Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines April 10, 2020

Version 2



Produced in cooperation with





Special Note: Novel Coronavirus (COVID-19) Response

This document is the early work of what was intended to be a comprehensive document developed by a multi-tiered team over an 18-month period. A steering committee was convened in the fall of 2019, recognizing a need for a robust Crisis Standards of Care plan within the Commonwealth of Pennsylvania that could be tactically implemented by health care facilities across the state. However, the rise of a novel Coronavirus (COVID-19) required that this document be "fast tracked" to be an interim guidance document and plan for the current global pandemic. While the committee has worked to obtain feedback and input from key stakeholders to ensure that the guidance provides a fair and balanced approach to a difficult topic, this document should be viewed as a "work in progress" and will likely include language or content that may change in future versions.

With that in mind, we ask all health care providers to use this document as the interim guidance that it is intended to be and recognize that once the current crisis is behind us, the broader review and improvement of this document will take place, ensuring that this document has the support of the commonwealth's health care community.

We continue to thank and appreciate all our commonwealth's health care providers, facilities and systems in the work that you do each and every day to ensure a healthy Pennsylvania for all.

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About the Guidelines

These guidelines were developed by the Pennsylvania Department of Health (DOH) and the Hospital & Healthsystem Association of Pennsylvania (HAP) as a guideline for pandemic and disaster situations.

The purpose of this document is to help guide the allocation of patient care resources during an overwhelming public health emergency of any kind when demand for services dramatically exceeds the supply of the resources needed. These Interim Guidelines represent a consensus view of the entire Crisis Standards of Care Stakeholder Workgroup. The document will be updated as needed and should be modified by facilities to meet the needs and abilities of each hospital. Application of these guidelines will require and depend on physician judgment at the point of patient care. The views expressed in the publication do not necessarily reflect the official policies of the U.S. Department of Health and Human Services or DOH.

Scope of this Document

When a situation is statewide: These triage guidelines may apply to all health care professionals, clinics, and facilities in the Commonwealth of Pennsylvania. The guidelines may apply to all patients.

When the situation is limited: By geography to a specific area of the state, these guidelines may only apply to the medical community affected and the immediate surrounding communities. However, if non-impacted community medical facilities are overwhelmed as a direct result of the event (population displacement, resource shortages, staffing shortages) consideration could be provided to extend the protections on a case-by-case basis.

When activated: Guidelines may be activated in the event of a disaster declaration declared by the governor of the Commonwealth of Pennsylvania. Individual health care facilities and organizations will manage their responses through their designated emergency operations plans and incident command structures. In turn, local hospitals will communicate with both local and state health department emergency operations centers as well as their regional health care coalitions to provide situational awareness and coordination regarding local response efforts and requests.

Disaster Progression

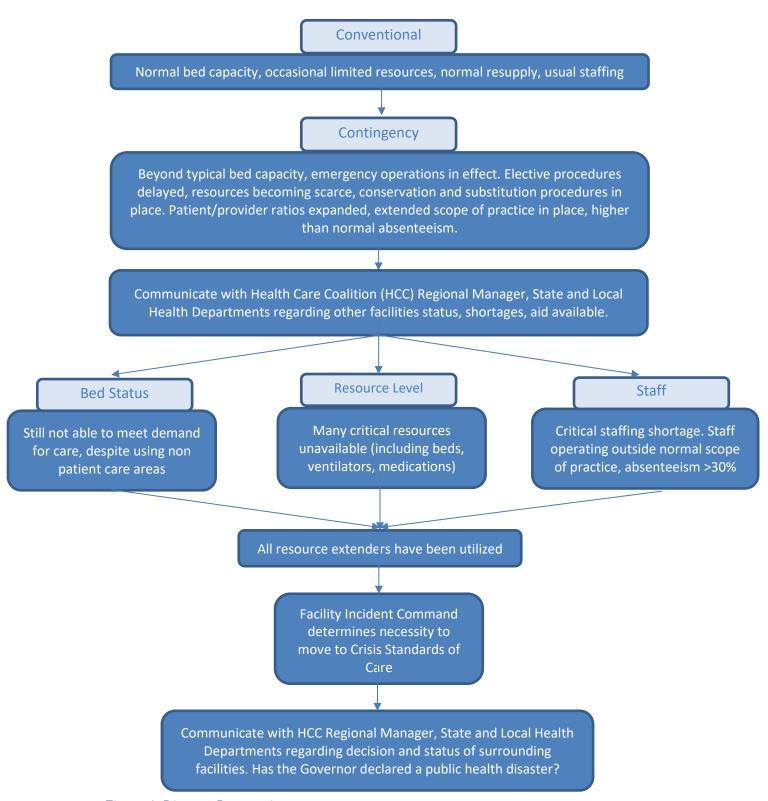


Figure 1: Disaster Progression

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Quick Reference Resources: Centers for Disease Control and Prevention (CDC)

The following resources are provided as quick reference tools and are current as of this update. Guidelines are frequently updated by CDC. To check for the most recent information for health care professionals go to: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html or Pennsylvania Department of Health PA Health Alert Network (HAN) or by calling the Pennsylvania Department of Health 1-877-PA-HEALTH (1-877-724-3258)

Persons Under Investigation (PUI)

- Interim Guidance for Public Health Personnel Evaluation Persons Under Investigation (PUIs) and Asymptomatic Close Contacts of Confirmed Cases at Their Home or Non-Home Residential Settings
- Evaluating and Reporting PUI Guidance

Clinical Care

- Clinical Care Guidance
- Disposition of Hospitalized Patients with COVID-2019
- Inpatient Obstetric Health care Guidance

Infection Control

- Guidance and Resources on Infection Control
 - Interim Infection Prevention and Control Recommendation for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Health care Settings
 - Interim Guidance for Collection and Submission of Postmortem Specimens from Deceased Persons Under Investigation (PUI) or COVID-19, February 2020

Supply of Personal Protective Equipment

- Guidance and Resources on Health care Supply of Personal Protective Equipment
- Strategies for Optimizing Supply of PPE
- Strategies for Optimizing Supply of N95 Respirators
- Frequently Asked Questions About Respirators and Their Use

Home Care

- Implementing Home Care of People Not Requiring Hospitalization
- Preventing COVID-19 from Spreading in Homes and Communities
- Disposition of Non-Hospitalized Patients with COVID-19

Additional References:

We would like to take this opportunity to thank those that went before us in developing pandemic and crisis standards of care plans throughout the country. The following documents were key references:

- Arizona Department of Health, *Arizona Crisis Standards of Care Plan: A Comprehensive and Compassionate Response*, February 2015
- Biddison ELD, Gwon HS, Schoch-Spana M, et al. *Scarce Resource Allocation During Disasters: A Mixed-Method Community Engagement Study*. Chest 2018;153:187-95.
- California Hospital Association, Emergency Preparedness: Preparing Hospitals for Disasters.
- Centers for Disease Control and Prevention, *Community Mitigation Guidelines to Prevent Pandemic Influenza* United States, 2017
- CHEST Consensus http://www.chestnet.org/Publications/CHEST-Publications/Guidelines-Consensus-Statements
- Crisis Standards of Care, CHEST 2014; 146 (4_Suppl): 8S 34S. ABBREVIATIONS: CCTL 5 Critical Care Team Leader; CHEST 5 American College of Chest Physicians, October 23, 2014.
- Daugherty Biddison EL, Faden R, Gwon HS, et al. *Too Many Patients...A Framework to Guide Statewide Allocation of Scarce Mechanical Ventilation During Disasters*. Chest 2019;155:848-54.
- Ethical Guidance for Disaster Response, Specifically Around Crisis Standards of Care: A Systematic Review, Leider et al., AJPH Law and Ethics, Sept 2017
- Florida Department of Health, Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines V10.5, April 5, 2011.
- Guidelines for Crisis Standards of Care during Disasters, June 2013, American College of Emergency Physicians ACEP Disaster Preparedness and Response Committee Workgroup. Leader: Amy Kaji, MD, MPH, FACEP Workgroup Members: Bhakti Hansoti, MD Milana Boukhman, MD
- Institute of Medicine 2012. Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1: Introduction and CSC Framework. Washington, DC: The National Academies Press. https://doi.org/10.17226/13351.
- Johns Hopkins Center for Health Security, What US Hospitals Should Do Now to Prepare for COVID-19 Pandemic, February, 2020
- Kenneth V. Iserson, M.D., MBA, FACEP, FAAEM Professor of Emergency Medicine Director, Arizona Bioethics Program The University of Arizona, Tucson kvi@u.arizona.edu
 Hardest Decisions-Resource Allocation-Ethical Justification part 1
 Hardest Decisions-How To Ration Healthcare Resources part 2
 Hardest Decisions-Who Allocates Scarce Healthcare Resources part 3
- Minnesota Department of Health, Crisis Standards of Care
- Nevada Division of Public and Behavioral Health, Developing a Standard of Healthcare During Catastrophic Public Health Emergencies, Nevada Crisis Standards of Care (CSC) Plan, June 2017
- Oregon Crisis Care Guidance Current January, 2017
- Pediatric Disaster Preparedness Guidelines for Hospitals, California Hospital Association

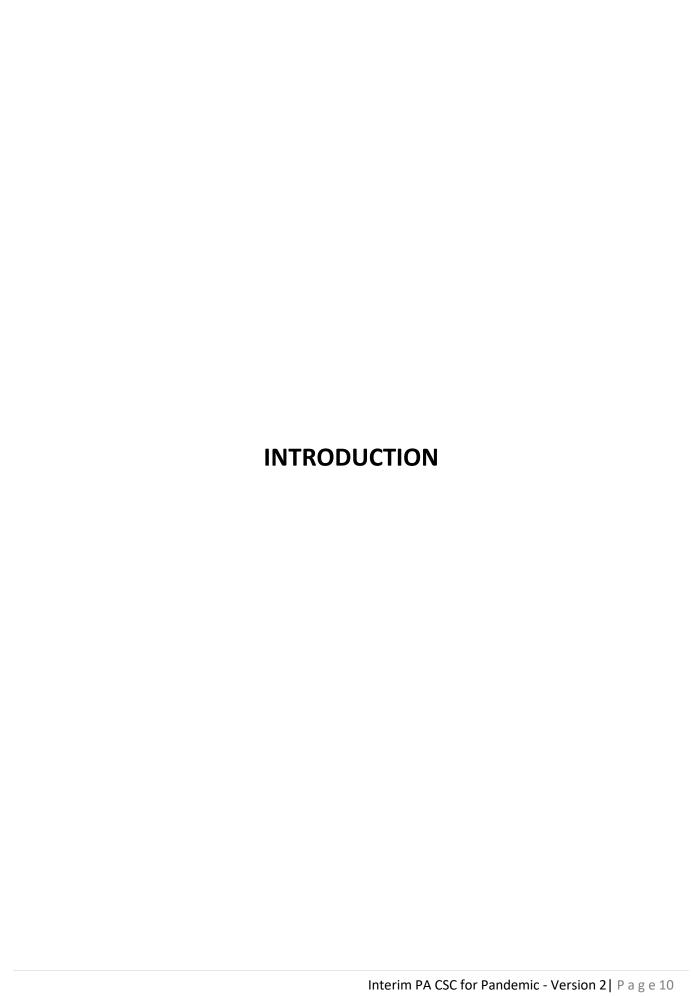
- Rady Children's Hospital, *Pediatric Surge Plan Documents ... Post- Disaster Reunification of Children:*A Nationwide Approach: National Consensus Conference, https://www.rchsd.org/pedsurgeplan/
- Stanford Hospital and Clinics, Lucile Packard Children's Hospital, Template For Crisis Standards of Care Plan Prepared for the CHA Disaster Planning, for California Hospitals Conference by Draft October 15, 2012
- Temporary Suspension or Modification of Statutes and Regulations in New York State During Emergencies: A collaboration between Healthcare Association of New York and the Iroquois Healthcare Association. August 2014
- Utah Crisis Standards of Care Guidelines, Version 2, June 2018.
- White DB, Katz MH, Luce JM, Lo B. Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. Ann Intern Med 2009;150:132-8.

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- Raphael Barishansky, MS, MPH, CPM, Deputy Secretary of Health Planning and Community Preparedness, Pennsylvania Department of Health, Committee Chair
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Introduction

Disasters like Hurricanes Katrina and Sandy and the Haiti earthquake have served as vivid reminders of the challenge of providing health care when demand for health care services sharply rises and places overwhelming demand on resources and medical staff, all in the midst of severe infrastructure damage. Severe pandemic influenza, catastrophic terrorist incidents and other natural disasters have the potential to place even greater demands on our health care system.

Catastrophic events occur over a longer timeframe and are more widespread, such as a pandemic. For example, an influenza pandemic can occur when a non-human (novel) influenza virus changes in such a way that it can infect humans easily and spread easily from person-to-person. The outbreak would begin in one or several locations and then grow, based on the speed and type of transmission.

Pennsylvania has 154 general acute care hospitals comprising of 34,416 licensed beds, of which there are 3,947 ICU beds on a given day. The spread would allow for some preparation for a surge of patients requiring hospitalization and critical care, but because a pandemic would likely affect all states, the possibility of federal assistance is severely limited.

Planning for these types of overwhelming situations can help health care organizations and providers, supported by the entire emergency response system, to take proactive steps that enable them to provide patients with the level of care they would usually receive, or care that is functionally equivalent, for as long as possible. In catastrophic disasters, health care resources may become so scarce that re-allocation decisions are needed, staff may have to practice outside of their normal scope of practice, and the focus of patient care may need to switch to promoting benefits to the entire population over benefits to individuals. In such crisis situations, strategies are necessary to avoid greater illness, injury, and death by enabling more effective use of limited resources. In addition, the use of a fair, just, and equitable process for making decisions about who should receive treatments that have limited availability, such as ventilators, is crucial.

The Institute of Medicine (IOM) has defined *crisis standards of care* as a substantial change in usual health care operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. These guidelines are the means to mount a response to an incident that far exceeds the usual health and medical capacity and capabilities of a medical community. Medical care shifts from focusing on individuals to promoting the thoughtful use of limited resources for the best possible health outcomes for the population as a whole. Resources are shifted to patients for whom treatment would most likely be lifesaving. Such patients should be given priority over those who would likely die even with treatment and those who would likely survive without treatment.

The Agency for Healthcare Research and Quality (AHRQ) developed the following characteristics of altered standards of care that might be manifest during a surge situation:

- Equipment and supplies will be in short supply and will need to be allocated to save the most lives.
- There will be an insufficient number of trained staff.
- Severe delays and backlogs in emergency and hospital care will likely exist.
- Treatment decisions may need to be based entirely on clinical judgment as other diagnostic tools

become inaccessible.

CDC utilizes a dual approach of containment and mitigation strategies for slowing the spread and minimizing the impact on the community. Nonpharmaceutical interventions include:

- Personal Daily personal protective measures, including home isolation of ill persons, hand hygiene;
- Community Social distancing measures, to keep sick away from uninfected, including school other mass gathering measures; and
- Environmental Surface cleaning and disinfectants.

Purpose

The purpose of the *Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines* is to provide a framework for responding to a catastrophic event and the challenges it brings to personnel, resources, and treatment decisions. These guidelines are designed only for disasters or pandemics when numbers of seriously ill patients greatly surpass the capability of available care capacity and normal standards of care can no longer be maintained, and then only after a disaster declaration from the governor.

By acknowledging the reality that patient care in the midst of catastrophe can be extremely limited, we hope to foster additional initiatives in planning, education, and practice by which we can do better in our roles as health care providers, even in the face of such adversity. The IPACSCPG should not be considered a substitute for the good planning in emergency management that health care organizations have already undertaken. It is intended to serve as a guide to the rational allocation of scarce resources after other measures, such as resource sparing and sharing strategies, have been exhausted.

These guidelines, consistent with the principles of all-hazard preparedness, are applicable to any catastrophe in which the demand for patient care greatly outweighs the supply of the resources needed. However, due to special circumstances that some situations may create, we have included appendices that specifically address pandemics, scarce resource strategies, Emergency Medical Treatment and Labor Act (EMTALA), 1135 disaster waivers, and mutual aid agreements.

Ethical Foundations

In the wake of a catastrophe, the need for health care professionals to care for patients will undoubtedly be strained. However, it is necessary to strive to sustain the patient-provider relationship, ensuring that patients are cared for in an ethical manner and mitigate potential misconceptions about the care they receive. During an event with scarce resources, some patients may not be prioritized for all therapies, but other curative and/or comfort care treatments should be provided. There also is an ethical duty to maximize preparedness efforts and adopt prevention and mitigation strategies that will minimize the scarcity of resources and the need to ration resources at some time during a disaster. These guidelines are based upon several ethical principles that have been recognized as central to a just process:

Fairness – every hospital should attempt to be fair to all those who are affected by the disaster.

Consistency – these standards will be applied equitably across populations in compliance with the Pennsylvania Human Relations Act (PHRA) and other state and federal anti-discrimination statutes and

regulation which prohibit discrimination in regard to patient age, race, gender, creed, religion or exercise of conscience, color, sexual orientation, gender identity or expression, disability, ethnicity, national origin (including limited English proficiency), or socioeconomic status.

Proportionality – any alteration in the standard of care will be commensurate with the degree of emergency and the degree of scarcity of any limited resources.

Transparency – these guidelines were developed with input from the community and efforts will be made to engage and educate our community about them.

Solidarity - when there are limited resources, consider the greater good of the entire community.

Additionally, research finds that certain issues need to be addressed within a crisis standards of care framework. Specifically:

- State underlying justifications and norms to achieve fairness and equity;
- Consider both broad and specific ethical issues, include scenario examples;
- Establish expectations of duty to care and reciprocity, including obligations and support;
- Select criteria for resource allocation; and
- Integrate both ethical and technical considers in plans.

