**DHHS/ Maine CDC**

**All Hazards**

**Emergency Operations Plan**

**Annex: Crisis Standards of Care**

**June 2017**

**Approval and Implementation Document**

**State of Maine**

**Department of Health and Human Services**

**Maine Center for Disease Control and Prevention**

**All Hazards Emergency Operations Plan**

**Annex: Crisis Standards of Care**

This Plan is hereby approved for implementation.

This Plan supersedes any and all previous editions.

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Sheryl Peavey, Chief Operating Officer Date

Maine Center for Disease Control and Prevention

**DHHS/Maine CDC Crisis Standards of Care Annex to EOP**

**Record of Changes**

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**Annex: Crisis Standards of Care**

# Introduction

The Maine CDC Crisis Standards of Care Plan and Guidelines were developed by a statewide Task Force initiated by the DHHS/Maine CDC with broad representation from stakeholders including but not limited to physicians and nurses, first responders, public health officials, attorneys, administrators, and state government officials. The Guidelines were developed within the framework of sound ethical principles.

The intent of the development of the Crisis Standards of Care by a group of subject matter experts across Maine is to firmly establish and define standards of care that would guide the provision of clinical care/decision making in Maine within the context of extreme scarce medical resources and the declaration of a public health emergency. This is to distinguish these standards of care as distinct from the standards of care that would guide clinical care/decision making under ordinary circumstances. These standards are considered appropriate for extreme austere circumstances only; a situation where business as usual would be inappropriate.

The Crisis Standards of Care (CSC) Plan describes the conditions required for activation of the CSC Plan and the process by which the CSC Plan would be activated.

The accompanying CSC Guidelines provide Maine health care providers with guidance in the event that there is a declared public health emergency that includes an extreme and prolonged lack of medical resources including: space, supplies and equipment and/or health care personnel within the context of catastrophic medical resource need. For example, in a situation similar to the 1918 Pandemic, envision that 100 people need ventilators and you have 10 ventilators. Which people receive the needed ventilators?

The clinical guidelines are designed to ensure the most benefit to the largest number of people by distributing scarce resources to those individuals who have a high likelihood of achieving significant benefit from the medical resources available.  Those people not receiving needed medical resources would receive comfort care. Crisis Standards of Care would be discontinued as needed medical resources become available.

# Purpose, Scope, Situation, Plan Format and Distribution, Planning Assumptions

## Purpose

The Crisis Standards of Care Plan describes the activation process and the roles and responsibilities of the State and other partners in such an event. The accompanying Crisis Standards of Care Guidelines are intended to allow health care providers the ability to redistribute scarce resources away from patients that either will live, even without the resources, or will expire, despite having the resources. There is a continuum of the provision of health care from standard care to contingency levels of care to crisis standards of care. The Crisis Standards of Care Guidelines are intended to describe the assignment of the limited available resources to those patients that will perish if they do not receive the resources, but will likely survive if they do receive the resources. Further, as an example, if ten patients are in need of a ventilator, and only six ventilators are available, an equitable, measurable, reproducible scoring system that is completed or confirmed by an impartial physician (or team of health care providers, including at least one physician) will determine which six of the ten patients have the highest probability of surviving whenever possible. These six patients will receive the life-saving ventilators. The remaining four will be provided with appropriate and compassionate end-of-life care unless additional resources become available.

## Scope

The Crisis Standards of Care Plan is led by the Maine CDC and is applicable to the Maine CDC and other partners and agencies involved in a response to an event leading to a severe lack of healthcare resources. The Plan is to be implemented when a catastrophic event has caused an overwhelming number of injured or ill persons and the fatality rate is mounting due to a lack of life-saving resources.

The overall functional objectives of this Plan are to delineate the roles and responsibilities of the Maine CDC and its response partners in the event of a catastrophic PH emergency requiring the activation of the CSC Plan provide guidance to healthcare facilities regarding the implementation of the CSC Guidelines. The Plan addresses the following:

* Assessing the overall situation which is causing the health care crisis
* Assessing the specific lack of resources state-wide and determine the potential time required and amount needed for resupply
* Determining the point at which the CSC Plan would be activated.
* Developing information to be used during catastrophic events to assist in the communication with the public, patients, family members, and others who are being impacted either directly or indirectly by the crisis.
* Discussing the ethical considerations framing the Crisis Standards of Care Guidelines.
* Overviewing the relevant legal issues when implementing CSC.

The accompanying CSC Guidelines addresses guidance for facilities regarding:

* Moving along the continuum from conventional care to contingency care to crisis care of care based on resources available and the implications for patient care.
* Developing guidelines and training for facility based predetermined, impartial health care team empowered to make the determination regarding which patients will receive the limited resources, while other patients receive appropriate and compassionate end-of-life-care.
* Selecting the applicable health scoring systems for use in the pre-hospital, emergency department, critical care and other areas or settings.

## Situation

On most days, health care is provided by a complex system of entities that ranges from the receipt of a 9-1-1 phone call, to the provision of care by volunteers and paid professionals within the emergency medical system, to an admission to an emergency department and subsequent care provided in medical or surgical units or intensive care units. Daily care is also provided by community-based providers which may include individual practices, medical groups, and community health care centers, out-patient services from a local or regional hospital, long term care, or home care.

There are many times when there is a lack of resources. These events are resolved by utilization of surge plans by health care facilities. Additional staff is enlisted; reserved resources are allocated; alternate or non-traditional spaces are made available. Within a fairly reasonable period of time, the shortage is resolved and the ability to provide routine levels of care returns.

At times, there is a shortage of a needed resource which cannot be met through the Medical Surge Plan. This could include health care staff, available space for the provision of care, or needed medical or surgical supplies or equipment. As the resource continues to become limited, operational plans will need to transition from the standards of daily care to contingency standards of care, for example: pre-hospital patients may need to wait longer for an available ambulance; patients in the ED may need to wait on stretchers in a hall until a treatment room is available; patients may also need to wait until a room in a hospital or ICU becomes available; patients who should be treated with a first-line medication may need to be treated with a second or third choice medication; patients who need surgery may need to wait until an OR suite and appropriate surgical team are available. Health care is provided to all persons, to the highest degree possible albeit not to the normal level of anticipated standards.

When the resources become extremely limited either due to a lack of supply or an overly high demand for the resource, a health care crisis may develop. The efforts encountered during the contingency period are not likely to be successful in resolving the disproportionate equation where demand outweighs resources. As the severity of this imbalance becomes more extreme, health care administrators and providers will need to determine which patients will receive the limited available resources. The Crisis Standards of Care Guidelines are designed to assist in making these decisions.

## Plan Format and Distribution

The Crisis Standards of Care Plan is an Annex to Maine’s Public Health Emergency Operations Plan (Public Health EOP). In turn, Maine’s Public Health EOP serves as Annex H. Public Health and Safety, Medical Services, Mortuary and Mass Fatality to Maine’s Comprehensive Emergency Management Plan (CEMP). This plan complies with the National Incident Management System and will be integrated with existing incident response systems.

The Plan and associated Guidelines will be shared with representatives of partner agencies and organizations. Otherwise, each agency involved with executing the Plan will be provided with the portion(s) that pertain to that agency. Appendices and Annexes will be provided only to those agencies and organizations with a specific need-to-know. (Note: dissemination plan to be developed)

## Planning Assumptions

1. A major disaster event occurs which leads to a severe and continued lack of a medical resource which could include staffing, material, or space. There could be a lack of the resource, or an extreme increase in the number of patients needing the resource.
2. The lack of the resource results in a crisis within the health care delivery continuum which results in an increase in morbidity and/or mortality among a large number of patients.
3. Adequate alternatives for the limited resources will not be available in such a period of time as to prevent further injury, illness, or death.
4. All local, regional, and broader reaches for the limited resources will be inadequate. The situation may be the result of a lack of the resource itself or the inability to deliver the resources to the needed area due to failure of transportation or other factors.
5. Health care administrators and providers will lack the resources to limit the crisis and resolution will not occur soon enough to prevent further loss of life.
6. All agencies responding to a CSC situation will utilize non-approved drugs or device following an FDA issued emergency use authorization.

# Understanding Crisis Standards of Care

## Core Principles for the Maine CSC Plan

Five key elements underlie the CSC Plan:

* A strong ethical grounding that enables a process deemed equitable and just based on its transparency, consistency, proportionality, and accountability;
* Integrated and ongoing community and provider engagement, education, and communication;
* The necessary legal authority and legal environment in which CSC can be ethically and optimally implemented[[1]](#footnote-1);
* Clear activation and coordination processes, and lines of responsibility; and
* Evidence-based clinical processes and operations.

