effectiveness of care affecting survival, and of resource utilization, rather than subjective determinations regarding the value of either the intervention or the value of the patient's life.
7. The final tier should ideally provide a numeric assessment of survival probability. This figure may be then compared within and between institutions and regionally to allow resources to be shifted to equalize the care provided and also provide a "sliding scale" of care guidelines that may be adjusted depending on the demand on the resources (e.g., unable to provide mechanical ventilation to patients with score > X, tomorrow may change to score > Y).
8. The numeric scoring system should rely on as many clinical variables (rather than laboratory) as possible. It should be easily correlated with survival. It should be available in the public domain (e.g., nonproprietary). It should be easily adapted to Internet or personal digital assistant calculation programs. Ideally, it should involve simple calculations and few variables.

The three tiers of criteria are designed to be a scalable framework for restricting mechanical ventilation (see table below). Withholding AND withdrawing ventilatory support are ethically indistinct, and are thus listed together in the criteria.

“First-tier criteria are solely related to respiratory failure with shock and multiple organ dysfunction.

Second-tier criteria are related to high potential for death, prolonged ventilation, and high levels of resource utilization. These tier 2 criteria are invoked when tier 1 restrictions are inadequate to meet resource demands. The first and second tiers require no familiarity with scoring systems and depend mainly on respiratory failure and poor prognosis based on current and underlying disease.

Third-tier criteria may involve additional restrictions or a numeric score and are invoked when determined necessary to maintain consistent standards of patient care and further restrict demand

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on resources. Any of the tiers may be modified during the event to account for disease-specific prognostic information.

The use of a predictive survival instrument in the final tier standardizes assessments and allows numeric comparisons of patients both within the institution and between institutions. This allows more efficient allocation of available resources to institutions in greatest need and provides as consistent a level of care (as possible) across the community and region. It also provides the physician with guidance for clinical care that is rational and quantitative rather than qualitative.

The standard of care that is applied in the setting of a large-scale disaster is a sliding scale of care appropriate to the resource demands of the event. A hospital attempting to manage a large influx of patients who require ventilator support during an epidemic may have to further ration resources in the face of increasing demand. This could potentially result in withdrawal of resources from an individual who might be stable, or even improving, but whose objective assessment indicates a worse prognosis than other patients who require the same resource (e.g., tier 3 criteria, where a score of X today might warrant a ventilator but, in the face of worsening shortages, might not be sufficient to justify continued ventilatory management tomorrow, or a patient who is already hospitalized when a disaster occurs, and whose resources are reapplied to a patient with a higher potential for a good outcome).

Many scoring systems have been developed to predict mortality in intensive care environments. Of the scoring systems that are currently available, the Sequential Organ Failure Assessment (SOFA) seems to be the most useful of the systems, generating a numeric score that offers good predictive accuracy based on a few clinical and simple (bilirubin, creatinine, platelet count) laboratory observations (Appendix 1). SOFA scores can also be used over time to evaluate prognosis and response to therapy.”<sup>V</sup>

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**Table: Three Tiers of Criteria**