Pennsylvania Resources

In a time of a public health crisis, the Pennsylvania Emergency Management Agency (PEMA) and DOH will establish an incident command structure through the Department's Operations Center (DOC). This center focuses on internal agency incident management and response. DOCs are often established within the Emergency Operations Center (EOC) to optimize communication channels for local, regional, or statewide response.

Pennsylvania General Acute Care Hospitals

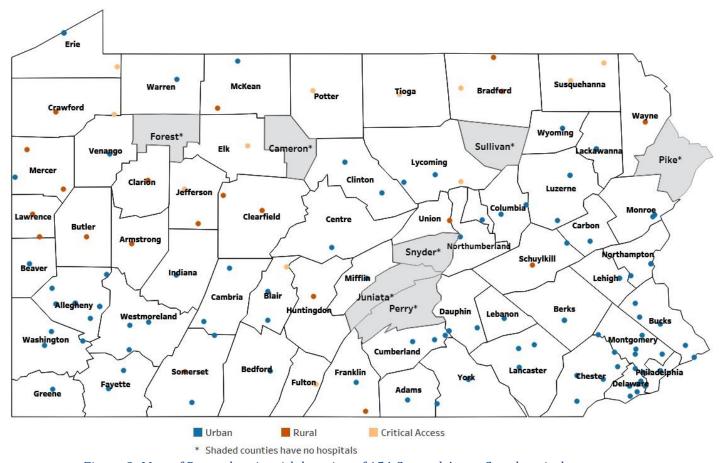


Figure 2: Map of Pennsylvania with location of 154 General Acute Care hospitals

Note: This information is subject to change. For the most up to date information on general acute care hospitals, view the Department of Health's list located here or the Hospital and Healthsystem Associations of Pa's interactive map here.

A CONTINU	UUM OF CARE
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A Continuum of Care

Three levels of care are defined by the IOM and are the basis for determining likely levels of surge, resources, and staffing during a disaster. The following levels are the basis for crisis standards of care planning:

Conventional care: the demand for care is less than the supply of resources. Level of care is consistent with daily practices in the institution.

Contingency care: the demand for care surpasses conventional resource availability, but it is possible to maintain a functionally equivalent level of care by using contingency care strategies. The facility's Emergency Operations Plan is activated.

Crisis care: the demand for care surpasses resource supply despite contingency care strategies. The normal standard of care cannot be maintained.

Refer to Figure 4 on the following page for more information on defining the three levels of care.

Determining the Available Level of Care

It is important to develop useful indicators to recognize where the incident has placed the health care system on the supply and demand curve, and then plan for triggers to alert the system to move from conventional to contingency and to crisis care, as well as back again during the recovery phase.

A list of system-wide potential triggers that might require activation of the *Interim Pennsylvania Crisis* Standards of Care for Pandemic Guidelines would include:

- An event (or disease) that affects a large portion of the state's population and/or health care resources.
- Lack of or critical shortage of essential equipment or medications such as mechanical ventilators, oxygen, antibiotics, antiviral medication or specific antidotes; vasopressors or other critical care medications; intravenous fluids or blood products; operating room equipment, space and staff, and hospital and/or ICU beds.
- Lack of or critical shortage of critical infrastructure, such as power, water and communications; security to maintain the safety of health care providers and patients; lack of personal protective equipment; lack of trained staff, and lack of or shortage of staff support (food, housing, water, etc.).

In the midst of a crisis, there is a very real risk of providing a lower standard of care than is necessary under the circumstances. The difficulties inherent in making informed decisions during a crisis situation cannot be overemphasized. It can be difficult to understand where a single health care entity is on the supply/demand curve at any given time, much less the health care system as a whole. There will be limited, or even inaccurate, information regarding the scale of a disaster, the current and future demand for patient care services, and the current and future supply of resources.

Continuum of Care Model

SITUATION	Conventional	Contingency	Crisis
SURGE STATUS	Hospitals utilize normal bed capacity. Occasional and temporary surges of demand may occur that are temporary and may incur longer wait times for non-critical care as hospitals, ICUs, and emergency departments temporarily reach capacity.	Hospitals have surged beyond maximum bed capacity. Emergency Operations Plans are in effect. Elective procedures delayed or canceled. Hospitals may be adding patients to occupied hospital rooms and nonpatient care areas. Community health care facilities may be requested to surge. Alternate care sites may be opened.	Expanded capacity is still not sufficient to meet ongoing demand for care. Some patients needing care cannot be admitted to hospitals and instead will be sent home or to alternate care sites. Hospitals are adding patients to occupied hospital rooms and non-patient care areas. Community health care facilities are operating beyond normal scope of practice.
RESOURCE LEVEL	Occasional, limited resource shortages may occur, typically of noncritical supplies or medications with substitution as the most common resource sparing strategy.	Some resources are becoming scarce. Attempts at conservation, reuse, adaptation, and substitution may be performed.	Some or even many critical resources are unavailable, potentially including hospital beds, ventilators, and medications. Critical resources are re-allocated to help as many patients as possible.
STAFF	Usual staffing. Hospital staff absenteeism is not a large problem.	Staff extension (increased patient/provider ratios, expanded scope of practice). Hospital staff absenteeism may be a problem.	Staffing levels at critical shortage. Staff are operating outside normal scope of practice and greatly increased patient/provider ratios. Hospital staff absenteeism may be greater than 30%.

Figure 3: Levels of care exist along a continuum as both demand for health care services and supply of resources changes over time.

Medical Surge Strategies

There are four core strategies to be employed (generally in order of preference) during or in anticipation of a scarce resource situation:

- Develop Care Capacity Develop extra supplies by stockpiling and developing supply chain
 resiliency. These activities should be conducted by facilities on a regular basis as part of their
 comprehensive emergency preparedness programs and executed in collaboration with other
 partners as part of regional health care coalitions. This can also include development of alternate
 resources, such as repurposing care spaces for surge conditions.
- Delay Care Delay care for less urgent conditions and focus on more emergent issues. For example, nurses or techs can cleanse and dress the wound and instruct the patient to return in 72 to 96 hours for suture closure.
- Degrade Care Early discharge of patients to lower levels of care to make space for new patients.
 Plan for alternate care sites. Expand the scope of practice for nurses through the use of standing orders. Reuse items after appropriate disinfection or sterilization. Substitute essentially equivalent device, drug, or personnel for one that is more available (e.g. morphine for fentanyl). Adapt equipment, drugs, or personnel that are not equivalent but can provide a similar level of care (e.g. anesthesia machine for mechanical ventilation). Conserve resources by using lower doses or changing utilization practices (e.g. minimizing use of oxygen-driven nebulizers).
- **Denial of Treatment** Reallocate resources to those patients with a better prognosis or greater need. Withdrawal of treatment.

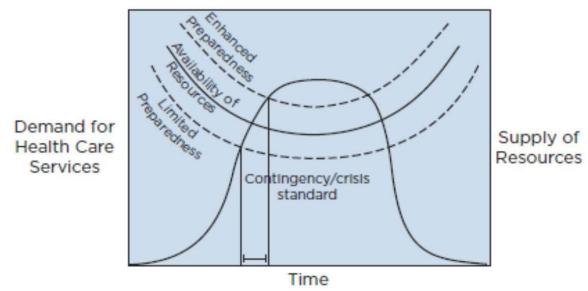


Figure 4: Through enhanced preparedness, we can practice conventional and contingency car for as much of the time that we are overwhelmed as possible, to minimize the amount of time that crisis standards of care would be required. Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response

Contingency Care Strategies

The goal of any hospital and health care system should be to remain in a state of contingency care for as long as is possible and to avoid initiating crisis standards of care. Examples of strategies that may be considered when conventional care is no longer sustainable and contingency care is needed include but are not limited to the following:

- Move Move appropriate patients from critical care units to "step-down" units and stable "step-down" patients to a general floor according to the facility's surge plans. Utilize a trained team of case managers and discharge planners with the treating physician to work with the house supervisors in determining where patients can be moved.
- **Early Discharge or Transfer** Early discharge or transfer of appropriate patients to alternative care sites, home or long-term care facilities with the necessary supports in place.
- **Expand** Expand patient care areas to include hospital corridors and hallways.
- **Rapid Admission Process** Use of a rapid admission process to move appropriate patients from the emergency department (ED) to hospital wards to make more room in the ED.
- Withholding of Treatment— More consistent withholding of care that is either futile (any care that is unlikely to be beneficial) or unnecessary (any care that has unproven benefit). This includes reducing the use of imaging and laboratory resources when reasonable.
- **Prioritize** Prioritize emergent procedures and surgeries and postpone or cancel non-emergent and elective procedures and surgeries.
- **Cohort Appointments** Use either a temporal strategy (sick visits at beginning or end of the day) or a different physical location for sick/well visits in the outpatient setting.
- **Leverage Technology** Expand usage of tele-medicine and online evaluations for both primary, specialty, urgent, and emergent care. This may allow for further triage and efficient provider usage during times of staff shortage while also decreasing exposure.
- Documentation Documentation should be increasingly focused on what is needed for patient care. Routine documentation practices (especially redundant documentation in multiple sites) may be minimized.
- Checklists Checklists or a "short form" medical record may be developed to speed the recording
 of critical information, including pertinent assessment, diagnosis and treatment information, and
 medications administered. Instead of performing and documenting routine assessments, consider
 only those assessments that are essential to monitor that patient's condition. Hard copy forms may
 be developed and available in case of loss of computer, printer, or internet capabilities.
- Expanded Staff Roles In the clinical setting, current available staff may become insufficient; shortages of specific types of practitioners may require expanding the roles of others. Move providers to areas needing additional resources, such as the emergency department and/or critical care areas. Expanded staff roles also should occur incrementally and only for as long as necessary. Those performing expanded roles should be under the supervision of an experienced, licensed MD or DO, APRN, RN or other person of appropriate discipline for the specific types of care, who delegates and directs a team of health care workers and oversees a patient caseload. Planning should incorporate volunteers who are part of the Medical Reserve Corps (MRC) system and other

- volunteers involved in organized efforts in the state. All staff should receive training and drill their expanded roles, if possible. Staff and volunteers should also receive just-in-time training as needed.
- Reduce Nursing Care Requirements Adjustments may need to be made in the frequency of assessments and routine care, e.g., a diabetic patient having four glucometer measurements each day may have them done twice a day, vital signs may be taken only twice a day for stable patients. If possible, rely on patient families for patient hygiene and feeding assistance if the conservation of staff resources would outweigh other risks. Specific treatments or interventions that are scheduled to be administered on a regular basis may have the interval between them extended. For example, if a patient is scheduled to have respiratory nebulizer treatments every six hours, the treatments may be reduced to every eight hours if tolerated. Some treatments or interventions may be discontinued completely if the potential harm to the patient is minimal, if there is an absolute lack of staff to perform the task or if no equipment is available. Decision-makers should strive to preserve equity between needs of patients.
- Modification of Consent/Refusal Process During a prolonged emergency situation, some of these
 requirements may need to be modified, or if there is not sufficient time to obtain the informed
 consent/refusal from a person authorized to make health care decisions for the patient, e.g. nextof-kin. Make certain that appropriate numbers of hard copies of these documents are available in
 case of computer or printer failure.
- Infection Control Standards Change infection control standards to permit group isolation for confirmed cases of COVID-19 or other communicable diseases rather than single person isolation units.
- **Family Support Center** Change privacy and confidentiality protection procedures temporarily to allow for the establishment and activation of a family support center. During a pandemic, visitation to the hospital may not be feasible or advised. The center will have the responsibility of confirming the identification of the relative, conducting updates and staging virtual visits if possible.
- Focus on Proven Medical Interventions Increased focus on proven medical interventions and therapies that provide significant benefit, while foregoing those interventions lacking clear evidence of benefit.
- Preserve oxygen capacity.
- **Communicate** with HAP regional emergency management representatives and other facilities both within the region and outside for assistance in accepting patients, as well as sharing staffing, pharmaceuticals and necessary equipment.
- Attempt to Comply with Regulatory Requirements While difficult, facilities may make every attempt to comply with regulatory requirements during a prolonged public health emergency. If it is not possible, the efforts should be documented, although documentation requirements may be waived in certain circumstances. When no longer able to comply, facilities should utilize the process for requesting emergency modifications and suspensions of regulatory requirements from both state and federal regulatory agencies including through coordination with the DOH, US Department of Health and Human Services, and Centers for Medicare and Medicaid services. (e.g., Health Insurance Portability and Accountability Act (HIPAA), provisions of the Emergency Medical Treatment and Labor Act (EMTALA), staffing ratios, scope of practice restrictions, 1135 waivers, etc.).

Crisis Care Strategies

Examples of strategies that may be considered when contingency care is no longer sustainable, include, but are not limited to:

- The contingency care strategies previously listed.
- Ensure facility security by restricting access to the facility to only one or two entrances.
- Other access points should be secured appropriately. Access to the emergency department should also be controlled and uniformed police presence should be in place, if at all possible.
- Create patient care areas in pre-designated locations, such as the hospital cafeteria(s), radiology suites, corridors, atrium, athletic centers or research buildings.
- Emergency Department access should be reserved for immediate-need patients; ambulatory patients
 may be diverted to other pre-designated ambulatory care settings, such as urgent cares and doctor's
 offices according to health care surge plans and 911 dispatch/EMS protocols.
- Create alternate care sites by requesting local, regional, state and/or federal response assets (such as Pennsylvania Surge Medical Assistance Teams, Disaster Medical Assistance Teams, Medical Reserve Corps) to be deployed. Other health care providers may also be utilized to assist in alternate care sites.
- More drastic changes to scope of practice may be needed, requiring health care staff to take on expanded roles, and function outside their specialties. These decisions should be made in conjunction with health care surge plans and appropriate licensing and regulatory authorities.
- More drastic reduction of nursing care requirements.
- Apply principles of accepted triage and graded scoring system to determine who should receive
 aggressive medical treatment and who should receive palliative care only. Under some
 circumstances, resource intensive interventions may be withheld.
- Providers should engage with their patients and/or their family members to understand personal
 preferences, including medical power of attorney and "do not resuscitate" orders, as well as
 religious preferences and access to clergy (as can be done safely).
- Credential providers on an emergency or temporary basis.
- Increased withholding of treatment and exclusive focus on medical interventions and therapies that have proven and significant benefit, while foregoing interventions and therapies that lack clear evidence of benefit or have high resource utilization.
- Documentation should be limited only to what is needed for patient care.
- Place limits on oxygen use, such as stopping hyperbaric treatments.
- Utilization of accepted triage guidelines and use of the Crisis Triage Officer or Committee.

Transferring Patients to Other Health care Facilities

In a pandemic situation, other local facilities will likely be in the same overloaded situation that your facility is facing, and they will rarely be able to accept transfers. Ambulance availability may also be impacted by the event.

In the normal course of care delivery, many hospitals do not regularly care for certain populations (burn or pediatric patients) and would normally transfer such patients out of their facility to a higher level of care. A disaster situation may necessitate keeping patients not normally cared for at a specific facility, despite the high level of stress this would place on any system. Planning for potential situations where providers would have to practice outside their normal scope and comfort area includes an assessment of hospital and staff capabilities and providing guidance for surge situations. Such guidance should include a robust plan of how, where and what a surge would entail, what would be expected of staff members as well as potentially augmenting their capabilities through "just in time" training assets.

Smaller Hospitals

Smaller hospitals, especially those in rural areas, are faced with limited resources and support from other agencies. Challenges include more distant local public health departments, limited technology, a greater reliance on volunteers, limited medical transport units and greater distances from tertiary care facilities. As a result, advance planning for medical surge and allocation of scarce resources is critical. Furthermore, these facilities should recognize and plan for their potential role in caring for populations they might not normally treat, such as pediatric, obstetric, or critical care patients.

A scalable plan, similar to what has been discussed in this document, should be developed to meet the needs of the individual facility. It is understood that most rural hospitals do not have the staffing capacity to fill all the positions suggested in the Hospital Incident Command System (HICS) plans or an Emergency Operations Center.

Therefore, it would be reasonable for hospital leadership to look to different health care resources in the community to fill those vacancies.

The hospital may look to private or retired health care providers (with notification well in advance of an event), such as local pediatricians or internal medicine physicians, to help guide decisions in their area of expertise. Community religious leaders might meet some of the needs normally falling to hospitalemployed ethicists and pastoral care. It will be up to each hospital's executive committee, as well as risk management, to determine the roles community resources could fulfill within their facility.

Furthermore, it will be advantageous for all hospitals to actively participate in Pennsylvania's established Regional Health care Coalitions. This will ensure consistent decision-making in all areas of the Region as well as decrease the burden of dual functioning roles on staff from the affected hospitals. This type of committee could consist of representation from area health care personnel, long-term care and pediatrics. Integration of facility plans into the regional emergency operations and response guidelines will occur during times of scarce medical resources.

The Hospital and Healthsystem Association of Pennsylvania works under contract from DOH to coordinate and oversee these regional coalitions. Figure 6 shows the health care coalitions across Pennsylvania.