# Activation and Coordination Process

|  |  |
| --- | --- |
| **Disaster occurs and escalates to crisis level** | **Conditions for Statewide CSC Include:**-The Governor has proclaimed a state of emergency -Resources are unavailable/undeliverable for a unknown period of time to healthcare facilities-Patient transfer not possible, at least in the short term-Access to medical countermeasures is likely to be limited-Supply caches have been distributed, no short term resupply-Multiple healthcare access points are impacted |
| **Governor considers Statewide CSC Activation** | **Considerations for Statewide CSC Activation:**-Healthcare Coalition and other healthcare partner organizations provides information to Maine CDC which leads to a Maine CSC recommendation to Maine DHHS Commissioner to request the Governor activate CSC-The Maine DHHS Commissioner recommends to the Governor’s Office the activation of the CSC Plan-Maine DHHS Commissioner evaluates any local, state, federal disaster declarations that may be in place |
| **Governor proclaims the Activation of CSC** | **CSC Activation Steps**-Governor proclaims the use of the CSC plan-Maine CDC staff notifies other local, state, tribal, and federal partners-Maine CDC works with public information officers and /or Joint information center (JIC) to distribute messaging |
| **Ongoing Response Coordination** | **Maine CDC Activities**-Maintain regular communication with response partners (e.g. Regional Resource Centers (RRC), Department of Public Safety, Maine Emergency Management Agency (MEMA), Dispatch Centers)-Evaluate the effectiveness of protocols and priorities and availability of resources throughout the response-Evaluate the suspension of regulations for use of equipment/countermeasures-Identify threshold(s) for the suspension or rescinding of CSC and resumption of contingency or conventional care-Maine CDC monitors status of healthcare entity situations through situational awareness information reported up from the RRCs |
| **Crisis Standards of Care Rescinded** | **Maine CDC Activities**-In close collaboration and communication with response partners, the Maine CDC will determine when the threshold is reached for discontinuing the CSC-The Maine CDC will recommend to the Maine DHHS Commissioner that he/she will recommend to the Governor to discontinue CSC activation and return to contingency or conventional methods |

* Except for the Governor’s state of emergency declaration, not every condition must be met for the crisis standards of care plan to be activated

# Responsibilities

## All state agencies will respond in accordance with their agency’s Emergency Operations Plan (EOP).

## State agencies may need to take on additional roles and responsibilities unique to CSC including but not limited to:

* 1. Governor:
* Signs proclamation of PH emergency; proclaim activation, and deactivation of CSC plan/guidelines
* Has the authority to leverage additional non-State resources, such as acquiring items from retail store, as indicated in the proclamations
	1. DHHS Commissioner:
* Recommends proclamation of a public health emergency to the Governor based on recommendation from Maine CDC
* Recommends activation and deactivation of the CSC plan to the Governor based on recommendation from Maine CDC
	1. Maine CDC:
* Public Health Emergency Preparedness Public Health Incident Command Center (PHEP PHICC):
	+ - * Assess situation and determine need for and recommendation of a proclamation of PH emergency as well as the activation and deactivation of  the CSC Plan
			* Coordinate with the commissioner’s office and governor’s office to write the proclamation and the waivers
			* Activate PH ICC to lead the PH response
			* Situational awareness, information sharing, public information messaging, manage any available resources, monitor CSC implementation
			* Ensure that all FDA emergency use authorizations for non-approved drugs or devices
* Infectious Disease/Epidemiology:
	+ - * Conduct heightened disease surveillance (review of data to identify escalation and decline)
* Health Environmental Testing Laboratory:
	+ - * Conducts laboratory sampling and analysis
* District Liaison:
	+ - * Provide situational awareness, information sharing,
			* Manage available community resources
			* Assist with the community comfort care centers
* Public Health Nurses:
	+ - * Provide healthcare to community members
* Disaster Behavioral Health:
	+ - * Assist with addressing stress and coping, grieving, fear and anxiety in the general public, patients, family members, caregivers, clinicians, and responders
			* Continue to provide care for those with mental illnesses and/or acute episodes of mental illness
* Volunteer Management:
	+ - * Recruit additional volunteers
			* Verify credentials and run background checks on volunteers
			* Deploy volunteers
			* Demobilize volunteers
	1. Department of Licensing and Regulatory Services:
* Review facility related licenses and consider waiving state regulations and standards
* Consider request licensing and standard waivers from Federal agencies
	1. Attorney General Office:
* Provide legal guidance
* Assist with writing declaration and waiver language
* File necessary petitions
* Assist with enactment of emergency rules
	1. Various licensing boards:
* Board of Medicine: Provide emergency license to any Medical Doctor for 100 days
* Board of Nursing: Provide temporary license to nurses from compact states
* The roles and responsibilities of the Boards of Veterinary Medicine, Osteopathy and Pharmacy will be further explored.

C. **Non-state Agencies; External Partners**

* 1. Regional Resource Centers:
* Provide situational awareness
* Gather and dissemination information
* Provide regional resource coordination and management
	1. Hospitals:
* CSC implementation of process and clinical guidelines
* Provide public information messages
	1. Long Term Care Centers:
* CSC implementation of process and clinical guidelines
* Provide public information messages
	1. Home Health Care Agencies:
* CSC implementation of process and clinical guidelines
* Provide public information messages
	1. Federally Qualified Health Centers:
* CSC implementation of process and clinical guidelines
* Provide public information messages
	1. Hospice:
* CSC implement comfort care guidelines
* Provide public information messages
	1. Community Mental Health Centers:
* Assist with addressing stress and coping, grieving, fear and anxiety in the general public, patients, family members, caregivers, clinicians, and responders
* Continue to provide care for those with mental illnesses and/or acute episodes of mental illness
	1. Maine Department of Public Safety, Emergency Medical Service:
* Respond to CSC event using established agency protocols
	1. Department of Defense, Veterans and Emergency Management, Maine Emergency Management Agency:
* Provide logistical support /coordination
* Provide security
* Assist with fatal management
* Assist with mass care efforts and provide assistance to American Red Cross comfort care centers
	1. County EMAs:
* Provide local logistical support
* Gather and disseminate information
	1. Medical Examiner:
* Provide mass fatality management
* Assist with decedent identification
* Identify locations for and assist with temporary internment
	1. Funeral Home Directors:
* Assist with mass fatality management
* Expedite processing of deceased
	1. Crematorium:
* Assist with mass fatality management
* Expedite cremation of deceased
	1. State National Guard:
* Assist with logistical, transportation and security needs
	1. Department of Transportation:
* Assist with transportation, logistical and material management needs
	1. Department of Public Safety, Maine State Police:
* Provide security
* Assist with the protection assets
* Control public unrest
	1. 2-1-1 Maine:
* Coordinate with Maine CDC to provide information and messaging to the public
	1. NE Poison Control Center:
* Manage and authorize use of Strategic National Stockpile assets and pharm cache assets
* Provide information on medical countermeasure dosing and formulation
* Establish an afterhours call center
	1. Pharmacists:
* Provide clinical expertise/advice on medication substitutions
* Provide vaccination
	1. Maine Hospital Association:
* Interface with hospitals
* Gather and disseminate information
* Coordinate and share information with PHICC
	1. Maine Medical Association:
* Interface with physicians
* Gather and disseminate information
* Coordinate and share information with PHICC
	1. Volunteers Active in Disasters (e.g. Civil Air Patrol, Coast Guard Auxiliary, Faith Based Organizations)
* Coordinate with the Maine CDC to provide assistance during a CSC response

# Legal / Government Administrative Considerations/Actions (The following text discussing legal issues relative to CSC is excerpted from a document prepared by Maine Assistant Attorney General, Deanna White; the full text is available in Appendix C)

## Legal and Regulatory Issues

The legal, regulatory, and accreditation implications of initiating a triage algorithm that allocates scarce resources to select patients (CSC) is daunting and should occur only in accordance with the law and in conjunction with plans established before the crisis. Maine’s proposed CSCs are predicated on the declaration of an extreme public health emergency.

##  Extreme Pubic Health Emergencies and Emergency Response.

*Executive Orders.* In an extreme public health emergency, when the CSC guidelines are triggered, it is likely that some temporary modifications of regulatory and legal requirements for health care providers and the hospitals will be necessary.

In a declared extreme public health emergency, the Governor can take certain actions pursuant to Executive Orders. Title 37-B MRS §742(C)(1)provides that the Governor, in a declared public emergency can:

* Suspend the operation of any statute prescribing the procedures for the conduct of state business, and suspend the order or rules of a state agency, if strict compliance with those would prevent, hinder or delay necessary action in coping with the emergency.