<p><b>Tier 1:</b> Do not offer AND withdraw ventilatory support for patients with any one of the following:</p> <ol style="list-style-type: none"><li>1. Respiratory failure requiring intubation <i>with</i> persistent hypotension (systolic blood pressure &lt; 90 mm Hg for adults) unresponsive to adequate fluid resuscitation after 6–12 hours of therapy <i>and</i> signs of additional end-organ dysfunction (e.g., oliguria, mental status changes, cardiac ischemia)</li><li>2. Failure to respond to mechanical ventilation (no improvement in oxygenation or lung compliance) and antibiotics after 72 hours of treatment for a bacterial pathogen (timeline may be modified based on organism-specific data)</li><li>3. Laboratory or clinical evidence of <math>\geq 4</math> organ systems failing<ol style="list-style-type: none"><li>a. Pulmonary (adult respiratory distress syndrome, ventilatory failure, refractory hypoxemia)</li><li>b. Cardiovascular (left ventricular dysfunction, hypotension, new ischemia)</li><li>c. Renal (hyperkalemia, diminished urine output despite adequate fluid resuscitation, increasing creatinine level)</li><li>d. Hepatic (transaminase greater than two times normal upper limit, increasing bilirubin or ammonia levels)</li><li>e. Neurologic (altered mental status not related to volume status, metabolic, or hypoxic source, stroke)</li><li>f. Hematologic (clinical or laboratory evidence of disseminated intravascular coagulation)</li></ol></li></ol> <p><b>Tier 2:</b> Do not offer AND withdraw ventilatory support from patients with respiratory failure requiring intubation with the following conditions (in addition to those in tier 1):</p> <p>Patients with pre-existing system compromise or failure including:</p> <ol style="list-style-type: none"><li>1. Known congestive heart failure with ejection fraction &lt; 25% (or persistent ischemia unresponsive to therapy and pulmonary edema)</li><li>2. Acute renal failure requiring hemodialysis (related to illness)</li><li>3. Severe chronic lung disease including pulmonary fibrosis, cystic fibrosis, obstructive or restrictive diseases requiring continuous home oxygen use before onset of acute illness</li><li>4. Acquired immunodeficiency syndrome (AIDS), other immunodeficiency syndromes at stage of disease susceptible to opportunistic pathogens (e.g., CD4 &lt; 200 for AIDS) with respiratory failure requiring intubation</li><li>5. Active malignancy with poor potential for survival (e.g., metastatic malignancy, pancreatic cancer)</li><li>6. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy</li><li>7. Acute hepatic failure with hyperammonemia</li><li>8. Irreversible neurologic impairment that makes patient dependent for personal cares (e.g., severe stroke, congenital syndrome, persistent vegetative state)</li></ol> <p><b>Tier 3:</b> Specific protocols to be agreed upon by guideline development committee. Possibilities include:</p> <ol style="list-style-type: none"><li>1. Restriction of treatment based on disease-specific epidemiology and survival data for patient subgroups (may include age-based criteria)</li><li>2. Expansion of preexisting disease classes that will not be offered ventilatory support</li><li>3. Applying Sequential Organ Failure Assessment scoring to the triage process and establishing a cutoff score above which mechanical ventilation will not be offered</li></ol>
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These triage criteria must be seen as guidelines and not standards. “More important than the specifics of any tool (which will require modification based on the event) is the establishment of a process for making decisions to limit care so that in a time of crisis, a mechanism is in place to apply as much science as possible to these decisions and the persons involved are prepared for their roles.”  
v

### Chapter V: Important Related Issues

Chapter V will use Chapter 4 of AHRQ's *Alternate Standard of Care in Mass Casualty Events*, which speaks to other important issues to address during a healthcare surge. Chapter V will provide a definition of "special needs" and will stress the importance of communicating with special needs populations and the community based organizations that care for individuals with special needs.

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### Caring for Populations with Special Needs

It is essential that plans for the delivery of health and medical care in a healthcare surge address how the special needs of several groups within the general population can be met. These needs may vary from providing for alternate means of decontamination for babies and other non-ambulatory persons, to having translators available at intake centers, to providing mental health assessment resources within the health care setting. Involving organizations and services designed to serve groups with special needs under normal conditions may be a successful approach. As mentioned earlier, a victim's underlying medical condition may affect their survivability, and therefore may be considered negatively in triage. In some cases resources may be diverted away from adults to children because of their greater life expectancy.

Populations recognized as having special needs in a healthcare surge include but may not be limited to the following:

- Children.
- Persons with physical or cognitive disabilities.
- Persons with preexisting mental health and/or substance abuse problems.
- Frail or immunocompromised adults and children.
- Non-English speakers.

### Tools to Promote Population-Based Outcomes

*This section identifies generic tools that will assist healthcare facilities, providers and healthcare workers in promoting population-based outcomes with regards informed consent and advance healthcare directives, special needs populations, and post-mortem care.*

Ideally, healthcare providers will be able to fully adhere to the standards established by existing laws and the core values and principles of public health law and ethics during a healthcare surge, and that such individuals will depart from those core values and principles only when the nature and extent of the healthcare surge precludes full adherence to them.

However, it is inevitable that during a healthcare surge, individuals providing healthcare services in licensed healthcare facilities and alternate care sites will be unable to fully adhere to statutes, regulations and professional standards of practice relating to patient rights and professional ethics, including obtaining informed consent; honoring advanced healthcare directives; communicating with healthcare agents, surrogates and next of kin; providing services to special needs populations; and disposing of human remains. As such, it is anticipated that the legal requirements concerning such rules will be waived by government authorities.

### Tool #1: Standards Related to Informed Consent during Healthcare Surge

California Business & Professions Code § 2397 states that 'a licensee shall not be liable for civil damages for injury or death caused in an emergency situation occurring in the licensee's office or in a hospital on account of a failure to inform a patient of the possible consequences of a medical procedure where the failure to inform is caused by any of the following:

- The patient was unconscious
- The medical procedure was undertaken without the consent of the patient because the licensee reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient.
- A medical procedure was performed on a person legally incapable of giving consent, and the licensee reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.'