Pennsylvania Regional Health Care Coalitions

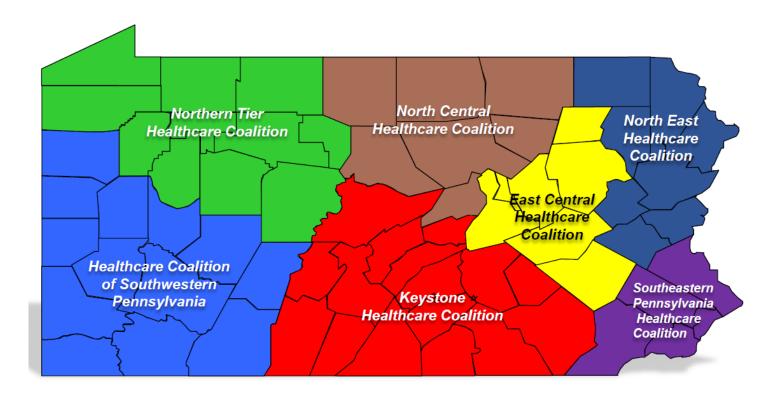


Figure 6: Pennsylvania Regional Health Care Coalitions

CRISIS TRIAG	E OFFICER TEAM
	Interim PA CSC for Pandemic - Version 2 P a g e 24

Crisis Triage Officer Team

In a catastrophe where crisis standards of care are needed, the focus of medical care may shift from the individual patient to promoting the thoughtful use of limited resources for the best possible health outcome of the population as a whole.

Because this change represents a significant paradigm shift in how we normally care for patients and prioritize treatments, it is important that **Crisis Triage Officers (CTOs)** be identified beforehand from among the facility's medical staff. These physicians should be familiar with the concepts of disaster operations specific to the incident, and should include trauma surgeons, intensive care physicians, emergency physicians, infectious disease and/or internists with extensive hospital experience. Whenever possible, CTOs should be identified ahead of time so that they can receive training in mass casualty triage, implicit bias, ethics, communications, incident management, and crisis resource management.

During an incident in which crisis standards are implemented, these CTOs should not be involved in the care of individual patients, but instead will be implementing the guidelines at the hospital level by making resource allocation decisions for individual patients. They will report to the Operations Section Chief, who is part of the Command Staff within the Hospital Incident Command System (HICS). Senior House Nursing Supervisors should also be identified to oversee the bed availability and patient placement and work closely with the Operations Section Chief and the CTOs.

Depending on the number of CTOs available, (which may be dependent on the size of the facility and scope of the incident) a CTO may be working independently, or preferably as a small group of 2-4, which will be termed the **Crisis Triage Officer Team (CTOT)**. When there are adequate personnel resources, additional members for this CTOT may include other physicians or nursing supervisors. For the purposes of this document, the CTO and CTOT can be used interchangeably as they represent the same role.

Each hospital must be prepared to receive patients from EMS as well as those that self-present, and match patients to their appropriate treatment according to need and likelihood of benefit. Initial treatment may include resuscitation, operative management, critical care, inpatient care, wound care, etc. This sorting will likely be best accomplished by an experienced team of providers, such as emergency physicians and nurses, and trauma or critical care physicians and advanced practice clinicians. The greater focus should be beyond merely categorizing patients based on acuity, and instead every attempt should be made to match patient need to available resources.

The CTO or CTOT will review all patients for whom those patients' individual providers (treating physicians) have requested a limited and critical resource (such as ICU admission, ventilator support, or surgical care). In addition, the CTO or CTOT will review patients currently receiving critical resources to assess ongoing need for and priority in receiving those resources.

The CTO has the ultimate responsibility and authority for making that decision. The CTO will communicate the triage decisions to the treating physician. When possible the triage officer and the treating physician should inform patients and family members of the triage decision.

The CTO process has three components:

- **1. Inclusion criteria:** These criteria attempt to identify patients who may be more likely to benefit from admission to critical care and primarily focuses on respiratory failure.
- 2. A patient evaluation tool
- 3. Criteria for withdrawal of critical care

Crisis Triage Officer Training

A successful CTO would need both clinical experience in fields such as emergency medicine, trauma surgery and critical care as well as advanced training in issues pertinent to crisis care situations, such as allocation of scarce resources, triage decision guidelines, ethics and legal issues.

PEMA and DOH have partnered with the Public Health Foundation to offer training for emergency response on the **Train PA** educational platform. Some of the current courses available include:

- COVID-19: Crisis Standards of Care Guidance for Health Care systems and Providers ID 1090855
- Disaster Triage for Epidemics ID 1012019
- Disaster Triage for Mass Causality Incidents ID 1012018
- Introduction to Triage and Public Health: Health care Response to Disaster (Podcast) ID 1012865
- PrepTalks: Triage, Ethics and Operations- health care Emergency Preparedness and Response ID 1081426
- Implicit Bias: The Influence of your Unconscious Mind ID 1085676
- Cultural Competency Curriculum for Disaster Preparedness and Crisis Response ID 1059113
- Personal Protective Equipment for COVID-19 ID 1090274

Train PA can be accessed via the following link: https://train.org/pa/

IMPLEMENTATION OF TRIAGE GUIDELI	NES

Implementation of Triage Guidelines

The heterogeneity of disasters dictates that while crisis standards of care provide guidance in allocation of limited resources, providers must have flexibility in their implementation. Physician judgement at individual facilities, coupled with incident-specific guidance from local and state health departments, will be necessary for effective implementation.

Pandemic Implementation – The following assumptions were made when the Pandemic Influenza Guidelines were developed:

- There are not enough beds to accommodate all patients needing hospital admission, and not enough ventilators to accommodate all patients with respiratory failure.
- There is a need for social distancing and patient isolation.
- Most patients can be treated at home.
- Comfort care should be provided outside of the hospital setting.
- Patients either require supportive care or ventilator assistance.

Therefore, the plan was designed to provide a framework to fairly allocate scarce medical resources.

Under the *Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines*, each facility should evaluate its resource availability and, in consultation with their local and state health departments, **consider** implementing criteria to restrict hospital admission. Use of a patient evaluation tool may be necessary to constrain admission/transfer to critical care units.

- Patients arriving at the hospital, by private means or EMS, should first be triaged using a START, SALT or JumpSTART triage system.
 - o Patients triaged as black or green should be placed in separate areas away from the main treatment area (either within the hospital or another location) for care.
 - o Red and yellow patients should receive initial stabilization.
- The Patient Evaluation Tool is to be used for patient evaluation.
- Taking into consideration the resources immediately available (ORs, surgical equipment, surgeons etc.), surgical patients should be re-triaged to determine priority for surgery.
- Patients determined to require post-operative ICU care should be triaged using the IPACSCPG and included in the ICU priority of admission list.
- Taking into consideration the resources immediately available (ICU beds, staffing ventilators, etc.), patients requiring ICU care should be re-triaged, using the IPACSCPG, to determine priority for admission to the ICU or other available beds.
- As stated in the Crisis Triage Officers section, the CTO process has three components:
 - o **Inclusion criteria**: These criteria attempt to identify patients who require critical arefor either ventilator or vasopressor support.
 - o **An evaluation tool**: The evaluation tool is a multi-principle rating that evaluates individual patients based on their likelihood of survival to hospital discharge with critical care (e.g., the sequential organ failure assessment score) and presence of advanced medical conditions that severely limit their near-term prognosis, as typically used in the Pandemic Influenza plans.
 - O Criteria for withdrawal of critical care

Adult Triage Guidelines (over age 14)

<u>Step 1: Determine if the Patient Meets Inclusion Criteria for Critical Care</u>: Patients being considered for critical care should have one of the following:

1. Requirement for invasive ventilatory support

- a. Refractory hypoxemia (Sp02 <90% on non-rebreather mask or FIO2 >0.85) or Respiratory acidosis (pH <7.2).
- b. Clinical evidence of impending respiratory failure.
- c. Inability to protect or maintain airway.

2. Hypotension* with clinical evidence of shock**

a. Refractory to volume resuscitation and requiring vasopressor or inotrope support that cannot be managed in a ward setting.

**Clinical Evidence of Shock = Altered level of consciousness, decreased urine output, or other evidence of end-stage organ failure.

SpO2/FIO2 ratio: SpO2 = Percent saturation of hemoglobin with oxygen as measured by a pulse oximeter and expressed as % (e.g., 95%); FIO2 = Fraction of inspired oxygen; e.g., ambient air is 0.21 Example: if SpO2=95% and FIO2=0.21, the SpO2/FIO2 ratio is calculated as 95/0.21=452

Step 2: Calculate the Patient's Evaluation Score Using the Patient Evaluation Tool

The scoring system applies to all patients presenting with critical illness, not simply those with the disease or disorders that arise from the public health emergency. For example, in the setting of a severe pandemic, those patients with respiratory failure from illnesses not caused by the pandemic illness will also be subject to the allocation framework.

Ethical goal of the allocation framework: Consistent with accepted standards during public health emergencies, a goal of the allocation framework is to achieve the most benefit for the entire populations of patients. It should be noted that this goal is different from the traditional focus of medical ethics, which is centered on promoting the wellbeing of individual patients. In addition, the framework is designed to achieve the following:

- To create meaningful access for all patients. All patients who are eligible for ICU services during ordinary circumstances remain eligible, and there are no exclusion criteria based on age, disabilities, or other factors.
- 2. To ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence.
- 3. To ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person's "worth" based on the presence or absence of disabilities or other factors.

No use of categorical exclusion criteria: The allocation framework described in this document differs in two important ways from other allocation frameworks. First, it does not categorically exclude any patients who, in usual circumstances, would be eligible for critical care resources. Instead, all patients are treated as eligible to receive critical care resources and are prioritized based on potential to benefit from those resources; the availability of critical care resources determines how many priority groups can

^{*}Hypotension = Systolic BP <90 mm Hg or relative hypotension

receive critical care. There are compelling reasons to not use exclusion criteria. Categorically excluding patients will make many feel that their lives are "not worth saving," leading to justified perceptions of discrimination. Moreover, categorical exclusions are too rigid to be used in a dynamic crisis, when ventilator shortages will likely surge and decline episodically during the pandemic. In addition, such exclusions violate a fundamental principle of public health ethics: use the means that are least restrictive to individual liberty to accomplish the public health goal. Categorical exclusions are not necessary because less restrictive approaches are feasible, such as allowing all patients to be eligible and giving priority to those most likely to benefit.

Second, within the context of keeping all patients eligible, the allocation framework also attempts to increase overall survival by giving some priority to patients who do not have a very limited near-term prognosis even if they survive the acute critical illness. There is precedent for using this criterion in allocation of scarce medical resources. The American Medical Association guidance on allocating scarce resources includes duration of benefit as a valid criterion. Frameworks for allocation of organs for transplantation, which is overseen by the U.S. Department of Health and Human Services, include near-term duration of benefit as a criterion (e.g., the Lung Allocation Score). The National Council on Disability's recent report on disabilities and organ transplantation did not recommend against using duration of benefit as a criterion. Extensive consultation with citizens, ethicists, and disaster medicine experts informed the principles and processes adopted in this document.

This allocation framework is based primarily on two considerations: 1) saving lives; and 2) saving lifeyears, both within the context of ensuring meaningful access for all patients and individualized patient assessments based on objective medical knowledge. Patients who are more likely to survive with intensive care are prioritized over patients who are less likely to survive with intensive care. Patients who do not have a severely limited near-term prognosis due to advanced underlying medical conditions are given priority over those who have such advanced conditions that they have a very limited near-term prognosis even if they survive the acute critical illness. As summarized in Table 1, the Sequential Organ Failure Assessment (SOFA) score (or an alternate, validated, objective measure of probability of survival to hospital discharge) is used to determine patients' prognoses for hospital survival. The presence of conditions in such an advanced state that they limit duration of benefit within one to five years of the acute illness is used to characterize patients' prognosis for near-term survival. Based on consultation with experts in disability rights and physical medicine and rehabilitation, we have intentionally not included a list of example conditions associated with life expectancy <1 year and <5 years. The rationale for this is that such lists run the risk of being applied as blanket judgments, rather than in the context of individualized assessments by clinicians, based on the best available objective medical evidence. For example, patients are assigned from 1 to 4 points according to the patient's total calculated SOFA score (range 0-24). They are assigned points for the presence of underlying conditions that limit near-term prognosis (2 points if life expectancy is predicted to be less than five years, 4 points for life expectancy less than one year). These points are then added together to produce a total raw priority score, which ranges from 1 to 8. Lower scores indicate higher likelihood to benefit from critical care; priority will be given to those with lower scores.

When evaluating patients against criteria such as the SOFA score or evaluating underlying conditions, care should be given by providers to ensure that certain underlying health conditions that do not have an impact on the immediate or near-term survivability of the patient should NOT be factored into the assessment. Clinicians have an obligation to follow all applicable anti-discrimination laws and regulations.

Table 1. Patient Evaluation Tool to Allocate Critical Care/Ventilators During a Public Health Emergency

Principle	Specification	Point System**			
		1	2	3	4
Save lives	Prognosis for short-term survival (SOFA score*)	SOFA score < 6	SOFA score 6-8	SOFA score 9-11	SOFA score ≥ 12
Save life- years	Prognosis for continued survival (medical assessment of underlying conditions that severely limit life expectancy)		Major underlying conditions that limit near-term prognosis; death likely within 5 years		Severely life- limiting conditions; death likely within 1 year

^{*}SOFA= Sequential Organ Failure Assessment, which is used as an example of how to integrate an objective measure of acute severity of illness.

Step 3: Assign patients to color-coded groups

Once a patient's evaluation score is calculated using the patient evaluation tool described in Table 1, each patient should be assigned to a color-coded triage group, which should be noted clearly on their chart/EHR (Table 2). This color-coded assignment of triage groups is designed to allow triage officers to create operationally clear groups to receive critical care resources. For example, individuals in the red group have the best chance to benefit from critical care interventions and should therefore receive priority over all other groups in the face of scarcity. The orange group has intermediate priority and should receive critical care resources if there are available resources after all patients in the red group have been allocated critical care resources. The yellow group has lowest priority and should receive critical care resources if there are available resources after all patients in the red and orange groups have been allocated critical care resources.

It is important to note that all patients will be *eligible* to receive critical care beds and services regardless of their priority score; there are no baseline exclusion criteria. The availability of critical care resources will determine how many eligible patients will receive critical care. Patients who are not able to receive critical care/ventilation will receive medical care that includes intensive symptom management and psychosocial support. They should be reassessed daily to determine if changes in resource availability or their clinical status warrant provision of critical care services. Where available, specialist palliative care teams will be available for consultation. Where palliative care specialists are not available, the treating clinical teams should provide primary palliative care.

^{**} Persons with the lowest cumulative score would be given the highest priority to receive mechanical ventilation and critical care services.

Table 2. Assigning Patients to Color-coded Groups

Level of Triage and Code Color	Evaluation score from Multi-principle Scoring System
RED Highest priority	Priority score 1-3
ORANGE Intermediate priority (reassess as needed)	Priority score 4-5
YELLOW Lowest priority (reassess as needed)	Priority score 6-8

Step 4: Make daily determination of how many groups can receive critical care resources

Hospital leaders and triage officers should make determinations twice daily, or more frequently if needed, about how many groups will have access to critical care services. These determinations should be based on real-time knowledge of the degree of scarcity of the critical care resources, as well as information about the predicted volume of new cases that will be presenting for care over the near-term (several days). For example, if there is clear evidence that there is imminent shortage of critical care resources (i.e, few ventilators available and large numbers of new patients daily), only patients in the highest group (Red group) should receive the scarce critical care resource. As scarcity subsides, more groups (e.g., first Orange group, then Yellow group) should have access to critical care interventions.

Other scoring considerations for adult patients:

- 1. Pregnancy. Pregnant patients will be assigned a priority score based on the same framework used for non-pregnant patients. If a pregnant patient at or beyond usual standards for fetal viability, the patient will be given a two-point reduction in their priority score (e.g., from a raw patient prioritization score of 5 to 3).
- 2. Giving heightened priority to those who are central to the public health and health care response. Individuals who are engaged in tasks that are vital to the public health and health care response, including all those whose work directly supports the provision of acute care to others, including those who provide wraparound supports to the provision of acute care to others, should be given heightened priority. Justifications for this prioritization include saving public health and health care responders so that they may help future patients, and to promote the effectiveness of their work by

signaling that certain protections are in place for the risks these workers take during the public health emergency. This can be operationalized by subtracting one point from the priority score of critical workers (e.g., from a raw patient prioritization score of 5 to 4). This category should be broadly construed to include those individuals who play a critical role in the chain of treating patients and maintaining societal order. Importantly, it would not be appropriate to prioritize front-line physicians and not prioritize other front-line clinicians (e.g. paramedics, nurses and respiratory therapists) and other key personnel (e.g., the maintenance staff that disinfects hospital rooms, infection preventionists).

3. Categorical exclusion criteria: A central feature of this allocation framework is that it avoids the use of categorical exclusion criteria to indicate individuals who should not have access to critical care services under any circumstances during a public health emergency. In a public health emergency, public trust will be essential to ensure compliance with restrictive measures. Thus, an allocation system should make clear that all individuals are "worth saving." We strive to accomplish this by keeping all patients who would receive mechanical ventilation during routine clinical circumstances eligible and allowing the availability of ventilators to determine how many eligible patients receive it. It should be noted that there are some conditions that lead to immediate or near-immediate death despite aggressive therapy such that during routine clinical circumstances clinicians do not provide critical care services (e.g., cardiac arrest unresponsive to appropriate ACLS, overwhelming traumatic injuries, massive intracranial bleeds, intractable shock). During a public health emergency, clinicians should still make clinical judgments about the appropriateness of critical care using the same criteria they use during normal clinical practice.

It is accepted that this IPACSCPG Patient Prioritization Tool is not perfect. It is hoped that it fosters both dialogue and further research to develop and validate objective resource allocation tools in the future. However, should a massive disaster occur today, the members of this committee believe clinicians can be assured using this matrix, as it was developed and approved by knowledgeable clinicians and ethicists with extensive experience in public health emergencies.