Other powers available to the Governor include:

* The ability to take property, supplies and materials by eminent domain (with reasonable compensation);
* The ability to enlist the aid of any person to assist in the effort and aid in the caring for the safety of persons; and
* Evacuate all or part of the population as necessary for the preservation of life or other disaster mitigation, response or recovery. 37 MRS §742(1)(C).

These provisions do not allow the Governor to enact new laws, or change non-statutory law (such as tort law). The Governor also would not have the authority to affect any federal requirements.

*Hospital licensure and payment.* State hospital licensing rules directly apply some of the same requirements of CMS, which are federal standards. While the Governor could lift or modify the state rules, this may have a different effect on licensure versus reimbursement. For example, a hospital might not need to worry about losing its state license, but that does not automatically mean they would meet federal reimbursement regulations.

* Because a state Governor cannot lift federal requirements, it would be important in a CSC situation for entities to seek a waiver to the Emergency Medical Treatment & Labor Act (EMTALA). This is done by way of a Social Security Act Section 1135 waiver. Section 1135 of the SSA states the authority of the Secretary of federal DHHS to waive numerous federal requirements during national emergencies.
* Similarly, other federal EMTALA requirements (like accepting everyone into ER that needs medical attention, doing the evaluation, stabilizing before transfer, etc.), would need to be part a waiver process since they could affect both licensing and payment.
* Standards that pertain to space, equipment, and physical facilities may have to be altered such as nurse to patient care ratios and bed allotment.

 *Scope of practice.* Currently, Maine law protects volunteer health care practitioners only when they are providing services within the scope of their licensure. 24 MRS §2904.

* It may be helpful to grant permission to certain professionals on a temporary and emergency basis to function outside their usual scope of practice. Some states have enacted statutes that broaden a health care licensee’s allowed scope of service during an emergency.

In Maine most of our liability protections are geared towards people operating within the scope of their employment or license:

* Any expansion of permissible scope of practice would require legislative changes.

Another issue is that most health care professionals do not have a clearly defined “scope of practice.” Rather most of them have a core set of competencies along with a (sometimes long) list of things they can do if appropriately trained, or if supervised.

* Maine may choose to use “just in time training” and granting “privileges” versus “expanded scope of practice,” since there is no “defined” scope of practice for health care professionals.  Thus in a declared public health emergency, licensed professionals would be allowed to do everything they can usually do, plus [just in time] training could be used to increase competencies needed for that particular emergency.

*Employment.* Title 26 MRS §875 regarding employment during extreme public health emergencies may need clarification or lifting by the Governor depending on the nature of the emergency. This would especially affect health care providers who would be on the front line and most vulnerable during an extreme public health emergency.

Also, in an extreme public health emergency, the Commissioner of DHHS may take certain actions. Title 22 MRS §820 outlines the powers of the Maine DHHS Commissioner during an extreme public health emergency. These include the authority to:

* Get health information directly from providers;
* Take people into custody and order prescribed care for up to 48 hours without a court order (when they constitute a serious and imminent risk to public health and safety);
* Implement rules (emergency major substantive) to address the risk or potential risk of a shortage of health care workers, and
* Implement rules (emergency major substantive) to address the need for dispensing drugs in an emergency situation.

Finally, the other significant powers DHHS has for the control of notifiable diseases and conditions remain in effect during any public health emergency. 22 MRS Chapter 250(§§801-835; 10-144 CMR Chapter 258. These laws provides for:

* Ongoing surveillance of notifiable conditions, and
* Provide for court ordered evaluations, hospitalization, and enforcement of any other requirements necessary to protect the public from a public health threat.

 *Privacy and confidentiality.* The Health Insurance Portability and Accountability Act (HIPAA) and Maine’s confidentiality of healthcare information laws do not prevent free flow of information necessary to provide health care. This would not change during an emergency. Title 22 MRS §1711-C states in part: “**…**A health care practitioner or facility may disclose, or when required by law must disclose, health care information without authorization …to another health care practitioner or facility for diagnosis, treatment or care of individuals or to complete the responsibilities of a health care practitioner or facility that provided diagnosis, treatment or care of individuals, as provided in this paragraph…..”

* Two areas where Maine confidentiality laws are more protective than federal law of confidentiality are HIV and mental health care. The Governor could lift those extra protections through an Executive Order.
* Similarly, some HIPAA requirements, such as the need to obtain patient consent to speak to family members or friends could be part of a SSA Section 1135 waiver.

 *Documentation of care*. Minimal acceptable levels of documentation of care provided to an individual may have to be established, both for purposes of patient care quality and as the basis for reimbursement from third-party payers.

* Contractual requirements of a third-party, such as an insurance company, would have to be addressed or modified with that party.

 *Federal Law.* The President and federal agencies have similar powers at the federal level. In any extreme public health emergency the federal government would likely be playing a significant part. In addition to the statutes and regulations already mentioned, there are other federal laws that could apply, most of them having state counterparts:

* Emergency Management Assistance Compact (EMAC)
* International Emergency Management Assistance Compact (I-EMAC)
* Federal Public Readiness and Emergency Preparedness Act
* Robert T. Stafford Disaster Relief and Emergency Assistance Act
* Post Katrina Emergency Management Reform Act
* Federal Volunteer Protection Act

## Immunity Laws Related to Crisis Standards of Care

 *Civil Immunity.* When using the CSC Plan during an extreme public health emergency, when state workers, volunteers, and health care providers would be working under extremely stressful and demanding circumstances, consideration of legal immunity is important. There are a number of Maine statutes and legal standards to consider.

* The Maine Tort Claims Act (MTCA) provides protection for state employees, like Public Health Nurses and employees of the Maine Emergency Management Agency (MEMA). The MTCA has a broad definition of “employee.” It includes persons acting on behalf of a government entity, temporarily or permanently, whether or not compensated, including volunteer firefighters, emergency medical service personnel and member of the Maine National Guard on active duty. 14 MRS §8102(1). It provides absolute immunity for discretionary acts, and greatly limits liability of a state employee (and the State) for negligent acts committed during the scope of employment.
* There is a federal law based on principles of sovereign immunity that provides similar protections for federal employees and the federal government. The federal tort claims act covers staff and facilities of Federal Qualified Health Centers and U.S. military hospitals.

The MTCA (and the federal equivalent) protects against civil lawsuits for negligent or intentional acts done within the state or federal employee’s scope of employment. It does not provide protection for intentional torts or acts that violate criminal statutes. There are also federal laws (Section1983 of the Human Rights Act) that protect individuals from governmental wrongdoing that violates people’s civil rights.

 MEMA can provide some legal protections for health care providers who they designate to be members of emergency management forces during an emergency.

* The Maine Emergency Management Agency may employ any person considered necessary to assist with emergency management activities. Any person called and employed for assistance either within the State or in another state under chapter 16 or in a Canadian province under chapter 16-A is deemed to be an employee of the State for purposes of immunity from liability pursuant to section 822.
* A person holding a professional license in the State may be designated a member of the emergency management forces in that professional capacity only after the individual or the license issuer provides confirmation of a valid license. 37-B MRS §784-A.

 *Volunteers.* Maine also currently has several laws that provide some immunity for persons *volunteering* to help during an extreme public health emergency. The broadest one is 24 MRS §2904. There is a similar law at the federal level – the Volunteer Protection Act of 1997.

 Maine’s “Good Samaritan Law” is at 14 MRS §164. This section shall not apply if such first aid or emergency treatment or assistance is rendered on the premises of a hospital or clinic.” These laws protect against suits for ordinary negligence, but do not cover gross negligence (recklessness) or intentional acts, or violations from criminal laws.

 More provisions to protect volunteer health care providers and licensed professionals, as well as officers and employees of compact states, are found in Maine’s version of the Emergency Management Assistance Compact (EMAC) – 37-B MRS Chapter 16 (§§921-933).