During a discussion with the Population Rights work team, it was decided that § 2397 would be used as a baseline to create standards relating to informed consent during healthcare surge. The standard suggested is as follows:

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A healthcare provider is not obligated to obtain informed consent, as that term is defined by applicable facility policy and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge, when any one or more of the following circumstances are present:

1. The patient is unconscious, the healthcare provider believes that the service or procedure should be undertaken immediately, and the healthcare provider believes the patient's legal representative for healthcare decisions is not immediately available. (See Tool #3 relating to communication with legal representatives for healthcare decisions.)
2. The medical service or procedure is undertaken without the consent of the patient because the healthcare provider believes that the service or procedure should be undertaken immediately and there is insufficient time to fully inform the patient.
3. A medical service or procedure is performed on a legally incapable of giving consent, and the healthcare provider believes that the procedure should be undertaken immediately and there is insufficient time to obtain the information consent of the person authorized to give such consent for the patient.

The Population Rights work team has suggested that healthcare providers should not be required to document the presence or absences of these circumstances.

### **Tool #2: Standards Related to Advanced Healthcare Directives during Healthcare Surge**

California Probate Code § 4734 states that 'A healthcare provider may decline to comply with an individual healthcare instruction or healthcare decision for reasons of conscience.' Also, 'a healthcare institution may decline to comply with an individual healthcare instruction or healthcare decision if the instruction or decision is contrary to a policy of the institution that is expressly based on reasons of conscience and if the policy was timely communicated to the patient or to a person then authorized to make healthcare decisions for the patient.'

During a discussion with the Population Rights work team, it was decided that § 4734 would be used as a baseline to create standards relating to advance healthcare directives during healthcare surge. The standard suggested is as follows:

A healthcare provider is not obligated to inquire about, read or adhere to an Advanced Healthcare Directive, as that term is defined under applicable facility policy, state law and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge, unless all of the following circumstances are present:

1. The healthcare provider is aware of the terms of the Advanced Healthcare Directive.
2. The healthcare provider believes that accommodating the terms of the Healthcare Directive will not require will not require time, staff or resources that would otherwise be utilized in the care of other individuals.

The Population Rights work team has suggested that healthcare providers should not be required to document the presence or absences of these circumstances.

### **Tool #3: Standards Related to Communicating with Legal Representatives for Healthcare Decisions during Healthcare Surge**

A health care provider is not obligated to locate or obtain informed or other consent from a patient's legal representative for health care decisions (including but not limited to the parent or guardian of a minor child, a conservator, an agent for health care decisions, a surrogate or next of kin), before rendering a health care service or procedure during a Health Care Surge, unless the following circumstance is present:

1. The health care provider knows that the legal representative for health care decisions is immediately available to the health care provider. "Immediately available" means the representative is physically present next to the patient.

The Population Rights work team has suggested that healthcare providers should not be required to document the presence or absences of these circumstances.

## POPULATION RIGHTS

### **Tool #4: Standards Related to Providing Services to Individuals with Special Needs during Healthcare Surge**

“Individuals with special needs” (definition will be defined in Chapter V of the *Guidelines Regarding the Transition from Patient-Based to Population-Based Outcomes*) have the same rights to health care services as individuals who do not have special needs during a Health Care Surge. Therefore, the decision by a health care provider as to whether an individual should be provided with health care services (including but not limited to health care services and procedures, pharmaceuticals and accommodations), should be based on the acceptable criteria for resource allocation as set forth in the *Guidelines Regarding the Transition from Patient-Based to Population-Based Outcomes*, and not on whether the individual meets the definition of an individual with special needs.

### **Tool #5: Standards Related to Disposal of Human Remains during Healthcare Surge**

The manner and process for disposing of human remains during a Health Care Surge will be based on directives from state and local health care authorities and not on the requests of the patient in an Advanced Health Care Directive or requests by the patient’s legal representative for health care decisions.

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<sup>i</sup> Augmentation of hospital critical care capacity after bioterrorist attacks or epidemics: Recommendations of the Working Group on Emergency Mass Critical Care; Rubinson, L et. Al; *Crit Care Med* 2005 Vol. 33, No. 10

<sup>ii</sup> Practice parameters for hemodynamic support of sepsis in adult patients in sepsis. Task Force of the American College of Critical Care Medicine, Society of Critical Care Medicine. *Crit Care Med* 1999; 27:639–660

<sup>iii</sup> Shojania KG, U.S. Agency for Healthcare Research and Quality, University of California SF-SE-BPC: Making Health Care Safer: A Critical Analysis of Patient Safety Practices (No. 01-E058ed). Rockville, MD, Agency for Healthcare Research and Quality, U.S. Dept. of Health and Human Services, 2001

<sup>iv</sup> Christian, M; Development of a triage protocol for critical care during an influenza pandemic; *CMAJ*, Nov 21, 06, 175(11), 1377-1381

<sup>v</sup> Hick, J.L., et al; Concept of Operations for Triage of Mechanical Ventilation in an Epidemic; *Acad Emerg Med* 2006; 13:223-9