4. Resolving "ties" in priority scores between patients

In the event that there are 'ties' in priority scores between patients and not enough critical care resources for all patients within the prioritized group, life-cycle considerations should be used as the first tiebreaker, with priority going to younger patients. We recommend the following categories, which roughly correspond to major life stages (age 12-40, age 41-60; age 61-75; older than age 75). The ethical justification for using the lifecycle principle as a tiebreaker is that it is a valuable goal to give individuals equal opportunity to pass through the stages of life—childhood, young adulthood, middle age, and old age. The justification for this principle does not rely on considerations of one's intrinsic worth or social utility. Rather, younger individuals receive priority because they have had the least opportunity to live through life's stages. Empirical data suggest that, when individuals are asked to consider situations of absolute scarcity of life sustaining resources, most believe younger patients should be prioritized over older ones. Public engagement about allocation of critical care resources during an emergency also supports the use of the lifecycle principle for allocation decisions. The moral argument in favor of life-cycle—based allocation is as follows: "It is always a misfortune to die . . . it is both a misfortune and a tragedy [for life] to be cut off prematurely."

If there are still ties after using the tiebreaker based on life cycle considerations, the raw score on the patient prioritization score should be used as a tiebreaker, with priority going to the patient with the lower raw score (e.g. a patient with a raw prioritization score of 1 should receive priority over a patient with a score of 3).

If there are still ties after these two tiebreakers are applied, a lottery (i.e., random allocation) should be used to break the ties.

Criteria for Patient Assessment and Withdrawal of Critical Care

The purpose of this section is to describe the process the triage committee should use to conduct reassessments on patients who are receiving critical care services, in order to determine whether he/she continues with the treatment.

Ethical goal of reassessments of patients who are receiving critical care services

The ethical justification for such reassessment is that, in a public health emergency when there are not enough critical care resources for all, the goal of supporting population outcomes would be jeopardized if patients who were determined to be unlikely to survive were allowed indefinite use of scarce critical care services. In addition, periodic reassessments lessen the chance that arbitrary considerations, such as when an individual develops critical illness, unduly affect patients' access to treatment.

Approach to reassessment

All patients who are allocated critical care services will be allowed a therapeutic trial of a duration to be determined by the clinical characteristics of the disease. The decision about trial duration will ideally be made as early in the public health emergency as possible, when data becomes available about the natural history of the disease. The trial duration should be modified as appropriate if subsequent data emerges which suggests the trial duration should be longer or shorter. Evaluation of patients undergoing critical care/ventilation for other medical conditions may also need to be reassessed at appropriate durations. However, patients who are utilizing personal (supplied by the patient, not supplied by the hospital where they present for care) ventilators for pre-existing respiratory conditions, should NOT be separated from their personally provided equipment for reallocation to other patients.

The triage committee will conduct periodic reassessments of all patients receiving critical care/ventilation. These assessments will involve re-calculating SOFA scores, or other mortality predictive tool used, and consulting with the treating clinical team regarding the patient's clinical trajectory. The assessments will necessarily involve the exercise of clinical judgment. Patients showing improvement will continue with critical care/ventilation until the next assessment. If there are patients in the queue for critical care services, then patients who upon reassessment show substantial clinical deterioration as evidenced by worsening SOFA scores or overall clinical judgment should not receive ongoing critical care/ventilation. Although patients should generally be given the full duration of a trial, if patients experience a precipitous decline or a highly morbid complication which portends a very poor prognosis (e.g., refractory shock and DIC, massive stroke) the triage team may make a decision before the completion of the specified trial length that the patient is no longer eligible for critical care treatment.

Patients who are no longer eligible for critical care treatment should receive medical care including intensive symptom management and psychosocial support. Where available, specialist palliative care teams will be available for consultation.

Patient Evaluation Model

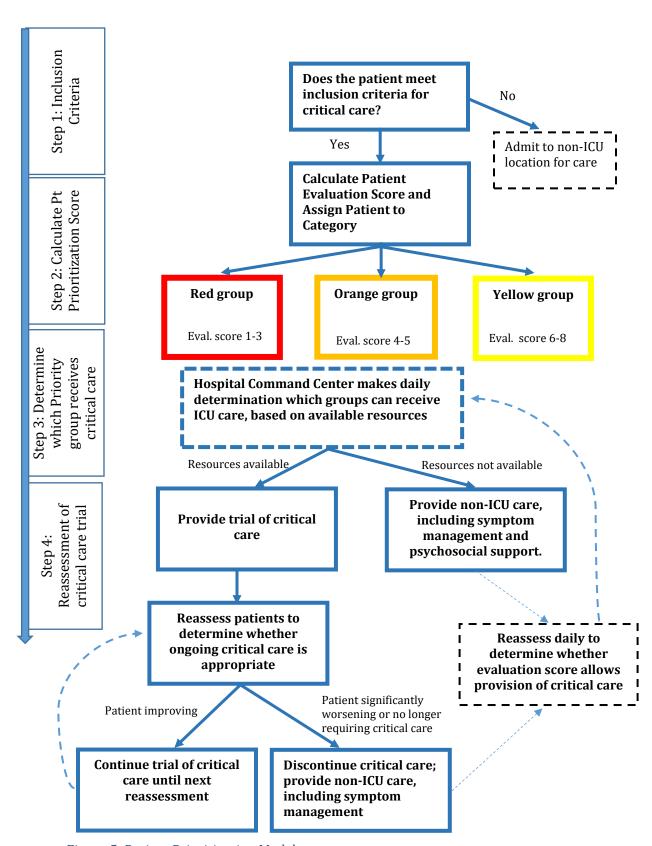


Figure 5: Patient Prioritization Model

Pediatric Triage Guidelines (Patients age 14 or younger)

Inclusion criteria for pediatric patients differ in important ways from the adult criteria and are listed below. Although the content of the patient evaluation tool is different from that for adults, the steps of the process are the same as described above for adults. Below are noted several important differences, including the content of the patient evaluation tool.

Inclusion Criteria

Applies to all patients except those infants not yet discharged from the NICU.

Patients must have at least one of the following Inclusion Criteria:

1. Requirement for invasive ventilatory support

- a. Refractory hypoxemia (Sp02 <90% on non-rebreather mask or FIO2 >0.85)
- b. Respiratory acidosis (pH <7.2).
- c. Clinical evidence of impending respiratory failure.
- d. Inability to protect or maintain airway.

2. Hypotension* with clinical evidence of shock**

Refractory to volume resuscitation and requiring vasopressor or inotrope support that cannot be managed in a ward setting.

Table 3. Patient Evaluation Tool to Allocate Critical Care/Ventilators During a Public Health Emergency

Principle	Specification	Point System*			
		1	2	3	4
Save lives	Prognosis for short- term survival (PELOD-2 score)	PELOD-2 score < 12	PELOD-2 score 12- 13	PELOD-2 score 14- 16	PELOD-2 score ≥ 17
Save life- years	Prognosis for continued survival (medical assessment of underlying conditions that severely limit nearterm life expectancy)		Major underlying conditions that limit near term prognosis; death likely within 5 years		Severely life- limiting conditions; death likely within 1 year

PELOD= Pediatric logistic organ dysfunction

^{*}Hypotension = Systolic BP: Patients age >10 = < 90 mm Hg; Patients ages 1 to 10 = < 70 + (2 x age in years); Infants < 1 year old = <60; Relative hypotension

^{**}Clinical Evidence of Shock = Altered level of consciousness, decreased urine output, or other evidence of end-stage organ failure.

^{*} Persons with the lowest cumulative score would be given the highest priority to receive mechanical ventilation and critical care services.

Other scoring considerations for pediatric patients:

Newborns with low survivability (< 20%) even after lengthy critical care stays (e.g. extreme preterm infants with very low birth weights) may undergo routine Neonatal Resuscitation Program (NRP); however, in the event of scarcity of NICU beds, these newborns would not be candidates for continued aggressive resuscitation and ICU support, to include prolonged intubation and ventilator support.

The use of ECMO will be decided on an individual basis by the Crisis Triage Officer (with input from the attending physician, and ECMO Medical Directors) based on prognosis, suspected duration of ECMO run, and availability of personnel and other resources. Patients should have an estimated survival of >70% with an estimated ECMO run of <7-10 days.

<u>Criteria for Patient Evaluation and Withdrawal of Critical Care</u>

There is a relative paucity of empirical research on strategies to identify, in real-time, pediatric patients who are unlikely to benefit from ongoing ICU treatment. Therefore, use of serial PELOD-2 scores for this purpose should be used with caution. The assessments will necessarily involve the exercise of clinical judgment. Patients showing improvement will continue with critical care/ventilation until the next assessment. If there are patients in the queue for critical care services, then patients who upon reassessment show substantial clinical deterioration as evidenced by high and significantly worsening PELOD-2 scores and overall clinical judgment should not receive ongoing critical care/ventilation. Although patients should generally be given the full duration of a trial, if patients experience a precipitous decline or a highly morbid complication which portends a very poor prognosis (e.g., refractory shock and DIC, massive intracerebral bleed) the triage team may make a decision before the completion of the specified trial length that the patient is no longer eligible for critical care treatment. If possible, such decisions should be made in consultation with a pediatric critical care expert.

TERMINATION O	F CRISIS STAN	NDARDS OF CAR	E

Termination of Crisis Standards of Care

As the severity of an event subsides, the scarcity of certain resources may be resolved at different times (e.g. critical care beds may be available, but ventilators may remain scarce). Each institution should apply the hospital triage plan based on the availability (or lack thereof) of resources during daily assessments. When resources are no longer scarce, termination of crisis standards of care should occur, and the department should be notified by the institution. Facilities should strive to return to Contingency or Conventional standards of care as quickly as possible.

COMMUNITY PARTNER	S IN THE CRISIS S GUIDELINES	TANDARDS OF CARE

Community Partners in the Crisis Standards of Care Guidelines:

Roles and Obligations

Every individual, institution, and business within the Commonwealth of Pennsylvania has a role in supporting our resiliency.

Pennsylvania Residents

Individuals must maximize their own preparedness to the best of their ability and means. We need to let our residents know that our medical care system may be unable to take care of every need in a timely fashion. People may need to take care of their own families and neighbors to the best of their abilities. Resident preparedness cannot stop at just having a "72-hour kit", but should include CERT (Citizens Emergency Response Training) education and enough first aid training that some individuals in the community could care for minor injuries themselves. Individuals going to a hospital for treatment should be prepared for extended wait times and differing levels of care from what they are used to receiving on a normal day.

Communities

County and local emergency management agencies as well as local health jurisdictions are responsible for developing and implementing community preparedness programs that include methods of ensuring care for vulnerable and special needs populations. Some of the methods available for this include **211** referrals, Special Needs Registries (available through local emergency management) and local church preparedness organizations.

Casualty Collection Points, such as fire stations, points of dispensing (PODS), or CERT Gathering Points, need to be pre-determined and planned by emergency management and public health partners so that communities and EMS agencies are familiar with their locations. Field triage can then be conducted there, and the patients allocated and transported as appropriate, thereby reducing strain on overwhelmed EMS agencies and hospitals.

Ambulatory Health care Services

Outpatient health care entities should have plans to continue to see patients and thus reduce the demand for care at hospitals. This should include private physicians, clinics, urgent care centers and pharmacies. Each entity should take the opportunity to become better trained in disaster life support methods and determine what their role will be in a disaster situation and educate their personnel.

Making these decisions in advance is essential, as history has shown that medical professionals without a distinct plan and role to play are less effective participants as they could be. Just as homes should have 72-hour kits, it is essential for ambulatory health care services to be prepared with education, additional medical supplies and food and water support for their employees.

Pharmacies

As a community partner, pharmacies could take a significant patient load from hospital emergency

departments by being willing and able to work with patients who have lost or run out of prescriptions for chronic conditions. Act 8 of 2018, Emergency Prescription Refill Bill allows:

 Pharmacists are permitted to dispense up to 30 days emergency supply with certain conditions, such as drug not available in 72-hour supply, not a controlled substance, and essential to maintain life.

Public Health and Government

Public health emergency preparedness planning can foster efforts to eliminate scarcity through the implementation of consistent and coordinated plans to share, stockpile, and estimate needed resources in advance of a predictable public health emergency scenario. Additional strategies may include sharing resources with other entities and possibly transferring patients to other settings that will have access to adequate resources.

Planners should anticipate, to the degree possible, the types of health care needs and resource shortfalls that will occur and identify policy and operational adjustments that will be needed in response.

- Assess regional and state surge capacity (beds, ventilators, etc.) to meet expected needs.
- Create procedures and policies for use of supplemental providers.
- Ensure policies are in place to test and manage deployment of nonhospital personnel at both the community and hospital levels.
- Ensure that a plan for managing volunteers is in place.
- Develop communication process so the community understands the rationale behind resource allocation policies.
- Stockpile supplies and equipment including personal protective equipment (PPE) (e.g., gloves, masks).
- Estimate increased need for medical equipment/supplies and develop strategy to acquire additional equipment/supplies if needed. Consider asking for access to the Strategic National Stockpile (SNS).
- Develop health care risk communication messages, including criteria for seeking health care, such as postponement of elective procedures or surgeries.
- Coordinate with state and federal partners, including surrounding states

Hospitals

All hospitals and acute care facilities are required by law to have emergency preparedness plans. These plans currently detail medical surge, evacuation, isolation and other plans specific to each facility's Hazard Vulnerability Assessment (HVA). Hospitals must consider the following as part of their catastrophic planning:

<u>Hospital Command Center</u> – In addition to activation of the Hospital Incident Command System and Emergency Operations Center for overall coordination of response activity, hospitals should consider additional tasks that will likely arise, including (but not limited to):

- Develop a well-trained group of case managers or discharge planners to assist in determining **patient movement** and arranging those moves.
- Activate a Family Support/Assistance Center because the hospital may find itself with multiple unaccompanied/unidentified minors and or adults unable to communicate. It should help with:
 - o Identifying and reunifying these patients with loved ones;
 - Coordinate with the American Red Cross for potential family care and crisis intervention support;
 - Coordinate with partners to provide assistance and education in multiple languages and in ways to meet the needs of those with functional or access needs;
 - Coordinate assistance for families that may have been made homeless during a disaster, as families without a home to go to may use the hospital as a sheltering facility; and
 - o Provide or refer to services to address emotional and logistical needs that families may face.
- Develop health care risk communication messages, including criteria for seeking health care, such
 as postponement of elective procedures or surgeries. Hospital administration should work with the
 facility's Public Information Officer (PIO), The Hospital and Healthsystem Association of
 Pennsylvania's PIO and local/state health department to create messaging.
- Each facility must determine where patients receiving **comfort care** will be housed and supported and should institute a team to provide counseling and care coordination as well as work with the families of loved ones who have been denied life-sustaining treatment.
- Plan to provide **psychological and emotional peer support** and expert consultation to medical staff making triage decisions.
- Develop facility access guidelines:
 - Define essential and non-essential visitors and develop policies for restricting visitors during a pandemic or other crisis, and mechanisms for enforcing the policies.
 - Plan to limit hospital entry to a few key entrances.
 - Plan for increased security needs.
- **Personnel Issues** Institutions should increase the "supply" of human resources if possible. SERV-PA is a registry for Pennsylvania's medical and non-medical volunteers.
 - For technical support, the SERV-PA support center can be reached at: 1-877-771-0911
- Develop a plan to expand staff capacity and meet staffing needs.
 - o Granting privileges to volunteer, licensed, independent practitioners.
 - Documents required for granting temporary privileges.
 - Requirements for oversight of medical volunteers.
 - Utilization of members of the Medical Reserve Corps (MRC) and/or DMATs.
 - Confirmation of documentation/primary source verification.
 - Use of health care profession students.

- Prospectively training individuals whose normal roles will be less urgently required during a mass casualty or disaster event to work in areas of likely shortfall.
- Develop a plan to ensure that the environment of each facility be as safe as possible by instituting
 infection prevention and control measures as dictated by the circumstances, by working with staff
 to create policies that promote staff safety, and by educating staff as to these protections and
 policies in advance of an emergency.
 - Staff safety begins with staff planning for their families. Facilities should work with their staff to
 ensure that their families are prepared for a prolonged public health emergency, and all staff
 should be assisted in developing family emergency plans.
 - Facilities should develop and implement policies to protect their staff. For example, facilities
 may stockpile personal protective equipment (PPE) and other infection control modalities, and
 fit and train staff to use the equipment when performing aerosol generating procedures,
 cardiopulmonary resuscitation, etc.
 - Facilities may also have a supply of antiviral medication for staff who have inadvertent exposure
 to patients with latent or active disease, and staff should understand the limitations of such
 medications. Staff should understand the likelihood and timeframe for securing vaccines,
 antivirals and other therapeutics, their limitations, and the established priorities for their
 administration.
 - Policies should be developed that address workplace absences during prolonged public health emergencies to care for sick family members, including leave policies and policies for payment of salaries.
 - Facilities may consider providing care for both well and sick family members at the facility or at alternative care sites, and may plan for transportation, housing, and dietary issues that will emerge as supporting infrastructures break down.
 - Facilities should encourage sick employees to stay home and implement procedures that enable well employees who are not physically needed at the facility to work from home.
 - o All employees should have advance knowledge of the options that will be available to them.
- Develop plans to support staff families to ensure their willingness to come to work.
- Develop contingency plans for staff absences.
- Create procedures and policies for use of supplemental providers such as staffing agencies or Medical Reserve Corps personnel.
- Ensure policies are in place to test and manage deployment of nonhospital personnel at both the community and hospital levels.
- Develop a plan for managing volunteers.
- Initiate discussions of allocation of hospital resources. Hospital administrators should meet with the hospital ethics committee early in the planning process to establish a hospital process for scarce resource allocation that is consistent with the guidelines in this document.