 There are similar provisions in the International Emergency Management Assistance Compact, 37-B MRS Chapter 16-A(§§935-947). (See Appendix Legal Issues for full discussion regarding legal protection for volunteers)

(See Appendix Legal Issues for the full discussion regarding civil immunity)

 *Employed health care providers.* In contrast, statutory protections for health care employees at hospitals, and the hospitals themselves are more limited. (See Appendix Legal Issues for additional discussion)

 *The Standard of Care*. Otherwise, private health care providers are held to the regular standard of care,which consists of parameters established by case law (and some statutes) that outline the duty owed by a health professional to a patient. It is important to note that during a public health emergency the standard of care would be different under tort law, even if no “crisis standards of care” were adopted. In Maine as in other states, the standard of care takes into account the surrounding circumstances. As the Maine Supreme Court has put it, “**a doctor should use ‘the ordinary skill of members of [the]profession in like situation … exercise ordinary or reasonable care and diligence in [the treatment of the case, and … use his [or her] best judgment in the application of … skill to the case.**” *Brawn v. Oral Surgery Associate*s, (2003 ME 11) ¶17, *emphasis added, further citation omitted*. While the standard of care does not provide protection for gross negligence (recklessness); intentional (willful) conduct or violations of criminal law, it likely provides some protection for triage and allocation of resource decisions made during the course of an extreme public health emergency when critical resources are scarce. In addition,

* The Maine legislature could broaden the scope of immunity statutes to cover private institutions and health care providers during an extreme public health emergency, as some other states have done.

 In addition, most hospitals and health care professionals protect themselves against these risks through liability and damage insurance. These policies offer varying protections for emergency situations. They generally cover liability for negligence but not intentional torts or criminal activity.

Moreover, to the extent hospitals and providers have Memoranda of Understanding with other providers, and vendors, those should be followed to help protect the providers.

 *Criminal liability.* In addition to civil liability some parts of the CSC Plan require consideration of criminal liability. Parts of the plan set up a method for “re-allocating” scarce resources during an extreme public health emergency. These “re-allocations” can result in “withdrawing a critical resource” from a person who is likely not going to survive, and giving that resource to someone else who is both more likely to survive with the resource, and who would most likely die without it. An example is taking a patient off a ventilator to give it to another patient, when the person doing so knows it will result in the death of the first patient. This process would result in considered actions that would result in death to the individual who is removed from the critical resource. Maine, like most states, has criminal statutes designed to criminalize such behavior, and there are no exceptions or defenses that would cover the re-allocation of a critical medical resource during an extreme public health emergency. 17-A MRS §§35, 201, & 203. Such activity would normally require the consent of the patient or their authorized representative.

* Before this part of the CSC Plan can be activated, statutes providing improved immunity to health care providers (whether employed, volunteer, or governmental) from civil or criminal liability for actions taken pursuant to the CSCs need to be enacted.
* Such laws also need to protect professionals taking such “re-allocation” actions from complaints regarding their licenses to practice.

# Finance

Each Maine CDC division directors will submit reports/ledgers to the Maine CDC PHICC Finance Section Chief relating to their department’s expenditures and obligations during the emergency situation as prescribed by the Department of Emergency Management and Homeland Security. All original documents will be forwarded to the Planning Section Chief for the official record. A financial report will be compiled, analyzed and submitted to DHHS for possible reimbursement following the event.

When local and state resources prove to be inadequate during emergency operations, requests should be made to obtain assistance from the Region I Emergency Coordinator and other agencies in accordance with existing mutual aid agreements and understandings including the Emergency Management Assistance Compact (EMAC) and International Emergency Management Assistance Compact (IEMAC), or any real time emergency negotiated agreements.

# Plan Maintenance and Evaluation

The CSC Plan shall be maintained and evaluated in accordance with the DHHS/Maine CDC All Hazards Emergency Operations Plan.

# Communication and Education Plan

A healthcare training is being developed to provide healthcare workers with orientation regarding the need for a CSC plan, Maine’s CSC Plan and associated roles and responsibilities of healthcare providers, organizations and agencies. The orientation training will be provided through the Regional Resource Centers may also be shared at the onset of an event in order refresh healthcare provider’s understanding of a CSC event and the associated Maine plan principles.

Public information templates will be developed for Maine CSC to customize and use at the onset and during a CSC event to educate the public about a CSC implications and provide an overview of the State response.

# Appendix

A. Acronyms

B. Ethical Considerations by Frank Chessa, Medical Ethicist, Maine Medical Center

C. Legal Issues by Deanne White, Maine Assistant Attorney General

D. Hospitals

1. Maine CSC Hospital Plan Template
2. Maine CSC Hospital Committee
3. Maine Strategies for Allocating Scare Resources (Cards sent previously)
	1. Oxygen
	2. Staffing
	3. Nutritional Support
	4. Hemodynamics Support and IV Fluids
	5. Mechanical Ventilation / External Oxygenation
	6. Renal Replacement Therapy
	7. Lack of Physical Space
	8. Critical Shortage of Personnel

E. Non-Hospitals

1. Non-Hospital CSC Plan Templates
2. Non-Hospital Healthcare Standards of Care (Community Health Care Centers, Home Care, Hospice, Long Term Care Facilities)
3. Staffing
4. Supplies and equipment
5. Space Assessment Tools
6. Standing Orders

F. Behavioral Health Plan

1. The Taskforce reviewed the State of Maine’s Behavioral Response Plan and determined that the existing state plan will be used for a CSC situation.

The State Behavioral Health Plan can be found here:

[**http://www.maine.gov/dhhs/mecdc/public-health-systems/phep/documents.shtml**](http://www.maine.gov/dhhs/mecdc/public-health-systems/phep/documents.shtml)

G. Comfort Care Center Plans (TBD)

Space

Trigger Points

Resources

Mental Health

Appendix A: Acronym List (In process)

|  |  |
| --- | --- |
| CSC | Crisis Standard of Care |
| CDC | Center for Disease Control |
| CEMP | Comprehensive Emergency Management Plan |
| COBRA | Consolidated Omnibus Budget Reconciliation Act |
| DHHS | Department of Health of Human Service |
| ED | Emergency Department |
| EDRS | Electronic Death Registration System |
| EIRRA | EMS Incident Response and Readiness Assessment |
| EMA | Emergency Management Agency |
| EMAC | Emergency Management Assistance Compact |
| EMS | Emergency Medical Service |
| EMT | Emergency Management Technician |
| EMTALA | Emergency Medical Treatment & Labor Act |
| EOP | Emergency Operations Center |
| HIPPA | Health Insurance Portability and Accountability Act |
| HVA | Hazard Vulnerability Assessment |
| ICU | Intensive Care Unit |
| I-EMAC | International-Emergency Management Assistance Compact |
| IOM | Institute of Medicine |
| JIC | Joint Information Center |
| Maine CDC | Maine Centers for Disease Control and Prevention |
| MEMA | Maine Emergency Management Assistance |
| NIMS | National Incident Management System |
| OR | Operating Room |
| PH | Public Health |
| Public Health EOP | Public Health Emergency Operations Plan |
| RRC | Regional Resource Center |
| SME | Subject Matter Expert |

Appendix B: Ethical Considerations

Prepared by Frank Chessa PhD, Medical Ethicist, Maine Medical Center

* Ethical Considerations

The Maine Crisis Standards of Care Taskforce recognizes its duty to serve the people of Maine by careful reflection on the ethical complexities and challenges that arise in planning for and responding to a crisis. While priorities may shift during a crisis, the ethical requirements for clinicians, first-responders and others are not relaxed. Indeed, responding to a crisis requires the moral courage to be our best selves. The Institute of Medicine suggests an ethical framework, as well as ethical questions that should be decided at a local level. This report follows the IOM framework, simplifying and adapting it to Maine’s needs (as is recommended in the IOM report itself).

**Ethical principles that guide response to crises:**

**Transparency**: Public trust depends on members of the public understanding the reasons why disaster response is organized in a certain manner. For example, if it is widely known that a vaccine preventable disease is life threatening primarily in infants and the elderly, then the policy of distributing scare vaccine supplies to these populations will make sense. Similarly, policies that favor first-responders and clinicians are justifiable if it is clear that the purpose of the policies is to preserve the community’s ability to respond to others in need. In addition to being open about policies and the reasons for adopting them, transparency requires a process for public input in developing the plans, and a process for revising the plans should they appear to be flawed in their implementation.

**Accountability**: Accountability is also important to promoting trust. Those planning for and responding to a crisis should not be viewed as free from ethical and legal standards, as if in a crisis individuals have complete autonomy to act as they desire. Rather, individuals are responsible for acting in accord with the standards that have been established to deal with the crisis.

**Duty to care**: Health care professionals have a duty to care for persons in medical need and this duty extends to crisis situations. However, it is recognized that health care professionals have other duties (to care for one’s minor children, for example) that may legitimately pull against the general duty to care. Planning efforts should address the potential conflict individuals may have in order to optimize the emergency response and clinical workforces. Finally, the duty to care extends to state agencies, health systems and other institutions: the most effective way to limit casualties in a crisis is to prepare in advance, so that first responders and clinicians on the front lines have the support they need during the crisis. Preparation requires resource expenditures, and these should be viewed as an ethically required investment in our community’s future well-being.

**Proportionality**: Measures which negatively impact a person’s rights or well-being should only be undertaken when they offer clear benefits that outweigh the burdens they impose. Examples of actions that may negatively impact a person include quarantine, school closures for social distancing, using the SOFA scale to determine access to hospital resources. The actions may be justified by their effectiveness in reducing harm during the crisis.

**Fairness (and consistency)**: A crisis may require choices about the distribution of emergency response and medical resources. Decisions should be made based on the important community goal of optimizing the well-being of community members. If one group receives favorable access to resources (for example, emergency room nurses receive a scarce vaccine), it should be because this strategy optimizes community well-being (the nurses are a critical resource to treating others sick in the epidemic). The IOM report emphasizes the ethical importance of protecting those who are most vulnerable to the crisis. While who is vulnerable will vary, the report indicates that lower socioeconomic status, lack of access to education, and lack of access to health care generally make a group more vulnerable during a crisis. The IOM report recommends increased attention to providing prevention and protection resources for such groups. Because vulnerable groups are more likely to suffer in a crisis, protecting them also supports the goal of optimizing community well-being and limiting harm to as many persons as possible. Consistency, as a corollary principle to fairness, requires that no one receive “special treatment.” That is, favorable distribution of resources to individuals or groups should occur only when it serves the overarching goal of optimizing community well-being.

**Stewardship**: Stewardship of resources takes on added importance in a time of crisis because the short- and medium-term unavailability of resources is likely to increase injuries and deaths. Efficiently using the resources that are available will save lives. Stewardship begins well-before a crisis, with practice drills, stockpiling supplies, planning for surge capacity at local institutions, organizing the efficient transport of patients to locations outside the crisis area, and relaxing rules so that responders may creatively use materials and supplies to their best efficiency. The goal in these preparations is to avoid periods of extreme scarcity. As discussed below, during a period of extreme scarcity, the principle of stewardship can generate pressing ethical challenges.

**Ethical principles in conditions of extreme scarcity**:

The purpose of planning and preparation for a crisis is to minimize the likelihood that clinicians will be forced to make tough choices in conditions of extreme scarcity. However, even with the best preparations, it may not be possible to avoid conditions of extreme scarcity. Indeed, the Crisis Standard of Care Taskforce works under the assumption that, despite the best preparations, the crisis has progressed to the point of extreme scarcity such that some persons will be disadvantaged because there are not enough resources to meet the needs of everyone in the crisis area.

In that case of extreme scarcity, stewardship and the duty to care can appear to be in conflict. In its most abstract form, the conflict can be understood in this way. Suppose that there are only 100 units of a resource. Of six patients, one patient requires all 100 units to survive, while 5 patients require 20 units each to survive. This is a tragic, morally difficult situation. It is tragic because at least one of the patients will die. It is morally difficult, because who dies will be determined by human choice, either in the moment as distribution decisions are made, or earlier because of the standard for distribution adopted by policymakers. In broad terms, the IOM report suggests that the five patients should receive the resources, because this saves as many lives as possible. The duty to care for the individual who needs 100 units is upheld in the form of non-abandonment and good palliative care. This is the consensus view among experts in disaster planning, but it is not without critics. At least some have argued that a lottery is the only way to resolve this tragic situation. The lottery removes human agency by relying on chance to determine who lives (although it is a choice to rely on chance in this way).

The Maine CSC Task Force understands the importance of working to avoid conditions of extreme scarcity by adequate planning and preparation. However, in conditions of extreme scarcity, the task force also endorses the standard of efficiently using resources with the goals of preventing as many deaths as possible and optimizing the health and well-being of the community affected by the crisis. The method for achieving these aims is detailed elsewhere in this report, but it utilizes traditional triage methods by prioritizing the delivery of life saving medical services to those who are most likely to benefit from them. This means that those who are lower risk for serious injury and death, and those who have a high likelihood of death even if they receive medical resources, have a lower priority in the distribution scheme. In addition, priority is given to providing resources to those individuals who have a crucial role in maintaining the crisis response because, again, this will is likely to result in more lives saved overall. In addition to the processes and procedures outlined in this report, the task force recognizes that some challenges during a crisis are unforeseeable and thus the ethically appropriate responses will need to be adapted to the actual details of the situation. Nonetheless, as plans are adapted in the midst of a crisis, they too should follow the general ethical principles outlined above.

Appendix C: Legal Issues

Prepared by Deanne White, Maine Assistant Attorney General

1. Legal and Regulatory Issues

The legal, regulatory, and accreditation implications of initiating a triage algorithm that allocates scarce resources to select patients (CSC) is daunting and should occur only in accordance with the law and in conjunction with plans established before the crisis. Maine’s proposed CSCs are predicated on the declaration of an extreme public health emergency.

1. Extreme Pubic Health Emergencies and Emergency Response.

*Executive Orders.* In an extreme public health emergency, when the CSC guidelines are triggered, it is likely that some temporary modifications of regulatory and legal requirements for health care providers and the hospitals will be necessary. In a declared extreme public health emergency, the Governor can take certain actions pursuant to Executive Orders. Title 37-B MRS §742(C)(1)provides that the Governor, in a declared public emergency can suspend the operation of any statute prescribing the procedures for the conduct of state business, and suspend the order or rules of a state agency, if strict compliance with those would prevent, hinder or delay necessary action in coping with the emergency. Other powers available to the Governor include the ability to take property, supplies and materials by eminent domain (with reasonable compensation); the ability to enlist the aid of any person to assist in the effort and aid in the caring for the safety of persons; and evacuate all or part of the population as necessary for the preservation of life or other disaster mitigation, response or recovery. 37 MRS §742(1)(C). These provisions do not allow the Governor to enact new laws, or change non-statutory law (such as tort law). The Governor also would not have the authority to affect any federal requirements.

*Hospital licensure and payment.* State hospital licensing rules directly apply some of the same requirements of CMS, which are federal standards. While the Governor could lift or modify the state rules, this may have a different effect on licensure versus reimbursement. For example, a hospital might not need to worry about losing its state license, but that does not automatically mean they would meet federal reimbursement regulations. Because a state Governor cannot lift federal requirements, it would be important in a CSC situation for entities to seek a waiver to the Emergency Medical Treatment & Labor Act (EMTALA). This is done by way of a Social Security Act Section 1135 waiver. Section 1135 of the SSA states the authority of the Secretary of federal DHHS to waive numerous federal requirements during national emergencies. Similarly, other federal EMTALA requirements (like accepting everyone into ER that needs medical attention, doing the evaluation, stabilizing before transfer, etc.), would need to be part a waiver process since they could affect both licensing and payment. Standards that pertain to space, equipment, and physical facilities may have to be altered such as nursing to patient care ratios and bed allotment.

 *Scope of practice.* Currently, Maine law protects volunteer health care practitioners only when they are providing services within the scope of their licensure. 24 MRS §2904. It may be helpful to grant permission to certain professionals on a temporary and emergency basis to function outside their usual scope of practice. Some states have enacted statutes that broaden a health care licensee’s allowed scope of service during an emergency. For example in New Hampshire, dentists, registered nurses, student nurses in training at licensed hospitals, and emergency medical care providers may in addition to the authority granted them by other statutes, administer anesthetics; do minor surgery, intravenous, subcutaneous, and intramuscular procedures; and give oral and topical medication under the general, but not necessarily direct supervision of a member of the medical staff of a legally incorporated and licensed hospital of this state, and assist such staff member in other medical and surgical procedures. They are also designated “emergency management workers and so are immune from liability for death or injury to persons as a result of that activity. 1 NHRS §21-P:41.

In Maine most of our liability protections are geared towards people operating within the scope of their employment or license, so any expansion of permissible scope of practice would require legislative changes. Another issue is that most health care professionals do not have a clearly defined “scope of practice.” Rather most of them have a core set of competencies along with a (sometimes long) list of things they can do if appropriately trained, or if supervised.

Other states use “just in time training” and granting “privileges” versus “expanded scope of practice,” since there is no “defined” scope of practice for health care professionals.  See, for example the Arizona Crisis Standards of Care Plan, dated February 2015. Thus in a declared public health emergency, licensed professionals would be allowed to do everything they can usually do, plus training could be used to increase competencies needed for that particular emergency.

*Employment.* Title 26 MRS §875 regarding employment during extreme public health emergencies may need clarification or lifting by the Governor depending on the nature of the emergency. This would especially affect health care providers who would be on the front line and most vulnerable during an extreme public health emergency.