<u>Training</u> - Adopting altered standards of care, even temporarily, will have a significant impact on health care delivery operations and therefore on the needs of providers for training and education to serve in

those circumstances. Hospitals should not assume that individual providers will know how to deliver appropriate care in a mass casualty event, but rather should develop or identify training programs to ensure a knowledgeable and systematic, coordinated response effort. Hospitals could even consider including requirements for physician disaster training in the granting of privileges. A wide array of preparedness training has been designed and is being delivered throughout the country. A beginning list of the types of training available includes but is not limited to the following:

- General disaster response, including an introduction to altered standards of care and how the move to such standards may affect triage and treatment decisions as well as facility conditions.
- Legal and ethical basis for allocating scarce resources in a mass casualty event.
- How to treat populations with special needs (e.g., children and elderly persons).
- How to recognize the signs and symptoms of specific hazards and a trend of similar types of signs and symptoms.
- Implicit bias training.
- How to treat specific conditions.
- How to recognize and manage the effect of stress on caregivers, patients, and themselves, including the effects of compassion fatigue.

Specific training regarding triage and being responsible for allocation or denial of scarce resources must be provided to ED physicians, intensivists and surgeons who might have to serve as Crisis Triage Officer or as the Medical Subject Expert in the Hospital Incident Command Structure.

While all physicians should participate in facility disaster response drills and respond to actual incidents, several physicians should be identified to fill the Crisis Triage Officer role discussed previously. Hospitals should also determine a chain of command within the hospital staff to determine who will participate in the Incident Command Structure and to prevent conflicts over who has medical command.

Training and other resource can be found in the following resources:

- ASPR TRACIE https://asprtracie.hhs.org
- PA TRAIN https://www.train.org/pa/

<u>Supply Chain Issues</u>- Health care organizations and providers should take proactive steps to use resources carefully if demand is expected to surge and/or resource shortages are anticipated. "Just in time" restocking practices have led to diminished stockpiles of supplies and can lead to severe shortages of medical supplies and pharmaceuticals, especially if community infrastructure is compromised.

Pre-event planning for these types of shortages should include implementation of a <u>PACE</u> plan for all supplies: <u>Primary Supplier</u>, <u>Alternate Supplier</u>, <u>Contingency Supplier</u> and <u>Emergency Supplier</u>.

- Stockpile supplies and equipment including PPE equipment (e.g., gloves, masks) in-house.
- Estimate increased need for medical equipment/supplies and develop strategy to acquire additional equipment/supplies if needed. Consult with local and state health departments about access to the Strategic National Stockpile (SNS).

<u>Ethics Policies</u> - All policies or crisis standards should be applied fairly and justly and implemented incrementally according to the severity and duration of the event. Educational initiatives such as disaster drills and public and provider education should be included in planning.

Professional ethics for clinicians generally discourage or prohibit practice outside the scope of one's expertise. Similarly, legal and ethical standards often prohibit laypersons from providing health services. However, during conditions of extreme scarcity of trained personnel, standards of competence may be justifiably lower than during normal conditions. For instance, employing a clinician who normally works in a specialty to instead work in primary care, or providing community volunteers with focused training to administer vaccinations could expand capacity and alleviate some of the scarcity of personnel. When the hospital can no longer meet the increased demand for patient care services using existing health care practitioners, each hospital should determine a tiered staffing model appropriate for their facility.

<u>Comfort Care</u> - Comfort care is defined as care that helps or soothes a person who is dying. The goal is to prevent or relieve suffering as much as possible. Comfort care resources should be provided consistently throughout a public health emergency. Access to comfort care resources and services should be provided to all patients not receiving more aggressive care based on allocation decisions. It is essential that each hospital develop the capacity to provide comfort care in-house, to potentially significant numbers of patients.

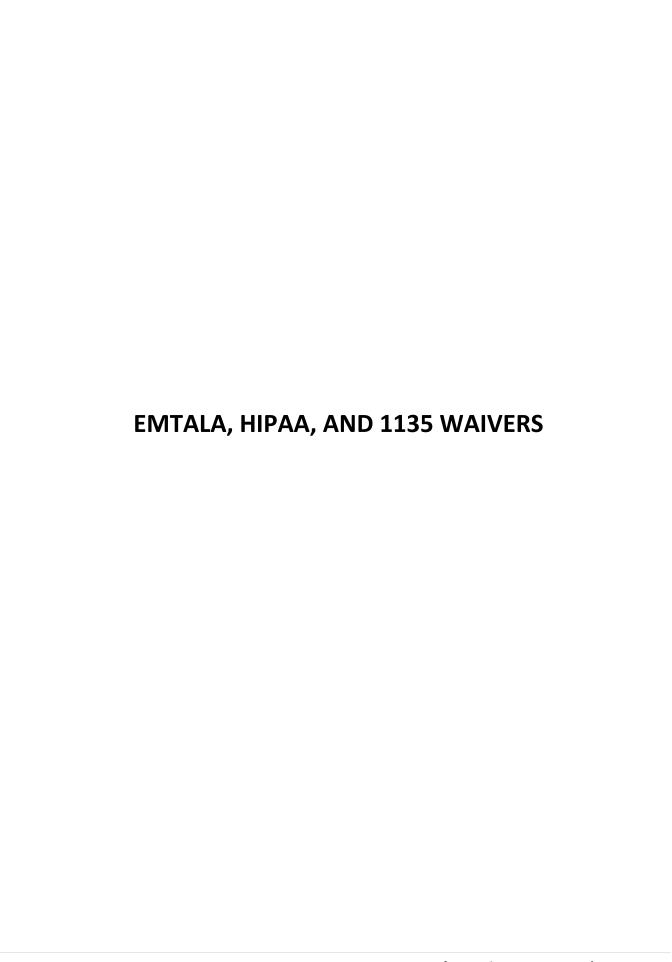
<u>Palliative</u> care is defined as relieving suffering and improving the quality of life for people of any age and at any stage in a serious illness, whether that illness is curable, chronic or life threatening.

<u>Hospice</u> is a specific type of palliative care for people who likely have six months or less to live. Hospice is simply a type of care that focuses on the current quality of life instead of continuing with treatments to prolong life. The vast majority of hospice or comfort care in Pennsylvania is provided in a home health care model. On any given day, home health and hospice providers are caring for 20,000-25,000 patients throughout the state. During a pandemic, home health agencies may have to work with their peers and local long-term care facilities to divide the care of their patients into accessible areas. It is strongly recommended that home health and hospice agencies work with the Regional Health care Coalitions and DOH in the development of medical shelters where patients could be congregated for care.

Mental Health Support Services - Hospitals implementing crisis standards of care into their response should be aware of the possible mental and emotional toll such decisions will have on providers, patients, and their families. Facilities should be prepared to ensure that appropriate staff and resources are in place to support these needs and can be rapidly activated and engaged to support the many diverse needs during a time of crisis. Providers and staff should also be encouraged to contact their Employee Assistance Program (EAP) which offers counseling, referrals, and assistance for personal and/or work-related problems to help support their emotional well-being. Additionally, the National Crisis Distress Hotline can be contact by calling 1-800-985-5990 or by texting "talkwithus" to 66746.

<u>Appeals and Oversight</u> – Even the proper execution of crisis standards of care and triage principals may cause discomfort or even anger from families or caregivers of patients. The improper execution of these standards would constitute a serious breach of conduct by the providers. In either regard, patients, family members, or caregivers who have concerns should be referred to the facility's Patient Rights and

Responsibilities procedures for concerns or complaints. This process typically involves a notification procedure for contacting the hospital department that support patients (e.g., patient relations, service excellence coordinators, patient advocacy, etc.) Unresolved complaints can be filed with the department by calling 1-800-254-5164.						



Emergency Medical Treatment and Labor Act (EMTALA) Factsheet

Reprinted with permission from the Assistant Secretary for Preparedness and Response (ASPR) Technical Resources Assistance Center and Information Exchange (TRACIE).

EMTALA and Disasters

Updated May 7, 2018

Originally Published: January 2018

This fact sheet addresses several frequently asked questions regarding the Emergency Medical Treatment and Labor Act (EMTALA) and disasters, and provides links to resources for more information. It is not intended to be used as regulatory guidance or in place of communications with or guidance from the Centers for Medicare & Medicaid Services (CMS) who oversee EMTALA compliance.

What is "EMTALA?"

EMTALA is a federal law that requires all Medicare-participating hospitals with emergency departments (ED) to perform the following for all individuals that come to the ED regardless of the individual's ability to pay:

- An appropriate medical screening exam (MSE) to determine if the individual has an emergency medical condition (EMC). If there is no EMC, the hospital's EMTALA obligation ends.
- · If there is an EMC, the hospital must:
 - Treat and stabilize the EMC within its capability (including admission) OR
 - Appropriately transfer the individual to a hospital that has the capability and capacity to stabilize the EMC if the presenting hospital is unable to do so. Outside of a mass casualty, transfers prior to stabilization are generally only "appropriate" if the transfer is requested in writing by the patient after being informed of the hospital's obligations and the risks of transfer, or a physician or qualified medical person in consultation with a physician, certifies that the benefits of transfer outweigh the risks. (Updated May 7, 2018)

Response modified from EMTALA & Surges in Demand for Emergency Department Services During a Pandemic

Can EMTALA be Waived in an Emergency or Disaster?

Under certain circumstances, sanctions for violations of EMTALA obligations may be waived for a hospital. The EMTALA MSE and stabilization sanctions can be waived under the following circumstances:

- The President declares an emergency or disaster under the Stafford Act or the National Emergencies Act; AND
- The Secretary of Health and Human Services declares that a Public Health Emergency (PHE)
 exists and also authorizes EMTALA waivers under section 1135 of the Social Security Act. Notice
 of EMTALA waivers will be provided through CMS to covered entities; <u>AND</u>
- 3) Unless EMTALA waivers are granted for an entire geographic area, the hospital applies for a waiver; <u>AND</u>
- 4) The hospital must have activated its emergency operations plan; AND
- The State must have activated its emergency operations plan or pandemic plan for an area that covers the affected hospital.



The waiver generally lasts for 72 hours after the emergency is declared and the facility's emergency plan is activated (in case of a pandemic the waiver will last until the termination of the PHE declaration). Even in the case of a waiver, however, the hospital is still responsible for ensuring the safety of the patients in its care.

Local or state declarations or waivers cannot alter, waive, or otherwise address EMTALA, as EMTALA is a federal law.

Response modified from EMTALA & Surges in Demand for Emergency Department Services During a Pandemic and CMS Public Health Emergency Declaration Questions and Answers

Can EMTALA be Waived Retroactively?

An EMTALA waiver can be applied back to the effective date of the emergency period AND activation of the hospital emergency operations plan. The emergency period begins on the date in which there are both a disaster or emergency declaration by the President and a PHE declaration by the HHS Secretary for the event. A waiver cannot be applied before the effective date of the emergency period.

For example, if a precipitating event occurs on a Saturday at noon, the hospital activates its emergency plan immediately following the event, a presidential declaration is made, effective Sunday at noon, and a public health emergency is declared and 1135 waiver authority invoked, effective Monday at noon, the EMTALA waiver could not be effective any earlier than Monday at noon. Please note that this is an extreme example to demonstrate the hierarchy of the declaration process. Generally, FEMA and HHS work together to ensure the effective dates of declarations are issued to provide the regulatory relief and aid necessary to support the response and the presidential declarations, PHE declarations, and 1135 waiver authorization can be issued and dated retroactively, as has been done numerous times during past responses.

Response modified from EMTALA & Surges in Demand for Emergency Department Services During a Pandemic

How Can Hospitals Comply with EMTALA in a Disaster or Emergency?

EMTALA was enacted to ensure the safety of all patients seeking care in EDs, therefore in disaster, mass casualty, or emergency situations, EMTALA provisions must be followed. In these cases, hospitals remain responsible for MSE examinations, which can be conducted by licensed health professionals including physicians, nurse practitioners, physician assistants, and nurses trained to conduct such exams. The MSE can be adjusted for the appropriateness of the event and for the presenting signs and symptoms, (e.g. assessing a group of people for high acuity injury or illness by visual exam and group questions by exclusion). After an MSE is conducted and documented to the best of the clinician's ability, under the circumstances, the patients can be transferred or referred to other hospitals that are less affected by the event/volume of patients in accordance with the hospital's emergency/community response plan. For tips for managing an influx of patients in a mass casualty, review the ASPR TRACIE tip sheet, No Notice Incidents: Hospital Triage, Intake, and Throughput.



What Strategies Can Hospitals Use to Manage Surge and Comply with EMTALA?

Hospitals may set up alternative screening sites on campus for emergencies such as pandemics or other events where an alternative area is appropriate.

Hospitals, working with their local emergency medical service (EMS) providers, can determine diversion criteria and protocols to limit the amount of patients arriving by EMS. Hospitals can also work with their local healthcare coalitions and emergency management agencies to develop emergency department saturation plans, public communication campaigns, and other appropriate measures to help evenly disperse patient load. Communities may also opt to establish alternate care sites not affiliated with any particular hospital or located on the grounds of any licensed facility. In this case/within these sites, EMTALA would not apply.

Most importantly, regardless of EMS diversion or plans in the community to direct patients to specific facilities, once a patient arrives at an ED, EMTALA applies. For example, a patient suspected of having a highly infectious disease that requires stabilization cannot be transferred to another facility without an MSE and any necessary stabilization or treatment.

NOTE: ASPR TRACIE has received inquiries regarding a specific scenario and recommended strategies to address surge under those specific circumstances:

In the event that an incident with the potential to massively overwhelm available resources occurs within close proximity to a hospital, the hospital may quickly become overwhelmed yet patients may continue to present to the hospital outside of EMS (e.g., walk-ins and in personally owned vehicles, police vehicles) and can't be diverted.

Question: Under this scenario, how can a hospital comply with EMTALA, while also ensuring patients receive care as quickly as possible, which may involve transfer to another facility?

Answer: A hospital can consider coordinating triage and redistribution of patients in partnership with EMS and other local hospitals. Triage can be established inside or outside the hospital. A qualified healthcare provider from the affected hospital can conduct an MSE as described above. Once triaged/evaluated, these patients can either be sent inside the affected hospital or appropriately redistributed to other receiving facilities that have agreed to accept patients through EMS, medical command, or other coordinating entities, based upon the number of patients and severity of injury.

For example, if it had been determined through pre-existing plans and planning or other real-time means (e.g., by onsite EMS, dispatch, a healthcare coalition, or other process specific to the affected jurisdiction) that local hospitals A, B, and C can accept 50 critical, 100 immediate, and 300 walking wounded, onsite EMS and the hospital-based qualified healthcare provider(s) could complete the MSE and redirect and coordinate transfer of those patients without having to speak (clinician to clinician) directly to the receiving hospitals for each individual patient.

In addition, for those providers affected by the CMS Emergency Preparedness Final Rule, these specific issues should be considered in the development of a facility's risk assessment and overall emergency preparedness program. MSEs can occur based on numerous hazards to include flooding and active shooter incidents, therefore it is encouraged that facilities document their policies and procedures for transfer situations. (Updated May 7, 2018)



Response modified from EMTALA & Surges in Demand for Emergency Department Services During a Pandemic, EMTALA Questions and Answers, and EMTALA Requirements and Implications Related to Ebola Virus Disease

Are there Additional Actions that Can be Taken to Address Patient Surge without an EMTALA Waiver? (Updated May 7, 2018)

CMS has provided considerable information on ways to increase inpatient and outpatient capacity without the need for 1135 waivers. Inpatient surge activities include early discharge planning, opening already certified beds or units, and the use of remote locations. Outpatient surge activities include the use of tents or mobile facilities located on/within the hospitals' campus as a temporary means of allowing for the management of outpatient surge. These temporary facilities must meet all of the CMS Conditions of Participation AND must comply with all state and county licensure and life safety code requirements.

This information is described in detail in the fact sheet Hospital Alternative Care Sites during H1N1 Public Health Emergency starting on page 7 of 14 for inpatient surge, and page 9 of 14 for outpatient surge actions and impacts on conditions of participation permissible without waivers. Page 13 and 14 of this fact sheet describe implications of surge sites on Life Safety Code and discuss degraded but safe conditions.

As always, when using surge strategies, notify your state licensing agency and CMS Regional Offices to discuss the specifics of your facility's solution.

Resources

ASPR TRACIE CMS and Disasters: Resources at Your Fingertips
ASPR TRACIE EMTALA and Disasters
Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Options for
Hospitals in a Disaster
Hospital Alternative Care Sites during H1N1 Public Health Emergency

Are there any EMTALA Provisions that Address Safety and Security of Staff, Patients, and Visitors in a Situation Where the Hospital is Potentially Unsafe?

In a situation where the hospital is a potential site of emergency operations (e.g., an on-campus shooter, fire, flood, or other event where the hospital is potentially compromised), ED personnel still have a duty to protect the health and safety of their patients, staff, and visitors. If an individual presents to the affected emergency department, despite security or safety issues, EMTALA still applies and the patient must receive an MSE to determine if an EMC is present. They must also receive stabilizing care and/or be transferred to an appropriate facility to provide care as warranted. The MSE can be adjusted to the specific patient and scenario, as appropriate. If a law enforcement perimeter is established that prevents patients from coming onto the campus or into the hospital, then EMTALA would not apply. Further, if there is an immediate risk to providers and the providers feel they cannot provide an MSE or stabilizing care without risking their lives, it might be necessary to delay care until the security or safety issue is resolved.



Does EMTALA Apply if a Shooting or Other Event Occurs Outside my Facility?

Yes. EMTALA applies to any injured, ill, or laboring person on the hospital grounds, which includes hospital-owned or operated parking areas, sidewalks, and other grounds. As previously mentioned, if the scene presents an immediate safety risk to the providers, the provision of an MSE and stabilizing treatment may have to await the arrival of law enforcement to secure the safety of the situation.