Also, in an extreme public health emergency, the Commissioner of DHHS (and by extension the Governor) may take certain actions. Title 22 MRS §820 outlines the powers of the Maine DHHS Commissioner during an extreme public health emergency. These include the authority to: get health information directly from providers; take people into custody and order prescribed care for up to 48 hours without a court order (when they constitute a serious and imminent risk to public health and safety); implement rules (emergency major substantive) to address the risk or potential risk of a shortage of health care workers, and implement rules (emergency major substantive) to address the need for dispensing drugs in an emergency situation.

Finally, the other significant powers DHHS has for the control of notifiable diseases and conditions remain in effect during any public health emergency. 22 MRS Chapter 250(§§801-835; 10-144 CMR Chapter 258. These laws provides for ongoing surveillance of notifiable conditions, and provide for court ordered evaluations, hospitalization, and enforcement of any other requirements necessary to protect the public from a public health threat.

 *Privacy and confidentiality.* The Health Insurance Portability and Accountability Act (HIPAA) and Maine’s confidentiality of healthcare information laws do not prevent free flow of information necessary to provide health care. This would not change during an emergency. Title 22 MRS §1711-C states in part: “**…**A health care practitioner or facility may disclose, or when required by law must disclose, health care information without authorization …to another health care practitioner or facility for diagnosis, treatment or care of individuals or to complete the responsibilities of a health care practitioner or facility that provided diagnosis, treatment or care of individuals, as provided in this paragraph…..” Two areas where Maine confidentiality laws are more protective than federal law of confidentiality are HIV and mental health care. The Governor could lift those extra protections through an Executive Order. Similarly, some HIPAA requirements, such as the need to obtain patient consent to speak to family members or friends could be part of a SSA Section 1135 waiver.

*Documentation of care*. Minimal acceptable levels of documentation of care provided to an individual may have to be established, both for purposes of patient care quality and as the basis for reimbursement from third-party payers. Contractual requirements of a third-party, such as an insurance company, would have to be addressed or modified with that party.

*Federal Law.* The President and federal agencies have similar powers at the federal level. In any extreme public health emergency the federal government would likely be playing a significant part. In addition to the statutes and regulations already mentioned, there are other federal laws that could apply, most of them having state counterparts:

* Emergency Management Assistance Compact (EMAC)
* International Emergency Management Assistance Compact (I-EMAC)
* Federal Public Readiness and Emergency Preparedness Act
* Robert T. Stafford Disaster Relief and Emergency Assistance Act
* Post Katrina Emergency Management Reform Act
* Federal Volunteer Protection Act
1. Immunity Laws Related to Crisis Standards of Care

*Civil Immunity.* When designing a plan to be used during an extreme public health emergency, when state workers, volunteers, and health care providers would be working under extremely stressful and demanding circumstances, a review of legal immunity provisions is important. There are a number of Maine statutes and legal standards to consider. The Maine Tort Claims Act (MTCA) provides protection for state employees, like Public Health Nurses and employees of the Maine Emergency Management Agency (MEMA). The MTCA has a broad definition of “employee.” It includes persons acting on behalf of a government entity, temporarily or permanently, whether or not compensated, including volunteer firefighters, emergency medical service personnel and member of the Maine National Guard on active duty. 14 MRS §8102(1). It provides absolute immunity for discretionary acts, and greatly limits liability of a state employee (and the State) for negligent acts committed during the scope of employment. Discretionary acts include any discretionary function or duty, reasonably encompassed by the duties of the employee, whether or not the discretion is abused, and any intentional act or omission within the course and scope of employment except for actions taken in bad faith. 14 MRS Chapter 741. There is a federal law based on principles of sovereign immunity that provides similar protections for federal employees and the federal government. The federal tort claims act covers staff and facilities of Federal Qualified Health Centers and U.S. military hospitals.

The MTCA (and the federal equivalent) protects against civil lawsuits for negligent or intentional acts done within the state or federal employee’s scope of employment. It does not provide protection for intentional torts or acts that violate criminal statutes. There are also federal laws (42 USC §1983, part of the Human Rights Act) that allow individuals to sue both government employees and private individuals acting under color of state law, who deprive anyone of their constitutional rights. Violations of peoples’ federal civil rights are not covered by tort claims protections in state law.

MEMA itself can provide some legal protections for health care providers who they designate to be members of emergency management forces during an emergency. The Maine Emergency Management Agency may employ any person considered necessary to assist with emergency management activities. Any person called and employed for assistance either within the State or in another state under chapter 16 or in a Canadian province under chapter 16-A is deemed to be an employee of the State for purposes of immunity from liability pursuant to sections 822. A person holding a professional license in the State may be designated a member of the emergency management forces in that professional capacity only after the individual or the license issuer provides confirmation of a valid license. 37-B MRS §784-A.

 Neither the State nor any of its agencies or political subdivisions nor a person called out pursuant to section 784-A, including a voluntary and uncompensated grantor of a permit for the use of the grantor's premises as an emergency management shelter, may, while engaged in any emergency management activities and while complying with or attempting to comply with this chapter or any rule adopted pursuant to this chapter, be liable for the death of or injury to any person, or damage to property, as a result of those activities. 37-B MRS §822. There are similar protections and powers for the Federal Emergency Management Agency (FEMA).

*Volunteers.* Maine also currently has several laws that provide some immunity for persons *volunteering* to help during an extreme public health emergency. The broadest one is 24 MRS §2904 which says an individual is not liable for an injury or death arising from medical services provided as described in this subsection unless the injury or death was caused willfully, wantonly or recklessly or by gross negligence of the individual if that individual is: a licensed health care practitionerwho voluntarily, without the expectation or receipt of monetary or other compensation either directly or indirectly, provides professional services within the scope of that health care practitioner's licensure… Two other groups have similar protections for volunteering under this law **-**emergency medical services persons who provide emergency medical services within the scope of that person's licensure, and a licensed physician, podiatrist or dentist who has retired from practiceand who provides professional services within the scope of that physician's, podiatrist's or dentist's licensureThere is a similar law at the federal level – the Volunteer Protection Act of 1997.

Maine’s “Good Samaritan Law” is at 14 MRS §164 and states: … any person who voluntarily, without the expectation of monetary or other compensation from the person aided or treated, renders first aid, emergency treatment or rescue assistance to a person who is unconscious, ill, injured or in need of rescue assistance, shall not be liable for damages for injuries alleged to have been sustained by such person nor for damages for the death of such person alleged to have occurred by reason of an act or omission in the rendering of such first aid, emergency treatment or rescue assistance, unless it is established that such injuries or such death were caused willfully, wantonly or recklessly or by gross negligence on the part of such person…. This section shall not apply if such first aid or emergency treatment or assistance is rendered on the premises of a hospital or clinic.” These laws protect against suits for ordinary negligence, but do not cover gross negligence (recklessness) or intentional acts, or violations from criminal laws.

More provisions to protect volunteer health care providers and licensed professionals, as well as officers and employees of compact states, are found in Maine’s version of the Emergency Management Assistance Compact (EMAC) – 37-B MRS Chapter 16 (§§921-933). Whenever a person holds a license, certificate or other permit issued by any state party to the compact evidencing the meeting of qualifications for professional, mechanical or other skills, and when such assistance is requested by the receiving party state, such person is deemed licensed, certified or permitted by the state requesting assistance to render aid involving such skill to meet a declared emergency or disaster, subject to such limitations and conditions as the governor of the requesting state prescribes by executive order or otherwise. 37-B MRS §925. Also, officers or employees of a party state rendering aid in another state pursuant to this compact are considered agents of the requesting state for tort liability and immunity purposes. A party state or its officers or employees rendering aid in another state pursuant to this compact are not liable on account of any act or omission in good faith on the part of such forces while so engaged or on account of the maintenance or use of any equipment or supplies in connection therewith. “Good faith” does not include willful misconduct, gross negligence or recklessness. 37-B MRS §926.

There are similar provisions in the International Emergency Management Assistance Compact, 37-B MRS Chapter 16-A(§§935-947). I-EMAC provisions on licenses and permits are at §939. The section on liability for persons and entities or party jurisdictions is §940. As usual, there is no protection for willful (intentional) acts that cause harm; or for violations of criminal law.

*Employed health care providers.* In contrast, statutory protections for health care employees at hospitals, and the hospitals themselves are more limited. For example in Title 22 there are provisions in Chapter 250, Control of Notifiable Diseases and Conditions providing MTCA immunity to: any private institution, its employees or agents for any acts taken to provide for the confinement or restraint of a person committed pursuant to this chapter or for participating in reporting under this chapter, or for engaging in any prescribed care within the meaning of this chapter in support of the State's response to a declared extreme public health emergency. "Prescribed care" means isolation, quarantine, examination, vaccination, medical care or treatment ordered by Maine DHHS or a court. 22 MRS §801(8-A).  Also, a private institution is immune from civil penalties and liability for any actions arising from allegations of inadequate investigation prior to that institution's hiring or engagement of a licensed health care worker, including but not limited to allegations of negligent hiring, credentialing or privileging, for services provided within the scope of that health care worker's licensure in response to an extreme public health emergency … as long as the private institution hires or engages the services of the licensed health care worker after the private institution shall first make a reasonable attempt to contact the appropriate occupational or professional licensing board…; and the private institution may rely on: … the representation of a volunteer health care worker registry that is operated or certified in accordance with federal or state requirements regarding appropriate screening of the worker that is registered on that registry, such as background investigation, primary source verification or credentialing; …22 MRS §816.

*The Standard of Care*. Otherwise, private health care providers are held to the regular standard of care,which consists of parameters established by case law (and some statutes) that outline the duty owed by a health professional to a patient. It is important to note that during a public health emergency the standard of care would be different under tort law, even if no “crisis standards of care” were adopted. In Maine as in other states, the standard of care takes into account the surrounding circumstances. As the Maine Supreme Court has put it, “**a doctor should use ‘the ordinary skill of members of [the]profession in like situation … exercise ordinary or reasonable care and diligence in [the treatment of the case, and … use his [or her] best judgement in the application of … skill to the case.**” *Brawn v. Oral Surgery Associate*s, (2003 ME 11) ¶17, *emphasis added, further citation omitted*. While the standard of care does not provide protection for gross negligence (recklessness); intentional (willful) conduct or violations of criminal law, it likely provides some protection for triage and allocation of resource decisions made during the course of an extreme public health emergency when critical resources are scarce. In addition the Maine legislature could broaden the scope of immunity statutes to cover private intuitions and health care providers during an extreme public health emergency, as some other states have done.

In addition, most hospitals and health care professionals protect themselves against these risks through liability and damage insurance. These policies offer varying protections for emergency situations. They generally cover liability for negligence but not intentional torts or criminal activity. Moreover, to the extent hospitals and providers have Memoranda of Understanding with other providers, and vendors, those should be followed to help protect the providers.

*Criminal liability.* In addition to civil liability some parts of the proposed CSC plan require consideration of criminal liability. Parts of the proposed plan set up a method for “re-allocating” scarce resources during an extreme public health emergency. These “re-allocations” can result in “withdrawing a critical resource” from a person who is likely not going to survive, and giving that resource to someone else who is both more likely to survive with the resource, and who would most likely die without it. An example is taking a patient off a ventilator to give it to another patient, when the person doing so knows it will result in the death of the first patient. This process would result in considered actions that would result in death to the individual who is removed from the critical resource. Maine, like most states, has criminal statutes designed to criminalize such behavior, and there are no exceptions or defenses that would cover the re-allocation of a critical medical resource during an extreme public health emergency. 17-A MRS §§35, 201, & 203. Taking a patient off a ventilator would normally require the consent of the patient or their authorized representative.

Addendum after Reviewing New York’s Ventilator Allocation Guidelines Chapter 4:Legal Considerations (November 2015) and Maryland’s *Public Health Emergency Preparedness – State’s Authority to Ration Ventilators during Pandemic - Physician Immunity,* 100 Op. Att’y Gen. 160 (December 28, 2015)(“Maryland AG Opinion.”). The Maryland AG Opinion is about the legal questions raised by having a plan for a catastrophic health event that includes removing someone from a ventilator when they are not improving and someone else has a much better chance of survival if given that resource. The ultimate conclusions of the Maryland AG were that under their laws:

A court would likely find that the Governor had the authority to adopt criteria for the allocation of ventilators pursuant to the Governor’s power to order public health officials to use quotas or ration scarce medical resources during a declared emergency under their Catastrophic Health Emergencies Act. Md. Code Ann, Public Safety (“PS”) 14-3A-03(b)(2). The Maryland AG Opinion notes that rationing means distributing or dividing (such as commodities in short supply) in an equitable manner to achieve a particular object, citing Webster’s Dictionary. Furthermore, the power to control, restrict or regulate the use of an item by rationing encompasses the power to allocate scarce medical resources. Thus the opinion concluded that a court would more likely than not, find that the Maryland laws grant the Governor the authority to set allocation criteria both for access to, and withdrawal from, ventilators during a flu pandemic. Furthermore if the Governor issues an executive order to implement the allocation criteria, a hospital or clinician would have immunity from liability for actions taken in accordance with those criteria under Maryland’s laws.

In Maryland, CSC criteria would be made mandatory by the state (they note this is different from most plans which call for non-binding criteria). Therefore constitutional limitations on what the state could do would apply, and would limit the state’s policy choices. To reduce risk of due process violations, the criteria should (1) be implemented only when there is no other choice (b) reduce the likelihood that individuals with a significant chance of survival will be removed from a ventilator without consent, and (c) afford procedural due process rights to patients who are removed from a ventilator or denied ventilator use.

The standard of care in normal circumstances is that as long as a person continues to need a ventilator, the patient will not be withdrawn from the ventilator without consent. Therefore, if a provider removes a ventilator without that patient’s or their family’s consent, and with foreseeable harm or death likely to result, the provider may be vulnerable to charges of negligent homicide, manslaughter, or criminal negligence as well as to civil liability. Maryland AG Opinion citing, Darren Mareiniss et al., *ICU Triage: The Potential Legal Liability of Withdrawing ICU Care During a Catastrophic Event*, 6:6 Am. J. of Disaster Med. 329, 333, 334 (2011). Normal standards of care assume the normal availability of ventilators, when decisions about one patient’s treatment do not affect other patients’ chances of survival. In a pandemic, however, both ventilators and the human resources to operate them would be in short supply. This would support triage when assigning a person to a ventilator in the first place.

The Maryland AG Opinion stated it was less clear whether their legislature intended to authorize only the use of allocations criteria that would govern which patients receive ventilators in the first instance, or whether it also intended to authorize criteria for reassessing and withdrawing patients from ventilators to make room for others, like those in New York’s Ventilator Allocation Guidelines (Nov. 2015). They noted that it is far more controversial to remove a patient from a ventilator than to withhold treatment in the first instance, citing, Phillip Levin & Charles Sprung, *Withdrawing and Withholding Life-Sustaining Therapies are not the Same*, 9 Critical Care 230 (2005). The Maryland AG also noted that there were procedural protections for individuals subject to isolation and quarantine, yet not for patients facing the withdrawal of potentially life-saving treatment. Nonetheless, they felt it was not clear whether there is any *legal* distinction between withholding and withdrawing medical treatment, noting that terminally ill or permanently comatose patients have a right to refuse life-sustaining threaten both by withholding consent initially, and also by revoking consent already given.

They do note the other view (as state in the ICU Triage article cited above) that if the decision to withhold or withdraw treatment is being made by the patient there is no difference, but if the decision is made against a patient’s wishes there may be greater risk of liability if a patient is removed from treatment than if treatment is merely withheld. They also cited dicta from the Maryland case of *In re Riddlemoser*, 317 Md. 496, 504 n. 5 (1989) –“the power to withhold treatment and the power to withdraw treatment are separate and distinct.” The Maryland AG points out the purpose of the Catastrophic Health Emergencies Act is to help save lives, and allowing the allocation of ventilators initially, while prohibiting their withdrawal and reallocation would not fully effectuate that purpose. “Such a plan would bind health care providers to a state of affairs where patients with hopeful prognosis are dying while those unlikely to survive even with ventilator treatment exhaust all of the available resources (citing the CDC Ventilator Workgroup.)

The Maryland AG Opinion then discussed constitutional issues raised by the allocation of ventilators during a pandemic. For example, the Equal Protection Clause of the Constitution would prohibit the use of arbitrary criteria or discrimination against protected classes of individuals. In addition the Fourth Amendment restrictions on unreasonable searches and seizures might also apply if the CSC criteria require doctors to conduct invasive tests that they otherwise could not perform in the course of treatment. For example the taking of a blood sample, urine sample, or buccal swab qualifies as a search or seizure when carried out within the context of law enforcement or public safety. The Maryland AG concluded that the state could likely fashion an allocation regime that is consistent with the Fourth Amendment.