Where Can I Find Examples of Previous EMTALA Waivers and Information on Requesting a Waiver?

The Secretary of Health and Human Services can waive EMTALA sanctions under section 1135 of the Social Security Act. CMS provides information on requesting an 1135 waiver, information to provide for an 1135 waiver, and related content on its 1135 waiver web page. ASPR has provided examples of previous waiver or modification of requirements under section 1135 of the Social Security Act on their website.

Who Can Answer Questions About my Hospital's Emergency Operations Plans and EMTALA Considerations?

Questions on EMTALA compliance and violations should be addressed to your regional/local CMS Office.

Additional Resources

American Academy of Emergency Medicine. (2017). EMTALA

American College of Emergency Physicians. (2017). EMTALA: News Media.

American Hospital Association. (2001). EMTALA Questions and Answers.

Centers for Medicare & Medicaid Services. (2017). Emergency Medical Treatment and Labor Act (EMTALA).

Centers for Medicare & Medicaid Services. (2014). Emergency Medical Treatment and Labor Act Requirements and Implications Related to Ebola Virus Disease (Ebola).

Centers for Medicare & Medicaid Services. (2009). Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Options for Hospitals in a Disaster.

Centers for Medicare & Medicaid Services. (n.d.). Public Health Emergency Declaration Questions and Answers. (Accessed 12/11/2017.)

Finan, S., et al. (2006). Disaster Preparedness: Legal Issues Faced by Hospitals in the Post-Katrina Environment. American Bar Association – ABA Health eSOURCE.

Zibulewsky, J. (2001). The Emergency Medical Treatment and Active Labor Act (EMTALA): What It is and What it Means for Physicians.



Health Insurance Portability and Accountability Act (HIPAA) Factsheet

Reprinted with permission from the Assistant Secretary for Preparedness and Response (ASPR) Technical Resources Assistance Center and Information Exchange (TRACIE)

HIPAA and Disasters: What Emergency Professionals Need to Know

Updated September 11, 2017

Disasters and emergencies can strike at anytime with little or no warning and the local healthcare system in the midst of an emergency response can be rapidly inundated with patients, worried family and friends looking for their loved ones, and media organizations requesting patient information. Knowing what information can be released, to whom, and under what circumstances, is critical for healthcare facilities in disaster response. This guide is designed to answer frequently asked questions regarding the release of information about patients following an incident.

NOTE: This guide does NOT replace the advice of your facility Privacy Officer and/or legal counsel who should be involved in planning for information release prior to an event, developing policy before a disaster that guides staff actions during a disaster, and during an emergency when contemplating disclosures.

This guide does address what information can be disclosed and under what circumstances. Covered entities can disclose needed patients' protected health information (PHI) without individual authorization:

- If necessary to treat the patient or a different patient or if the information would help treat a different patient
- To a public health authority, as outlined below
- At the direction of a public health authority, to a foreign agency acting in collaboration with the public health authority
- To persons at risk of contracting or spreading a disease or condition (if authorized by other law)
- With certain people involved with patient's care/ responsible for the patient
- · When there is imminent threat to public health/ safety

What is HIPAA and the Privacy Rule?

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its implementing regulations, the HIPAA Privacy, Security, and Breach Notification Rules, protect the privacy and security of patients' PHI, but is balanced to ensure that

Covered entities:

- · Health plans
- Healthcare clearinghouses
- Healthcare providers (e.g. hospitals, clinics, pharmacies, nursing homes) who conduct one or more covered healthcare transactions electronically.

Business associates:

- Persons or entities that perform functions or activities on behalf of, or provide certain services to, a covered entity that involve creating, receiving, maintaining, or transmitting PHI.
- Subcontractors that create, receive, maintain, or transmit PHI on behalf of another business associate.



appropriate uses and disclosures of the information may still be made when necessary to treat a patient, to protect the nation's public health, and for other critical purposes.

Does HIPAA Apply to Me or My Organization?

The HIPAA Privacy Rule applies to disclosures made by employees, volunteers, and other members of a covered entity's <u>or business associate's workforce</u>. Covered entities are health plans, healthcare clearinghouses, and those healthcare providers that conduct one or more covered healthcare transactions electronically, such as transmitting healthcare claims to a health plan.

<u>Business associates</u> generally include persons or entities (other than members of the workforce of a covered entity) that perform functions or activities on behalf of, or provide certain services to, a covered entity that involve creating, receiving, maintaining, or transmitting PHI. Business associates also include subcontractors that create, receive, maintain, or transmit PHI on behalf of another business associate.

<u>HIPAA</u> does not apply to disclosures made by those who are not covered entities or business <u>associates</u> (although such persons or entities are free to follow the standards on a voluntary basis if desired).

When Can PHI Be Shared?

Patient health information, or PHI, can be shared under the following circumstances:

Treatment. Under the HIPAA Privacy Rule, covered entities may disclose, without a patient's authorization, PHI about the individual as necessary to treat the patient or to treat a different patient. Treatment includes the coordination or management of healthcare and related services by one or more healthcare providers and others, consultation between providers, providing follow-up information to an initial provider, and the referral of patients for treatment.

Public Health Activities. The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to PHI that is necessary to carry out their public health mission. Therefore, the HIPAA Privacy Rule permits covered entities to disclose needed PHI without individual authorization:

- To a public health authority that is authorized by law to collect or receive such
 information for the purpose of preventing or controlling disease, injury or disability, or
 to a person or entity acting under a grant of authority from or under contract with such
 public health agency,. This could include, for example: the reporting of disease or injury;
 reporting vital events, such as births or deaths; and conducting public health
 surveillance, investigations, or interventions.
- At the direction of a public health authority, to a foreign government agency that is
 acting in collaboration with the public health authority.



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 To persons at risk of contracting or spreading a disease or condition if other law, such as state law, authorizes the covered entity to notify such persons as necessary to prevent or control the spread of the disease or otherwise to

carry out public health interventions or investigations.

Disclosures to Family, Friends, and Others Involved in an Individual's Care and for Notification. A covered entity may share PHI with a patient's family members, relatives, friends, or other persons identified by the patient as involved in the patient's care. A covered entity may also share information about a patient as necessary to identify, locate, and notify family members, guardians, or anyone else responsible for the patient's care, of the patient's location, general condition, or death. This may include—if necessary to notify family members and others—the police, the press, or the public at large.

- The covered entity should get verbal permission from individuals or otherwise be able to reasonably infer that the patient does not object, when possible; if the individual is incapacitated or not available, covered entities may share information for these purposes if, in their professional judgment, doing so is in the patient's best interest.
- In addition, a covered entity may share PHI with disaster relief organizations such as the American Red Cross, which are authorized by law or by their charters to assist in disaster relief efforts, for the purpose of coordinating the notification of family members or other persons involved in the patient's care, of the patient's location, general condition, or death. It is unnecessary to obtain a patient's

permission to share the information in this situation if doing so would interfere with the organization's ability to respond to the emergency.

Imminent Danger. Healthcare providers may share patient information with anyone as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public – consistent with applicable law (such as state statutes, regulations, or case law) and the provider's standards of ethical conduct.

Disclosures to the Media or Others Not Involved in the Care of the Patient/Notification. Upon request for information about a particular patient by name, a hospital or other healthcare

Covered entities can disclose needed PHI without individual authorization:

- If necessary to treat the patient or a different patient
- To a public health authority authorized by law to collect or receive such information
- At the direction of a public health authority, to a foreign agency acting in collaboration with the public health authority
- To persons at risk of contracting or spreading a disease or condition (if authorized by other law)
- With certain people involved with patient's care/ responsible for the patient for reunification or when in the patient's best interest
- When there is imminent threat to public health/ safety



facility may release <u>limited facility directory information</u> to acknowledge an individual is a patient at the facility and provide basic information about the patient's condition in general terms (e.g., critical or stable, deceased, or treated and released) if the patient has not objected to or restricted the release of such information or, if the patient is incapacitated, if the disclosure is believed to be in the best interest of the patient and is consistent with any prior expressed preferences of the patient. Reference 45 CFR 164.510(a). In general, except in the limited circumstances described elsewhere, affirmative reporting to the public or media of specific information about treatment of an identifiable patient, such as specific tests, test results or details of a patient's illness, <u>may not be done</u> without the patient's written authorization (or the written authorization of a personal representative who is legally authorized to make healthcare decisions for the patient).

General or aggregate information in mass casualty events that does not identify an individual or meets the requirements of the HIPAA Privacy Rule's de-identification provisions is *not* considered PHI (e.g., X number of casualties were received by the hospital with the following types of injuries).

Minimum Necessary. For most disclosures, a covered entity must make reasonable efforts to limit the information disclosed to that which is the "minimum necessary" to accomplish the purpose. (Minimum necessary requirements do not apply to disclosures to health care providers for treatment purposes.) Covered entities may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the purpose.

Note: The disclosures listed above are at the discretion of the covered entity and are <u>not</u> <u>required</u> disclosures under the Rule. Some of these disclosures may be required by other federal, state or local laws (for example, mandatory reporting of positive infectious disease test results).

Does the HIPAA Privacy Rule Permit Disclosure to Public Officials Responding to a Bioterrorism Threat or other Public Health Emergency?

Yes. The HIPAA Privacy Rule recognizes that various agencies and public officials will need PHI to deal effectively with a bioterrorism threat or emergency. The public health threat does not have to reach a declared emergency status. If information is needed by a government agency to protect the health of the public (e.g., a food-borne outbreak), the agency may request and receive appropriate clinical and other information about the patient's disease, care, and response to treatment. To facilitate the communications that are essential to a quick and effective response to such events, the HIPAA Privacy Rule permits covered entities to disclose needed information to public officials in a variety of ways. Further, if the covered entity has obligations to report test results and other information to public health agencies by statute, rule, or ordinance, the HIPAA Privacy Rule generally permits these disclosures.



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Covered entities may disclose PHI, without the individual's authorization, to a public health authority acting as authorized by law in response to a bioterrorism threat or public health emergency (reference 45 CFR 164.512(b)), public health activities). The HIPAA Privacy Rule also permits a covered entity to disclose PHI to public officials who are reasonably able to prevent or lessen a serious and imminent threat to public health or safety related to bioterrorism (reference 45 CFR 164.512(j)), to avert a serious threat to health or safety). In addition, disclosure of PHI, without the individual's authorization, is permitted where the circumstances of the emergency implicates law enforcement activities (reference 45 CFR 164.512(f)); national security and intelligence activities (reference 45 CFR 164.512(k)(2)); or judicial and administrative proceedings (reference 45 CFR 164.512(e)).

Is the HIPAA Privacy Rule "Waived" or "Suspended" During an Emergency?

The HIPAA Privacy Rule is not suspended during a public health or other emergency; however, under certain conditions the Secretary of the U.S. Department of Health and Human Services may waive certain provisions of the HIPAA Privacy Rule section 1135(b)(7) of the Social Security Act, if such a waiver is deemed necessary for the particular incident when the Secretary declares a public health emergency and the President declares an emergency or disaster under the Stafford Act or National Emergencies Act. For more information, access "Is the HIPAA Privacy Rule suspended during a national or public health emergency?" Access Hurricane Irma and HIPPA Bulletin: Limited Waiver of HIPAA Sanctions and Penalties During a Declared Emergency for an example of how sanctions and penalties could be waived in a declared emergency.

Does the HIPAA Privacy Rule Permit Disclosure to Law Enforcement?

A HIPAA-covered entity may disclose PHI to law enforcement with the individual's signed HIPAA authorization. A covered entity may disclose directory information as mentioned above to law enforcement upon request. Further disclosures to law enforcement for purposes of reunification and family notification are permitted as discussed above.

A HIPAA-covered entity also may disclose PHI to law enforcement without the individual's signed HIPAA authorization in certain incidents, including:

- To report to a law enforcement official reasonably able to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public.
- To report PHI that the covered entity in good faith believes to be evidence of a crime that occurred on the premises of the covered entity.
- To alert law enforcement to the death of the individual, when there is a suspicion that death resulted from criminal conduct.
- When responding to an off-site medical emergency, as necessary to alert law enforcement about criminal activity.
- To report PHI to law enforcement when required by law to do so (such as reporting gunshots or stab wounds).
- To comply with a court order or court-ordered warrant, a subpoena or summons issued



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by a judicial officer, or an administrative request from a law enforcement official (the administrative request must include a written statement that the information requested is relevant and material, specific and limited in scope, and de-identified information cannot be used).

- To respond to a request for PHI for purposes of identifying or locating a suspect, fugitive, material witness or missing person, but the information disclosed must be limited to certain basic demographic and health information about the person.
- To respond to a request for PHI about an adult victim of a crime when the victim agrees
 (or in limited circumstances if the individual is unable to agree). Child abuse or neglect
 may be reported, without a parent's agreement, to any law enforcement official
 authorized by law to receive such reports.

How Does the HIPAA Privacy Rule Apply to Disclosures Involving Foreign Nationals?

Covered entities may disclose PHI for all persons, regardless of nationality, according to the disclosures listed in the Privacy Rule and discussed above. Disclosure of PHI to embassies, consulates or other third parties, such as the American or International Red Cross acting in a capacity to facilitate notifications or repatriation following an emergency, is permitted under the existing disclosures of the HIPAA Privacy Rule, as referenced above.

For More information

- Bulletin: HIPAA Privacy in Emergency Situations
- Can healthcare information be shared in a severe disaster?
- Health Information Privacy Is HIPAA Privacy Rule Suspended during a National or Public Health Emergency?
- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement
- HIPAA Privacy Rule: Disclosures for Emergency Preparedness A Decision Tool
- Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situations
- Incorporating Active Shooter Incident Planning into Health Care Facility Emergency Operations Plans. Appendix A: Information Sharing. (Page 29 of 33)
- When does the Privacy Rule allow covered entities to disclose PHI to law enforcement officials?
- HIPAA Policy Brief

For more information on HIPAA and Public Health:

http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/publichealth/index.html For more information on HIPAA and Emergency Preparedness and Response: http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/index.html General information on understanding the HIPAA Privacy Rule may be found at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html



Requesting an 1135 Waiver

PREREQUISITES FOR A SECTION 1135 WAIVER

There are four requirements that must be met before a hospital can seek a waiver under Section 1135 of the Social Security Act:

- 1. The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act;
- **2.** The Secretary of HHS has declared a Public Health Emergency (PHE) under Section 319 of the Public Health Service Act;
- **3.** The Secretary of HHS has invoked his authority under Section 1135 of the Social Security Act and authorized CMS to waive sanctions for certain EMTALA violations that arise as a result of the circumstances of the emergency; and
- **4.** The hospital in the affected area has implemented its hospital disaster protocol.

WAIVERS AVAILABLE UNDER SECTION 1135

When the President of the United States declares a major disaster or an emergency and the HHS Secretary declares a public health emergency, they are authorized to take certain actions in addition to his regular authorities. The HHS Secretary has the authority to waive or modify certain federal laws. Examples of these 1135 waivers or modifications include:

- Conditions of participation or certification under Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP).
- Preapproval requirements under Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP).
- State licenses for physicians and other health care professionals (this waiver is for purposes of Medicare, Medicaid, and SCHIP reimbursement only the state determines whether a non-Federal provider is authorized to provide services in the state without state licensure).
- Emergency Medical Treatment and Labor Act (EMTALA) sanctions for redirection of an individual to another
 location to receive a medical screening examination pursuant to a state emergency preparedness plan or
 transfer of an individual who has not been stabilized if the transfer arises out of emergency
 circumstances. A waiver of EMTALA requirements is effective only if actions under the waiver do not
 discriminate on the basis of a patient's source of payment or ability to pay.
- Stark self-referral sanctions.
- Performance deadlines and timetables may be adjusted (but not waived).
- Limitations on payment to permit Medicare+Choice enrollees to use out of network providers in an emergency situation.
- In addition, the Secretary may waive Health Insurance Portability and Accountability Act (HIPAA) sanctions and penalties relating to the following:
 - Obtaining a patient's consent to speak with family members or friends;
 - Honoring a patient's request to opt out of the facility directory;
 - Distributing a note of privacy practices; and
 - o Honoring the patient's right to request privacy restrictions or confidential communications.

The waiver of HIPPA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay.

These waivers under section 1135 of the Social Security Act typically ends with the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the HHS Secretary extends the waiver by notice for additional periods of up to 60 days. Waivers for EMTALA (for emergencies that do not involve a

pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic related emergency. The waiver for licensure applies only to Federal requirements and does not automatically apply to State requirements for licensure or conditions of participation.

PROCEDURE FOR OBTAINING A SECTION 1135 WAIVER

Currently there are no formal procedures for obtaining a Section 1135 waiver. During a disaster or emergency situation, CMS and DOH will be monitoring the situation to determine when HHS should be contacted. If a hospital has a problem potentially worthy of a Section 1135 waiver, it should contact DOH and provide the relevant information. DOH will then pass this information along to CMS who would then decide whether to recommend a waiver to the HHS Secretary.

In the absence of a Pennsylvania waiver specific procedure, it is suggested the following process should be implemented by affected hospital(s):

- Collection of information described below to those above to facilitate timely and successful submission and approval.
- Notification of HAP regional Manager for Emergency Preparedness for assistance with this process and notifications of regional and state preparedness agencies via the "PA Unmet Needs" process. (HAP Regional Manager Contact information attached).
- Submission of request with information described below to the CMS Regional Office (Northeast Consortium): ROPHIDSC@cms.hhs.gov as well as DOH's Licensure and Regulatory Division through normal channels.