The Fourteenth Amendment is even more important for mandatory ventilator allocation and reallocation guidelines. The Fourteenth Amendment says that the state cannot deprive any person of life, liberty, or property, without due process of law. This safeguard has both a substantive and procedural components. Note that these analyses depend on state action of some kind, so while mandatory ventilator allocation reallocation guidelines likely would fall under these standards, voluntary guidelines may not. Maryland’s plan was for mandatory guidelines issued in a declared catastrophic health emergency. Besides being mandatory, a person who knowingly and willfully fails to comply with an order, requirement or directive under their act is subject to criminal penalties. New York however, has voluntary guidelines and yet went into considerable analysis of due process. Their position was that guidelines for resource allocation during a public health emergency must comply with tenets of the U.S. Constitution, though courts may be reluctant to find state action if the guidelines are voluntary. I will review the basic concepts below since a court could find the necessary state action from a governor’s declaration of an extreme public health emergency that provides for the use of the CSCs.

Substantive due process protects people from arbitrary exercise of government powers without reasonable justification. If the deprivation is of a fundamental liberty interests, any infringement must be narrowly tailored to serve a compelling state interest. The Maryland AG thought it possible that courts might recognize a fundamental right to make health care decisions free from government interference, or a right not to be withdrawn from potentially life-saving treatment without consent. Even so, the opinion noted the compelling state interests in saving lives and in the fair and orderly allocation or scarce resources during a flu pandemic.

Whether a state’s CSC plan is narrowly tailored to meet those ends is another difficult question. The opinion notes that such a plan would only be activated in a major health emergency, when all other options have been exhausted. Also a court would be expected to focus on the criteria for withdrawing a patient from a ventilator. Thus the less likely that someone with a significant chance for survival is withdrawn from a ventilator without consent, the more likely the criteria will pass strict scrutiny. Such a policy will also be more likely to pass scrutiny if (like New York’s guidelines) patients are only removed from a ventilator if their condition has not sufficiently improved and other patients who are waiting have a significantly better prognosis. The Maryland AG’s opinion also cites the American Medical Association Code of Ethics (2.03 – Allocation of limited Medical Resources (1993)) noting that only very substantial difference among patients are ethically relevant and the greater the disparities, the more justified the use of allocation criteria becomes.

Procedural due process requires that when a government deprives individuals of life, liberty or property they must do so using procedures that are fundamentally fair (such as a pre-deprivation hearing or appeal). The purpose is to prevent mistaken or unjustified deprivations. The fundamental requirement of due process is the opportunity to be head at a meaning full time and in a meaningful manner. The factors that must be balanced include (1) the private interest at stake, (2) the risk of an erroneous deprivation of such interests through the procedures used, and the probable value of additional or other procedural safeguards and (3) the Government’s interests. The individual’s interest in using the ventilator is strong as is the Government’s interest is saving lives. If the procedures are complicated or lengthy, patients may die while waiting. Plus staff devoted to implementing the procedural safeguards will not be available to respond the emergency in other ways. Criteria that are clear, objective and easy to administer with decrease the risk of an erroneous deprivation of rights.

Finally in reviewing the states that have already formulated allocation criteria, Maryland noted the consensus about some minimum procedural safeguards:

* Clear objective criteria that provide advance notice about the standards that will be applied and transparency in the process for implementing the standards.
* Allocation decisions would be made by a neutral decision maker, and not an attending physician.
* The hospital should give notice to patients when they are denied a ventilator or before they are withdrawn form a ventilator and explain the reasons for that decision, including how the allocation criteria operate and how they were applied in the particular patient’s case.
* As the New York Guidelines point out, an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process. Attending doctors, patients, and family members should have a means for requesting review of triage decisions. New York recommends a real-time individual case review for procedural technical injustices only - for example when a withdrawal decision was made without considering all relevant clinical triage criteria. Maryland noted however that there was significant disagreement among experts about the workability of even a limited opportunity to challenge the procedural errors, like how a score was calculated.

As a result of my reviews, I make two primary recommendations:

1. Maine’s protections from liability for health care providers providing care in a declared extreme public health emergency should be greatly increased. This is especially important before promoting the use of the reallocation guidelines since those will be the most controversial part of the plan. A statute providing improved immunity to health care providers (whether employed, volunteer, or governmental) from civil or criminal liability for actions taken pursuant to the CSCs should be enacted. Such laws also need to protect professionals taking such “re-allocation” actions from complaints regarding their licenses to practice. For example a statute could state “A healthcare provider is immune from civil or criminal liability, or from a disciplinary action regarding their license to practice, if the health care provider acts in good faith and under a declaration of Extreme Public Health Emergency.” These liability protections should apply whether or not an entity chooses to use the CSCs. (Also, remember that tort claims protections in state law would not prevent people from claiming violations of their federal civil/constitutional rights in federal court, 42 USC §1983.)
2. After carefully reviewing the Maryland AG opinion and comparing our statutes to Maryland’s, I noted that their governor’s powers in an extreme public health emergency specifically include the power to restrict, or regulate the use, sale, dispensing, distribution, or transportation of anything needed to respond to the medical consequences of the catastrophic health emergency by *rationing or using quotas*… Md. Code Ann, PS 14-3A-03(b)(2). Maine’s statutes are of course different but I was struck that neither the Governor nor the Commissioner has the specific authority to ration or use quotas regarding most medical resources. Furthermore, the Governor *does* have this authority for an *energy* emergency, during which the Governor may “Establish and implement programs, controls, standards, priorities and quotas for the allocation, conservation and consumption of energy resources…” 37-B MRS §742(2)(B)(1). It seems odd that the Governor has this explicit authority regarding energy resources but not health care resources. Also while the Commissioner has the authority to implement rules to both address the risk of a shortage of health care workers or the address the need for dispensing drugs in an emergency situation (22 MRS §820(C)&(D)) there is no such mention of other health care resources. A potential argument against Maine’s CSC’s then is that because he does not have this authority over health care resources like ventilators, but does have it for energy resources; the Governor does not have the authority to purvey CSCs regarding health care resource allocation/reallocation in the first place. The potential fix would be to have a provision like 37-B MRS §742(2)(B)(1) for health care resources.

**Response from Maine CDC:**The CSC Plan and Guidelines have been developed in good faith in a thoughtful and careful manner by a Task Force comprised of various subject matter experts from across the state convened by the Maine CDC. The CSC Plan and Guidelines are consistent with published Institute of Medicine Crisis Standards of Care Guidelines and based on promising practices from across the country.

The CSC Plan and Guidelines are implemented only in emergency events of the most extreme nature. The crisis would overwhelm the medical care system. Resources would be limited, dwindling or fully depleted. It is recognized that chaos would likely result without adequate advance preparation. The Maine CDC under guidance from the Health and Human Services Assistant Secretary of Preparedness and Response has chosen to leverage peacetime, prior to such an event, to give careful thought as to how the health care providers in the State would provide care in the context of this extreme challenge.

The issue of most concern is reflected within the Legal Issues Appendix of the document ending in two recommendations from Maine Deputy Attorney General, Deanna White.

1. *“Maine’ protection from liability for health care providers providing care in a declared extreme public health emergency should be greatly increased.... A statute providing improved immunity to health care providers (whether employed, volunteer, or governmental) from civil or criminal liability for actions taken pursuant to the CSCs should be enacted.  Such laws also need to protect professionals taking such “re-allocation” actions from complaints regarding their licenses to practice.... These liability protections should apply whether or not an entity chooses to use the CSCs....”*

It is the intent of the CSC Taskforce to not shirk from this challenge but to pursue it. In a medical crisis health care providers will need to provide patient care without fear of civil or criminal liability. The Taskforce plans to propose legislation to provide the needed liability protection for health care providers who provide care in the event of an extreme public health emergency.

1. Atty White goes on to note:

*“that neither the Governor nor the* [DHHS]*Commissioner has the specific authority to ration or use quotas regarding most medical resources.  Furthermore, the Governor does have this authority for an energy emergency,... Also while the Commissioner has the authority to implement rules to both address the risk of a shortage of health care workers or the address the need for dispensing drugs in an emergency situation (22 MRS §820(C)&(D)) there is no such mention of other health care resources.... The potential fix would be to have a provision like 37-B MRS §742(2)(B)(1)* [for energy resources] *for health care resources.*”

Here again, the CSC Taskforce is planning to move forward with legislation to allow the Governor and the Commissioner greater powers including “*establish and implement programs, controls, standards, priorities and quotas for the allocation,* [reallocation]*, conservation and consumption of health care resources*” similar to those powers associated with energy resources in crisis events.

1. Currently, healthcare providers are not legally protected during a CSC event. The Maine CDC is exploring options related to enacting legislation to protect healthcare providers during a CSC event. [↑](#footnote-ref-1)