Information needed to Request an 1135 Waiver

- DOH will need the following basic questions for any impacted provider seeking a potential 1135 waiver to provide to CMS:
 - Provider Name/Type;
 - Full Address (including county/city/town/state) CCN (Medicare provider number);
 - Contact person and his or her contact information for follow-up questions should the Region need additional clarification;
 - Brief summary of why the waiver is needed. For example: CAH is sole community provider without reasonable transfer options at this point during the specified emergent event (e.g. flooding, tornado, fires, or flu outbreak). CAH needs a waiver to exceed its bed limit by X number of beds for Y days/weeks (be specific);
 - Consideration Type of relief you are seeking or regulatory requirements or regulatory reference that the requestor is seeking to be waived; and
 - There is no specific form or format that is required to submit the information but it is helpful to clearly state the scope of the issue and the impact.

If a waiver is being requested, the information should be submitted directly from the impacted provider to the appropriate Regional Office mailbox with a copy to DOH to make sure the waiver request does not conflict with any State requirements and all concerns are addressed timely.

Email Addresses for CMS Regional Office (Northeast Consortium):

ROPHIDSC@cms.hhs.gov

References:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.html

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Appendix A: Mutual Aid Agreement

The following pages include a copy of the Hospital & Healthsystem Association of Pennsylvania Health care Mutual Aid Agreement, which was originally developed and implemented in 2006. The purpose of the document is to facilitate the ability of hospitals and health care facilities and agencies throughout the state to share personnel, equipment, supplies and pharmaceuticals as well as accepting patient transfers during a disaster situation. The agreement details definitions, implementation methods, indemnification, limitations, and reimbursement procedures. No participating hospital, health care facility and agency shall be required to provide assistance unless it determines that it has sufficient resources to do so.

The following document is an example of the Pennsylvania Health care Mutual Aid Agreement currently in use. Signed copies from each hospital, health care facility and agency are maintained by the Hospital & Healthsystem Association of Pennsylvania. This document will be reviewed and re-issued every three years unless circumstances dictate otherwise.

Pennsylvania Regional Health Care Coalition Mutual Aid Agreement

Introduction and Background

This Mutual Aid Agreement ("MAA" or "Agreement") is entered into by and between the undersigned Pennsylvania or neighboring health care organizations. The parties intend by this MAA to establish a mutually beneficial partnership.

As in other parts of the nation, the Commonwealth of Pennsylvania and its regions are susceptible to "emergencies" or "disasters", both natural and manmade that could exceed the resources of any individual health care organization. An emergency could result from a single incident or a series of incidents generating an overwhelming number of patients, from patients whose specialized medical requirements exceed the resources of the impacted health care organization (e.g., hazardous materials injuries, pulmonary, trauma surgery, etc.), or from incidents such as building or physical plant problems resulting in the need for partial or complete health care organization evacuation.

Historically, hospitals across the Commonwealth have established mutual aid agreements (MAA) that are based upon regional response and communication plans. Many of these activities have been conducted in a manner that crosses geo-political boundaries and encompass the continuum of health care delivery organizations.

This document establishes a regional level mutual aid agreement that extends across corporate, county, regional and state geo-political boundaries as well as across the continuum of health care delivery from acute care and long term care to home care and ambulatory care organizations.

The signatories to this document commit that they will use their best efforts to collaborate to meet the operational and patient care challenges that may arise in connection with such emergencies regardless of the cause or event. While the MAA will be executed and administered at the regional coalition level, the intent is for any organization that is party to the agreement to seek and/or provide assistance during emergencies to any other signatory to this MAA regardless of geopolitical boundaries.

This Agreement establishes provisions under which each health care organization will endeavor to transfer or receive patients in the event of a partial or total health care facility evacuation in an emergency situation. The evacuation of any

of the participating health care organizations would occur only in extreme emergencies which would render a participating health care facility, or a portion of a participating health care facility, unusable for patient care.

Definition of Terms

- a) Assisting Facility: A facility / health care organization which provides aid such as supplies, equipment and personnel to another facility under the terms of this Agreement.
- b) Evacuation: The process of moving patients from a health care facility or organization due to an emergency that threatens the life, safety or health of patients and/or the ability of the Sending Facility to provide health care services.
- c) Emergency Health care Support Zone (EHSZ): A regional substructure that aids in the planning and coordination of medical facilities and resources for mass casualty incidents or large-scale emergencies requiring the involvement of more than one hospital or medical facility within a community or region.
- d) Emergency: (Historically referred to as "Emergency or Disaster"). Any event or situation resulting in a challenge or disruption of normal health care care services at a facility or multiple facilities across the region or state. Any event prompting facility(s) to activate their Emergency Management process and/ or Emergency Operations Plan. These events may, for example, include a surge of persons presenting for care, a disruption of utilities or community services impacting normal facility operations; an internal situation disrupting normal operations or occupancy; and an external or environmental situation impacting safe access or egress from a facility. This may (or not) include a formal Declaration of Emergency from Local, State or Federal government.
- e) HAP: The Hospital and Healthsystem Association of Pennsylvania Health Care Coalition: A multi-institutional regional organization recognized by the Pennsylvania Department of Health as the core regional health care preparedness entity. Membership is open to Hospitals, EMS agencies, long-term and post-acute care facilities as well as specialty centers (i.e. dialysis units.)
- f) **Knowledge Center:** A web based information sharing and emergency management program purchased by DOH for use by Pennsylvania health care coalition members.
- g) **Participating Health care Organization:** A hospital, health care system or health care organization that has agreed to provide mutual aid under the terms of this Agreement.
- h) **Requesting Facility:** A health care facility which has requested aid such as supplies, equipment and personnel under the terms of this Agreement.
- (j) **Transferring Facility:** A health care facility transferring patient(s) to a Receiving facility during an Emergency such as an evacuation.

<u>Acronyms</u>

- a) EMTALA: Emergency Medical Treatment and Active Labor Act
- b) HIPAA: Health Insurance Portability and Accountability Act
- c) EHSZ: Emergency Health care Support Zone
- d) ASPR: The Assistant Secretary for Preparedness and Response of the US Department of Health and Human Services (HHS)

- e) HPP: The Hospital Preparedness Program a congressionally funded program via HHS/ ASPR to promote regional health care preparedness activities
- f) HAP: The Hospital and Healthsystem Association of Pennsylvania
- g) TJC: The Joint Commission
- h) EOP: Emergency Operations Plan
- i) HVA: Hazard Vulnerability Assessment
- j) ICS: Incident Command System (The established organizational structure and approach to incident management.)
- k) NIMS: National Incident Management System- A US Homeland Security mandated approach to Incident Management built on the ICS (above)
- I) KC: Knowledge Center- A web based information sharing and emergency management program (See above).
- m) DOH: The Pennsylvania Department of Health n)

MAA: Mutual Aid Agreement

Recitals

WHEREAS, the health care provider community has had a long standing tradition of helping providers, citizens, and others during times of crisis, normally without formal written agreements, hospital and health care providers nonetheless recognize the importance of now formalizing this MAA to:

- (a) Ensure that underlying principles are stated and agreed upon;
 - (b) Ensure that the agreement will continue even if personnel or other institutional processes change; and
 - (c) Provide documentation for accreditation agencies, standards organizations, and the community at-large regarding the health care community's high level of commitment regarding emergency preparedness.
 - (d) Ensure a coordinated emergency response plan is in place to address emergencies and incidents.

WHEREAS, this Agreement represents the commitment of the undersigned that in the event of an emergency, the health care needs of the community will be best met if the undersigned health care organizations use their best efforts to cooperate with each other and coordinate their response efforts.

WHEREAS, the goal of this document is establish that the undersigned will use their best efforts to mutually work together to assist each other consistent with their abilities to do so during an Emergency.

WHEREAS, This Agreement is designed to promote safety, and responsibility as well as to establish principles for mutual assistance to be rendered by, to, and among the participating health care facilities, health care organizations and other providers in the preparation for, response to, and recovery from any Emergency (defined above) that results in a state of emergency as determined by a Facility's Incident Commander, or that is formally declared by a local governmental unit,

the Commonwealth, or the federal government. The members of the health care provider community who agree to the terms of this Agreement commit to serve

their communities in the most efficient and effective manner possible. as set forth in this Agreement.

WHEREAS, the undersigned desire to set forth the basic tenants of a relationship to establish and maintain a cooperative and coordinated regional response plan in the event of an Emergency.

Now, THEREFORE, in order to provide for continuity of care for patients in emergencies as defined, the health care organizations within the region, and adjoining regions as needed, hereby mutually agree as follows:

Article I Ongoing Preparation Activities - Absent an Emergency

The undersigned health care organizations will:

- 1.1.1 Identify a primary point-of-contact and secondary individuals for communication purposes. These individuals will be responsible for the distribution of information within their health care organization. The organization will provide the Designate HAP Representative timely updates upon any change of these points of contacts, as well as upon request.
- 1.1.2 Will assure appropriate personnel are trained and competent in the use of Knowledge Center (KC) to provide timely response for information and coordination during emergencies. One of the registered KC users will be assigned responsibility to maintain accurate facility contact and profile information (as noted in 1.1.1).
- 1.1.3 Assure that a representative of the facility actively participates in regional health care preparedness coalition activities.
- 1.1.4 Participate in regional coalition training and "emergency exercises" to establish and maintain core organizational competency in the processes and means of communication and coordination that would be utilized during the alerting, response and recovery phases of an emergency.

Article II Communication and Coordination - During an Emergency

The undersigned health care organizations will use their best efforts to:

- 2.1.1 Establish an Incident Command System (ICS) and process consistent with the National Incident Management System (NIMS) as appropriate to the emergency event and organizational involvement.
- 2.1.2 Communicate and coordinate their efforts to respond to an emergency via the organization's ICS structure.
- 2.1.3 Receive information, notifications and alerts via the Knowledge Center and other coalition members, DOH and coordinating agencies.
- 2.1.4 Respond to alerts and action requests received with requested information in a timely manner.
- 2.1.5 Communicate with other coalition partners, as necessary, by whatever means available such as phone; fax; email; county, regional, or statewide radio systems; Knowledge Center; and other technologies.
- 2.1.6 Appoint a Public Information Officer (PIO) during emergency operations. They shall be made available to the Facility command center and participate in a Joint Information Center (JIC) during an emergency to allow their public relations personnel to communicate with other Coalition members and lead agencies to facilitate the release of consistent community and media educational/ advisory messages.

Article III Implementation

3.1.1 Requests for Assistance: A Participating Health care Organization may request the assistance of any other Participating Health care Organization in preparing for, responding to, mitigating against, and recovering from Emergencies that result in a need for assistance. Requests for assistance will be made through the organizations' established ICS structures. The Requests may be verbal, written, emailed or via KC (preferred). All verbal requests will be documented in KC or in writing as soon as possible.

Article IV <u>Staff. Medical Supplies, and Pharmaceutical Supplies</u>

- 4.1.1 Each participating health care organization will use its best efforts to provide aid and assistance to other Participating Health care Organizations as requested. However, no participating health care organization will be expected to provide assistance unless the organization's incident commander determines that it has sufficient resources to do so.
- 4.1.2 In the event of an emergency, when staff is available at one of the undersigned health care organizations and lacking at another, the

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undersigned health care organizations, with the available staff, will provide staff as appropriate to support the impacted organization's ability to provide patient care, provided such assistance will not negatively impact the ability of such health care organization to care for its own patients.

- 4.1.3 Each health care organization agrees to work cooperatively to avoid undue interruptions in patient care and, where necessary, will grant temporary privileges to clinical staff based on applicable laws, regulations, standards, policies and procedures.
- 4.1.4 Unless specifically agreed upon and documented otherwise, the Requesting Facility will be responsible for providing food and housing for the personnel of the Assisting Facility from the time of their arrival at the designated location to the time of their departure. The Requesting Facility will also provide an initial briefing and just-in-time instruction on personal and patient safety practices as well as other needed job / site specific information.
- 4.1.5 During the term of assistance, the personnel of an Assisting Facility will continue to be subject to the salary and benefits; workers compensation and medical liability coverages; human resources policies and procedures of the Assisting Facility. However, the personnel of an Assisting Facility will be under the supervision and control of the appropriate management and ICS of the Requesting Facility, and will follow the medical protocols and standard operating procedures of the Requesting Facility.
- 4.1.6 In the event that needed supplies including pharmaceuticals are available at a Participating Health care Organization and lacking at another, the organization with the available supplies, will when requested, use their best efforts while complying with DEA and other regulations, to share these supplies to help the other organization provide patients with necessary emergency care, provided such assistance will not negatively impact the ability of Assisting Facility to care for its own patients.
- 4.1.7 In the event that needed equipment such as ventilators or infusion pumps are available at one of the undersigned health care organizations and lacking at another, the undersigned health care organization with the availability will use its best efforts to share equipment to help the other to provide necessary treatment and services during an emergency, provided such assistance will not negatively impact the ability of such health care organization to care for its own patients.
- 4.1.8 The above staff, supplies and equipment sharing will occur in accordance with the ICS structure of the involved organizations. All involved parties must be in agreement prior to any sharing of resources.

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- 4.1.9 Supplies and equipment of a Sending Facility will be considered loaned for the purpose of this Agreement, and the Requesting Facility will ensure the safe and prudent operation and use of said supplies and equipment by appropriately licensed, trained and professional personnel. The Requesting Facility will clean and disinfect, or otherwise remove any potentially infectious materials on the loaned equipment before returning it in the same working condition, to the Assisting Facility. Likewise any supplies provided by the Assisting Facility and used by the Requesting Facility will be replaced by the Requesting Facility.
- 4.1.10 The Requesting Facility will in all circumstances assume financial responsibility for the personnel, pharmaceuticals, supplies and equipment from the Assisting Facility. The Requesting Facility will reimburse the Assisting Facility, to the extent permitted by federal law, for all of the Assisting Facility's direct costs in providing personnel, pharmaceuticals, equipment, or supplies. Costs include all use, breakage, damage, replacement, and return costs of borrowed materials, as well as for personal injuries that result in disability, loss of salary, and related expenses.
- 4.1.11 The Assisting Facility will provide the Requesting Facility with an invoice for the costs of the provided personnel, pharmaceuticals, equipment, and supplies within 60 days of the termination. of the emergency event. Unless otherwise agreed to between the Assisting and Requesting Facility, the Assisting Facility will provide its assistance at its cost and will

not mark-up or otherwise increase its invoice to the Requesting Facility for reimbursement. This reimbursement request will consist of:

- (a) A cover letter summarizing the assistance provided and requesting reimbursement for expenses incurred. The financial representative responsible for the request should be identified as the point-of-contact for ongoing questions and follow up.
- (b) A copy of the KC Resource request or written request for assistance.
- (c) A single invoice listing resources provided with the total cost.
- (d) Supporting documentation (copies of invoices, travel claims, etc.)
- 4.1.12 An Assisting Facility may agree in writing to donate, in whole or in part, the costs associated with any loss, damage, expense or use of personnel, equipment and resources provided.
- 4.1.13 The Requesting Facility shall reimburse the Assisting Facility for all documented costs within 90 days following receipt of the invoice.
- 4.1.14 Unless the facilities agree otherwise, the Requesting Facility will coordinate and submit all billings, applications, or submissions to

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third parties such as government agencies (FEMA) or relief organizations

Article V Evacuation of a Participating Health care Organization

- 5.1.1 Subject to medical capability, space, and staffing availability, each health care organization agrees to use its best efforts to accept a Transferring health care organization's patients in the event of an emergency evacuation. Patients should be evacuated to facilities providing the most appropriate level of care. (Preferably same level of care as the Transferring Facility) The transfer to a higher level of care may be appropriate if there is a need to do so based on the medical condition or situation.
- 5.1.2 In the event of an evacuation, the Transferring Facility will coordinate with their respective Designate HAP Representative to assist with identifying facilities with available capacity and their local /County Emergency Management Agency for assistance in organizing appropriate transportation for the evacuation and distribution of patients to Receiving Facilities.
- 5.1.3 If the requested Receiving Facility does not have the medical capability and/or available capacity, it may decline to accept a particular patient(s).
- 5.1.4 The Transferring Facility will provide the Receiving Facility with as much advance notice and health care information as possible under the circumstances for patients being transferred to the Receiving facility.
- 5.1.5 The Transferring Facility will send all records, test results, x-rays, patient belongings and necessary medical equipment and supplies including 48 hours of medications unless it would result in a delay that could increase the risk of the transfer; the safe evacuation of the Facility, or the treatment of others affected by the emergency. If records are not transferred with the patient, the patient's name, Date of Birth, identification number, and any known medication allergies should be written with a permanent marker

directly onto the patient's arm. Records should be transferred as soon as possible.

5.1.6 The Transferring Facility will bear the responsibility for all unreimbursed fees associated with patient transportation.

- 5.1.7 The Receiving Facility will provide medically necessary health care services for patients that may be transported to them subject to 4.1.1. Each Receiving facility will follow their procedures for admission and care of patients. Additionally, the Receiving facilities may discharge patients received in accordance with its normal procedures.
- 5.1.8 The services will be provided at the Receiving Facility's prevailing rates. The Transferring facility shall not be obligated to pay any charges imposed by the Receiving facility unless such liability would exist separate and apart from this Agreement. The Receiving facility will collect such charges from the patient or the patient's third party payer.
- 5.1.9 The Transferring Facility agrees to readmit patients when services are restored at the Transferring Facility.
- 5.1.10 The parties hereto agree that they will not discriminate against any patient affected by this Agreement on the basis of race, age, creed, color, sex, national origin, sexual orientation, inability to pay or disability.
- 5.1.11 The undersigned will comply to the extent possible and applicable, with all federal, state and local laws and regulations, i.e. EMTALA, as well as with patient confidentiality laws and regulations, i.e. HIPAA.

Article VI Miscellaneous Provisions

- 6.1.1 Except as may be required by Federal law and regulations applicable to Federal facilities and programs, the laws of the Commonwealth of Pennsylvania shall govern this Agreement. Any changes in the governing laws, rules, and regulations during the terms of this Agreement shall apply, but do not require an amendment to this Agreement.
- 6.1.2 Should a court of competent jurisdiction rule any portion, section or subsection of this Agreement invalid or a nullity, that fact will not affect or invalidate any other portion, section or subsection; and all remaining portions, sections or subsections will remain in full force and effect.
- 6.1.3 Nothing contained herein is intended to permit practitioners who have not been granted privileges with a particular health care organization the right to practice at that health care organization without first having obtained

clinical privileges from the applicable health care organization in accordance with its policies and procedures.

6.1.4 The term of this Agreement will commence on the date that this Agreement is signed by the health care organization, and will continue in

full force and effect, regardless of personnel or ownership changes, unless and until terminated.

- 6.1.5 This Agreement represents the entire Agreement between the parties with respect to the subject matter hereof and may not be amended except by written notice forwarded to the appropriate Designate HAP Representative and signed by both parties (The Participating Health care Organization and The HAP Representative).
- 6.1.6 A participating individual health care organization may elect to terminate this Agreement by providing sixty (60) days written notice to the appropriate who will then notify in writing all other participating organizations.
- 6.1.7 This document is not exclusive. Participating health care organizations may sign other outside memorandums of understandings / mutual aid agreements.
- 6.1.8 This Agreement may be executed in any number of counterparts, each of which together will constitute one and the same instrument. This Agreement may be modified at any time upon the mutual written consent of all parties to this Agreement
- 6.1.9 The master copy of this Agreement will be maintained by HAP and coordinated by the appropriate HAP Regional Manager. A list of signatory organizations will be distributed to the designated health care organization "emergency" point of contact and the office of the signatory on at least a semi-annual basis.
- 6.1.10 This Mutual Aid Agreement is intended to set forth the present understandings and objectives of the undersigned parties.

Pennsylvania Regional Health Care Coalition Mutual Aid Agreement

The undersigned agrees to a Agreement on behalf of following facility(s):	the attached Pennsylvania	•	Coalition Mutual Aid ganization). For the
Facility Name	City	County	
Facility Name	City	County	
Facility Name	City	County	
Facility Name	City	County	

Facility Name	City	County	
Facility Name	City	County	
Facility Name	City	County	
Facility Name	City	County	
Facility Name	City	County	
The person executing this Agreeby represents and warran enter into this Agreement on b he/she signs.	ts that he/she has the ri	ght, power, legal and co	orporate authority to
Signature	 Date		
Printed Name and Title	Health	care Organization	
Received by The Hospital and	d Healthsystem Associa	tion of Pennsylvania:	
Signature	 Date		
Printed Name and Title			



Appendix B: Scarce Resource Strategies

Oxygen Recommendations

Inhaled Medications		
Restrict use of Small Volume Nebulizers when inhaler substitutes are available.		
Restrict continuous nebulization therapy.		
Minimize frequency through medication substitution that results in fewer treatments (6h -12h instead of 4h-6h applications).		
High-Flow Applications		
Restrict use of high flow cannula systems (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 (require 10 to 75 LPM flows).		
Eliminate oxygen-powered Venturi suction systems (consume 15-50 LPM).		
Air-Oxygen Blenders		
Eliminate the low-flow reference bleed occurring with any low-flow metered oxygen blender. Reserve air-oxygen blender use for mechanical ventilators using high-flow non-metered outlets.		
Disconnect bleeders when not in use.		
Oxygen Conservation Devices		
Use reservoir cannulas at 1/2 the flow setting of standard cannulas.		
Replace simple and partial rebreather mask use with reservoir cannulas at flowrates of 6-10 LPM.		
Oxygen Concentrators if Electrical Power is Present		
Use hospital-based or independent home medical equipment supplier oxygen concentrators if available to provide low-flow cannula oxygen for patients and preserve the primary oxygen supply for more critical applications.		
Monitor Use and Revise Clinical Targets		
Employ oxygen titration protocols to optimize flow or % to match targets for SP02 or PaO2.		
Minimize overall oxygen use by optimization of flow.		
Discontinue oxygen at earliest possible time.		
Starting Example	Initiate 02	02 Target
Normal Lung Adults	SP02 <90%	SP02 90%
Infants and Peds	SP02 <90%	SP02 90 - 95%
Severe COPD History	SP02 <85%	SP02 90%

Note: Targets may be adjusted further downward depending on resources available, the patient's clinical presentation or measured Pa02 determination	
Expendable Oxygen Appliances	
Use terminal sterilization or high-level disinfection procedures for oxygen appliances, small and 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 chlorohydrin formation with polyvinyl chloride plastics.	
Oxygen Re-Allocation	
Prioritize patients for oxygen administration during severe resource limitations.	
Mechanical Ventilation/External Oxygenation	
Access Alternative Sources for Ventilators/Specialized Equipment	
Obtain specialized equipment from vendors, health care partners, regional, state, federal stockpiles via usual emergency management processes and provide just- intime training and quick reference materials for obtained equipment.	
Decrease Demand for Ventilators	
Increase threshold for intubation/ventilation.	
Use non-invasive ventilatory support when possible.	
Re-use Ventilator Circuits	
Appropriate cleaning must precede sterilization.	
If using gas (ethylene oxide) sterilization, allow full 12-hour aeration cycle to avoid accumulation of toxic by-products on surfaces.	
Use irradiation or other techniques as appropriate.	
Use Alternative Respiratory Support Technologies	
Use transport ventilators with appropriate alarms- especially for stable patients without complex ventilation requirements.	
Use anesthesia machines for mechanical ventilation as appropriate/capable.	
Use bi-level (BIPAP) equipment to provide mechanical ventilation.	
Consider bag-valve ventilation as a temporary measure while awaiting definitive solution/ equipment (as appropriate to situation) - extremely labor intensive and may consume large amounts of oxygen.	
Assign Limited Ventilators to Patients Most Likely to Benefit if no Other Options are Available	

Medication Administration

Cache/ Increase Supply Levels	
Patients should have at least 30 d epidemic or evacuation is immine	ays supply of home medications and obtain 90 day supply if pandemic, ent.
Examine formulary to determine demand.	commonly-used medications and classes that will be in immediate, high
Increase supply levels or cache cr	itical medications, particularly for low cost items and analgesics.
Analgesia	Morphine, other narcotic and non-narcotic (non-steroidal, acetaminophen) class, injectables and oral (narcotic conversion tool at http://www.globalrph.com/narcoticonv.htm).
Sedation	Particularly benzodiazapine (lorazepam, midazolam, diazapam) injectables
Anti-Infective	Narrow and broad spectrum antibiotics for pneumonia, skin infections, open fractures, sepsis (e.g. cephalosporins, quinolones, tetracyclines, Macrolides, aminoglycosides, clindamycin, etc.) select antivirals.
Pulmonary	Metered dose inhalers (albuterol, inhaled steroids), oral steroids (dexamethasone, prednisone)
Behavioral Health	Haloperidol, other injectable and oral anti-psychotics, common anti-depressants, anxiolytics
Other	Sodium bicarbonate, paralytics, induction agents (etomidate, propofol,) proparacaine/tetracaine, atropine, pralidoxime, epinephrine, local anesthetics, antiemetics, insulin, common oral anti-hypertensive and diabetes medications.
Use Equivalent Medications	
Obtain medications from alterna	te supply sources (pharmaceutical representatives, pharmacy caches)
Pulmonary	Metered dose inhalers instead of nebulized medications.
Analgesia/Sedation	Consider lorazepam for propofol substitution and other agents in short supply.
	ICU analgesia/sedation drips Morphine 4-10mg IV load then 2mg/hr and titrate/re-bolus as mg IV load as needed. Usual 3-20 mg/h; Lorazepam 2-8mg or midazalam 1-5mg IV load then 2-8mg/h drip

Anti-infective	Examples: cephalosporin, gentamicin, clindamycin substitutes for
	unavailable broad spectrum antibiotic

	Target therapy as soon as possible based upon organism identified.
Other	Beta blockers, diuretics, calcium channel blockers, ace inhibitors, anti-depressants, anti-infectives

Reduce Use During High Demand

Restrict use of certain classes if limited stocks likely to run out. Restrict prophylactic/empiric antibiotics after low risk wounds, etc.

Decrease dose; consider using smaller doses of medications in high demand/likely to run out (reduce doses of medications allowing blood pressure or glucose to run higher to ensure supply of medications adequate for anticipated duration of shortage).

Allow use of personal medications (inhalers, oral medications) in hospital.

Do without - consider impact if medications not taken during shortage (statins, etc.).

Modify Medication Administration

Emphasize oral, nasogastric, subcutaneous routes of medication administration.

Administer medications by gravity drip rather than IV pump if needed. IV drip calculation - drops/minute = amount to be infused x drip set/time(minutes) (drip set = qtt/mL - 60, 10, etc.)

Rule of 6: Pt wgt(kg) x 6 = mg drug to add to 100 mL fluid = 1mcg/kg/min for each 1mL/hour. Note: For examples, see http://www.dosagehelp.comiv rate drop.html

Consider use of select medications beyond expiration date. (Legal protection such as Food and Drug Administration approval or waiver required.)

Restrict Allocation of Select Medications

Allocate limited stocks of medications with consideration of regional/state guidance and available epidemiological information (e.g. anti-viral medications such as oseltamivir).

Allocate limited stock to support other re-allocation decisions (ventilator use, etc.)

Staffing Strategies

Focus Staff Time on Core Clinical Duties

Restrict elective appointments and procedures.

Reduce documentation requirements.

Cohort patients to conserve PPE and reduce staff PPE donning and doffing time and frequency.

Use Supplemental Staff

Bring in equally trained staff from whatever resources available.

Adjust personnel work schedules (longer but less frequent shifts, etc.) If this will not result in skill/PPE compliance deterioration.

Use family members/lay volunteers to provide basic patient hygiene and feeding, releasing staff for other duties.

Focus Staff Expertise on Core Clinical Needs

Personnel with specific critical skills (ventilator, ICU) should concentrate on those skills; specify job duties that can be safely performed by other medical professionals.

Have specialty staff oversee larger numbers of less-specialized staff and patients (for example, a critical care nurse oversees the intensive care issues of nine patients while three medical/surgical nurses provide basic nursing care to three patients each.)

Use Alternative Personnel to Minimize Changes to Standards of Care

Use less trained personnel with appropriate mentoring and just-in-time education (e.g. health care trainees or other health care workers, Medical Reserve Corps, etc.)

Use less trained personnel to take over portions of skilled staff workload for which they have been trained.

Provide just-in-time training or specific skills.

Hemodynamic Support and IV Fluids

Recommendations

Cache additional IV cannulas, tubing, fluids, medications and administration supplies.

Use scheduled dosing and drip dosing when possible

Reserve IV pump use for critical medications such as sedatives and hemodynamic support.

Minimize invasive monitoring

Substitute other assessments (e.g., clinical signs, ultrasound) of central venous pressure (CVP).

When required, assess CVP intermittently via manual methods using a bedside saline manometer or transducer moved between multiple patients as needed, or by height of blood column in CVP line held vertically while patient is supine.

Emphasize oral hydration instead of IV hydration when possible.

Utilize appropriate oral rehydration solution

Oral rehydration solution: 1 liter of water (5 cups) + 1 tsp salt +8 tsp sugar, add flavor such as 1/2 cup orange juice, as necessary.

Rehydation for moderate dehydration = 50-100ml/kg over 2 to 4 hours.

Pediatric hydration

Pediatric maintenance fluids:

4ml/kg/h for first 10kg of body weight (40ml/hr for 1st 10 kg).

2 ml/kg/hr for second 10kg of body weight (20 ml/hr for 2nd 10 kg = 60ml/hr for 20kg child.)

1 ml/kg/h for each kg over 20 kg (60ml/hr plus 20ml/hr = 80ml/hr

Supplement for each bout of diarrhea or emesis.

Note: Clinical (urine output, etc. and laboratory (BUN, urine specific gravity) assessments and electrolyte correction are key components of fluid therapy and are not specifically addressed by these recommendations. For further information and examples, see http://www.ped.med.utah/cai/howto/IntravenousFluidOrders.PDF

Provide Nasogastric Hydration instead of IV hydration when practical.

Patients with impediments to oral hydration may be successfully hydrated and maintained with nasogastric tubes.

For fluid support, 8-12 f tubes (pediatric infant 3.5 f, <2yrs 5f) are better tolerated than standard sized tubes.

Substitute Epinephrine for other vasopressor agents

For hemodynamically unstable patients who are adequately volume resuscitated, consider adding 6mg epinephrine (6ml of 1:1,000) to 1000ml NS on minidrip tubing and titrate to target blood pressure.

Epinephrine 1:1000 (1mg/ml) multi-dose vials available for drip use.

Re-use CVP, NG and other supplies after appropriate sterilization/disinfection

Cleaning for all devices should precede high-level disinfection or sterilization.

High-level disinfection for at least twenty minutes for devices in contact with body surfaces (including mucous membranes); gluteraldehyde, hydrogen, peroxide 6%, or bleach (5.25%) diluted 1:20 (2500ppm) are acceptable solutions.

Note: Chlorine levels reduced if stored in polyethylene containers. Double the bleach concentration to compensate.

Sterilize devices in contact with bloodstream (e.g., ethylene oxide sterilization for CVP catheters.

Intraosseous/Subcutaneous (hypodermoclysis) replacement fluids

Consider as an option when alternative routes of fluid administration are impossible/unavailable.

Intraosseous before percutaneous.

Intraosseous

Intraosseous infusion is not generally recommended for hydration purposes, but may be used until alternative routes are available. Intraosseous infusion requires a pump or pressure bag. Rate of fluid delivery is often limited by pain of pressure within the marrow cavity. This may be reduced by premedication with lidocaine 0.5 mg/kg slow iv push.

Hypodermoclysis

Cannot correct more than moderate dehydration via this technique.

Many medications cannot be administered subcutaneously.

Common infusion sites: pectoral chest, abdomen, thighs, upper arms.

Common fluids: normal saline (NS), D5NS, D5 1/2 NS (Can add up to 20-40 mEq potassium if needed.)

Insert 21-24 gauge needle into subcutaneous tissue at a 45-degree needle. Adjust drip rate to 1-2 ml per minute. May use 2 sites simultaneously if needed.

Maximal volume about 3 liters/day: requires site rotation.

Local swelling can be reduced with massage to area.

Hyaluronidase 150 units/liter facilitates fluid absorption but not required; may not decrease occurrence of local edema.

Consider use of veterinary and other alternative sources for intravenous fluids and administration sets.

Blood Products

Health care Facility Recommendations

Packed Red Blood Cells

Use cell-saver and auto-transfusion to degree possible.

Limit O negative use to women of child-bearing age.

Use O positive in emergent transfusion in males or non-child bearing females to conserve O negative.

More aggressive crystalloid resuscitation prior to transfusion in shortage situations (blood substitutes may play future role).

Long term shortage, collect autologous blood pre-operatively and consider cross-over transfusion.

Enforce lower hemoglobin triggers for transfusion (for example, HGB 7).

Consider use of erythropoietin (EPO) for chronic anemia in appropriate patients.

Further limit PRBC use, if needed, to active bleeding states, consider subsequent restrictions including transfusion only for end organ damage, then shock states only.

Consider limits on use of PRBCs (for example, only initiate for patients that will require <6 units PRBCs and/or consider stopping transfusion when >6 units utilized).

Fresh Frozen Plasma

Though not a true substitute, consider use of fibrinolysis inhibitors or other modalities to reverse coagulopathic states (tranexamic acid, aminocaproic acid, activated coagulation factor use, or other appropriate therapies).

Consider reduction in red cell: FFP ratios in massive transfusion protocols in consultation with blood bank medical staff.

No anticipatory use of FFP in hemorrhage without documented coagulopathy.

Platelets

Though not a true substitute, consider use of desmopressin (DDAVP) to stimulate improved platelet performance in renal and hepatic failure patients.

Transfuse platelets only for active bleeding; further restrict to life-threatening bleeding if required by situation.

No prophylactic use of platelets.

Blood Bank Recommendations

All Blood Products

Increase donations if required, and consider local increase in frozen reserves.

Increase O positive levels.

Consider maintaining a frozen blood reserve if severe shortage.

Increase recruitment for specific product needs.

Consider adjustments to donor HGB/HCT eligibility.

Relax travel deferrals for possible malaria and BSE (bovine spongiform encephalitis) (FDA approval/variance required via American Association of Blood Banks).

Packed Red Blood Cells

Change donations from whole blood to 2x RBC apheresis collection if specific shortage of PRBCs.

Reduce or waive usual 56 day inter-donation period (FDA approval/variance required via American Association of Blood Banks) based upon pre-donation hemoglobin.

Reduce weight restrictions for 2x RBC pheresis donations according to instruments used and medical director guidance. (FDA approval/variance required via American Association of Blood Banks).

Fresh Frozen Plasma

Obtain FDA variance to exceed 24 collections per year for critical types (FDA approval/variance required via American Association of Blood Banks).

Platelets

May use leukoreduced whole blood pooled platelets (and, if required, consider non-leukoreduced whole blood pooled platelets).

Convert less needed ABO whole blood to apheresis.

Accept female platelet donors without HLA antibody screen.

Apply for variance of 7 day outdate requirement (FDA approval/variance required via American Association of Blood Banks).

Consider a 24 hour hold until the culture is obtained and immediate release for both Pool and Apheresis.

Obtain FDA variance to allow new Pool and Store sites to ship across state lines. (FDA approval/variance required via American Association of Blood Banks).

Reduce pool sizes to platelets from 3 whole blood donations.

Based upon documents from the Minnesota Health care System Preparedness Program.

End of Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines