

California Department of Public Health Standards and Guidelines for Healthcare Surge During Emergencies

Foundational Knowledge



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Volume I: Hospitals

Volume II: Government-Authorized Alternate Care Sites

Volume III: Payers

Volume IV: Licensed Healthcare Clinics (available 2008)

Volume V: Long-Term Care Facilities (available 2008)

Volume VI: Licensed Healthcare Professionals (available 2008)

Hospital Operational Tools Manual

Government-Authorized Alternate Care Site Operational Tools Manual

Foundational Knowledge Training Guide

Hospital Training Guide

Government-Authorized Alternate Care Site Training Guide

Payer Training Guide

Reference Manual

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1. California's Healthcare System Response to a Healthcare Surge

An attack using biological, chemical, or radiologic agents, the emergence of diseases such as severe acute respiratory syndrome or pandemic influenza or the occurrence of a natural disaster are threats capable of imposing significant demands on California's healthcare resources and state-wide healthcare delivery system. While California has built a strong network of healthcare services and agencies through local health departments, local emergency medical services agencies, hospitals, clinics, long term care facilities and healthcare professionals, developing a coordinated response to a dramatic increase in the number of individuals requiring medical assistance following a catastrophic event will be challenging. The overwhelming increase in demands for medical care arising out of such an event is called healthcare surge. While many hospitals, clinics and other healthcare providers have developed individualized healthcare surge plans, the sheer magnitude of a disaster or wide-spread disease may require a different planning approach.

In *Emergency Management Principles and Practices for Healthcare Systems*¹, the Institute for Crisis, Disaster, and Risk Management has found that healthcare system response during emergencies demonstrates the following recurrent findings:

- Local response is primary: The initial response to any medical event will be almost entirely based upon locally available health and medical organizations.
- Medical response is complex: The response to a large scale emergency impacts an entire community and involves numerous diverse medical and public health entities, including healthcare systems and facilities, public health departments, emergency medical services, medical laboratories, individual healthcare practitioners, and medical support services.
- Coordinated response is essential: An effective healthcare system response to major events usually requires support from public safety agencies and other community response entities that are not normally partnered with the community healthcare systems during everyday operations.
- Bridging the "public-private divide": Healthcare organizations have traditionally planned and responded to emergencies as individual entities. This has occurred in part because of the "public-private divide," the legal, financial, and logistical issues in planning and coordination between public agencies and primarily private healthcare entities. Healthcare organizations must view themselves as an integrated component of a larger response system.
- Public health as an essential partner: Public health departments are not traditionally integrated with other community emergency response operations, including the acute



care medical and mental health communities. Public health departments are an essential partner in any successful response to a healthcare surge.

- The need for robust information processing: Medical issues that arise from large scale incidents are rarely immediately apparent, and complex information must be collected from disparate sources, processed and analyzed rapidly in order to determine the most appropriate course of action. This requires a robust information management process that can differ markedly from any routinely used healthcare system.
- The need for effective overall management: Medical response to a healthcare surge situation can be exceedingly complex, with many seemingly diverse tasks. Responsibility for each of these activities can vary significantly among organizations in different communities. Even within a single healthcare system, many actions require coordination between disparate operating units that don't work together on a regular basis. Despite these challenges, all necessary functions must be adequately addressed for a successful mass casualty or mass effect response.
- Medical system resiliency: A major hazard impact that creates the need for healthcare surge capacity also is likely to impact the normal functions of the everyday healthcare systems (i.e., some degree of mass effect). Medical system resiliency is necessary for the system to maintain its usual effectiveness and, at the same time, to provide a reliably functioning platform upon which medical surge may occur. Medical system resiliency is achieved by a combination of mitigation measures and adequate emergency preparedness, assuring continuity of healthcare system operations despite emergency.

Healthcare providers face several challenges achieving optimal emergency preparedness. The traditional approaches to delivering healthcare do not typically support an integrated community-wide response that is usually necessary during a healthcare surge. Therefore, it is critical that healthcare systems and providers not only be prepared to provide services on individual basis but also be prepared to participate in an overall emergency community response. An effective response will assure healthcare system resiliency as well as the most efficient care for victims given the severity of the event.

1.1 California Department of Public Health Initiates Planning for Healthcare Surge

In order to assist communities and healthcare providers to successfully plan for a healthcare surge, in 2007 the California Department of Public Health (CDPH) launched a project to address the issues of surge capacity during an emergency. The *Development of Standards and Guidelines for Healthcare Surge during Emergencies* project was initiated to develop standards and guidelines manuals to assist healthcare providers develop plans for responding



to a healthcare surge. A key predecessor to the *Development of Standards and Guidelines for Healthcare Surge during Emergencies* project was the California Hospital Surge Capacity Survey that CDPH conducted in February 2006. Survey findings determined that many California healthcare providers could improve their planning process to identify the resources that would be needed to treat patients during surge emergencies. Based upon these findings, the State Budget Act for fiscal year 2006-2007 authorized CDPH to initiate the *Development of Standards and Guidelines for Healthcare Surge during Emergencies* project to identify obstacles hindering healthcare delivery during a healthcare surge and to identify strategies and recommendations to mitigate the identified obstacles.

To identify key surge planning issues, CDPH undertook a multi-phase process that involved bringing together participants representing federal agencies, national organizations, state agencies, local health departments, healthcare providers, health plans and community organizations to identify issues and develop recommendations to address those issues. The project placed particular emphasis on a framework for standards of care and scope of practice during an emergency, liability of healthcare providers during a surge, reimbursement of care provided during an emergency, planning for and operating alternate care sites and surge capacity operating plans at individual hospitals.

The results of these earlier activities form the basis for the healthcare standards and guidelines manuals, operational tools, reference manual and training curriculum which are intended to help every community and healthcare provider in California plan and put into operation an effective surge response to major disasters.

1.2 Healthcare Surge Standards and Guidelines Manuals, Operational Tools and Training Curriculum

The surge planning materials have been assembled into healthcare surge standards and guidelines manuals which contain recommendations and options for consideration by communities and providers planning for a healthcare surge. Materials should be evaluated for implementation based upon specific needs of the emergency but should not be considered mandates or requirements issued by the State of California. Applicability of an individual guideline and recommendation will be dependent upon the specific emergency or the surrounding circumstances as well as community and provider structure.

The Standards and Guidelines Manuals issued from this project are:

- **Foundational Knowledge.** This manual defines healthcare surge, describes the existing emergency response system in California and how healthcare providers participate in this system. It also discusses transitioning patient care from individually-focused to population-based care in a severe surge. This manual is



prerequisite to volumes I -III, operational tools, reference manual and training curriculum described below.

- **Volume I: Hospitals.** Primarily developed for use by hospitals, but also beneficial for use by other providers and health plans, this manual contains information on general emergency response planning and related integration activities for hospitals. This manual also includes guidance for hospitals related to increasing capacity and expanding existing workforce during a surge, augmenting both clinical and non-clinical staff to address specific healthcare demands, addressing challenges related to patient privacy and other relevant operational and staffing issues during surge conditions. This manual addresses the assets under a hospital's control that can be used to expand capacity and respond to a healthcare surge.
- **Volume II: Government-Authorized Alternate Care Sites.** This manual contains planning information related to the establishment of government-authorized Alternate Care Sites that may be used for healthcare delivery during a healthcare surge. It includes specific guidance and general planning considerations for coordinating site locations, developing staffing models, defining standards of care and developing administrative protocols. Specific guidance on federal and State reimbursement at government-authorized alternate care sites is also provided.
- **Volume III: Payers.** This manual outlines specific sets of recommendations for commercial health plans to consider when working with providers, employers and others during the surge planning process. Recommended approaches to changes in contract provisions which focus on simplifying administrative and reimbursement requirements are included. This volume also contains specific information on the impact that a healthcare surge may have on a health plan's administrative and financial relationship with Medicare Advantage, Medi-Cal Managed Care and Workers' Compensation.
- **Other Reference Material:**

Operational Tools Manuals. Includes forms, checklists and templates that might be used by providers and health plans to assist in the implementation of recommendations and strategies outlined in the respective Standards and Guidelines Manual.

Reference Manual. The reference manual contains an overview of federal and State regulations and compliance issues, including statutes, laws, regulations and standards and their corresponding legal interpretations and potential implications for use during a healthcare surge. Also included in the reference manual is detailed information regarding Hospital Incident Command System roles and responsibilities to assist with planning for command staff at a hospital. In addition, information regarding funding



sources that may be available during a declared healthcare surge is included as well as those funding sources that were used during previous states of emergency.

Training Curriculum. Outlines the intended audience, methods of delivery and frequency of training for the information presented in the manuals.

These volumes are meant to be actively used for community and provider planning for a healthcare surge. The information contained in the materials will be updated as new information is learned and community surge planning practices evolve.

Additional volumes, operational tools and training curriculum that address clinics, licensed healthcare professionals and long-term care facilities are in development and are scheduled to be issued in 2008.

1.3 Key Healthcare Surge Planning Concepts for California

The following key healthcare surge planning concepts provide the context and perspective to understand the information presented in the healthcare surge standards and guidelines manuals for California.

During a catastrophic emergency, the movement from individual-based care to population-based outcomes challenges the professional, regulatory, and ethical paradigms of the healthcare delivery system. The standard of care will focus on saving the maximum number of lives possible. The standard of care during a healthcare surge is defined as the utilization of skills, diligence and reasonable exercise of judgment in furtherance of optimizing population outcomes that a reasonably prudent person or entity with comparable training, experience or capacity would have used under the circumstances.

Under current state statute and regulations, a move to a population-based healthcare response may be challenging. When a State statute or regulation does not provide flexibility during a healthcare surge, Executive Standby Orders issued by the Governor following his/her issuance of a declaration of emergency may result in suspensions that allow for flexibility. The manuals provide relatively straightforward examples of Executive Standby Orders and possible suspensions that may be put into effect during surge conditions.

In California, a healthcare surge is proclaimed in a local jurisdiction when an authorized local official, such as a local health officer or other appropriate designee,² using professional judgment determines, subsequent to a significant emergency or circumstances, that the healthcare delivery system has been impacted, resulting in an excess in demand over capacity in hospitals, long-term care facilities, community care clinics, public health departments, other primary and secondary care providers, resources and/or emergency medical services. The



local health official uses the situation assessment information provided from the healthcare delivery system partners to determine overall local jurisdiction/Operational Area medical and health status.

The coordination of activities during a healthcare surge entails significant responsibilities for local government as well as hospitals and other community healthcare professionals. Local government will be responsible for determining the state of the healthcare surge and the identification of and planning for the operations of Government-Authorized Alternate Care Sites. While the ultimate determination regarding surge related activities will be made by local government, healthcare providers and payers will be kept informed to provide a coordinated and integrated response.

A key barrier to effective healthcare surge response is the complexity of the healthcare delivery system. The intent of the *Development of Standards and Guidelines for Healthcare Surge during Emergencies* project is not to solve the challenges of the current healthcare delivery system but to operate within it. This is primarily addressed by considering the elements of response from an operating rather than a regulatory point of view.

While the current healthcare delivery system is complex, several areas can be simplified, such as professional scope of practice, recruitment of personnel, and patient tracking for clinical and administrative purposes. This simplification emphasizes the operational necessities of a coordinated response in a catastrophic event.

Preserving the overall financial liquidity of the healthcare delivery system during a catastrophe is an issue that is larger than any single stakeholder. There are practical ways that hospitals can take proactive steps to preserve a revenue stream during a surge event, while payers (government and commercial) can more effectively meet their obligations for their covered beneficiaries under the traditional third party payer system.

Ultimately, effective surge response requires all stakeholders to accept new responsibilities, behave differently than they may have been trained, and cooperate with each other in unprecedented ways. The purpose of these and future surge standards and guideline materials is to proactively engage California communities in advance planning for a healthcare surge and provide tools and training to support the surge planning process.

1.4 Overview of Foundational Knowledge

A catastrophic emergency, whether a natural disaster, infectious disease or terrorist attack, will dramatically impact California's healthcare system. It is critical that hospitals, healthcare professionals and health plans doing business in California proactively work together to redefine the nature of their relationships to prepare for a healthcare surge and mitigate its potential impact on patient care, access and funding. Given the unpredictable nature of a



disaster and its potential to significantly impact the healthcare delivery system, sufficient planning and coordination between providers and payers will be essential to maintain business continuity and sustain operations at facilities providing medical care.

During a healthcare surge, the delivery of care will be different. The standard of care may change based on available resources. The scope of a provider's practice may change based on need, sites of care may look different due to access issues, and the traditional methods of claims identification and submission may be forced to undergo adjustments that require practical solutions. Additionally, during a catastrophic emergency, the primary focus of the healthcare community will be on responding to the emergency and caring for the ill and injured. These changes will require providers to work with health plan partners to meet the needs of the healthcare surge environment and ensure adequate provisions of care and cash flow.

“Healthcare surge” has varying meanings to participants in the healthcare system. For planning a response to a catastrophic emergency in California, “healthcare surge” is defined as follows: A healthcare surge is proclaimed in a local health jurisdiction when an authorized local official, such as a local health officer or other appropriate designee, using professional judgment, determines, subsequent to a significant emergency or circumstances, that the healthcare delivery system has been impacted, resulting in an excess in demand over capacity in hospitals, long term care facilities, community care clinics, public health departments, other primary and secondary care providers, resources and/or emergency medical services.

The foundational knowledge contained in this volume provides all participants involved in surge planning activities with a general understanding of the conditions which define a healthcare surge and its potential impact on the healthcare delivery system.

Key considerations and learnings from the foundational knowledge volume include the following:

- The roles of healthcare providers, local communities and government during a healthcare surge cannot be predicted and will vary based on the nature of the surge. The importance of working collaboratively is a critical component during planning activities. A coordinated response is vital.
- The state response and regulatory activities that can be expected related to emergency preparedness and the obligations of providers and others associated with this activity can provide a framework for future planning activities.
- An understanding of the operational impact that a healthcare surge has on hospital capacity, staffing and the management of patients, as well as recommended approaches to address these issues will enable providers and others to take a proactive approach to surge planning.



2. Healthcare Surge

This section defines healthcare surge for the purposes of this project, discusses developing community-based surge capacity and the community partners necessary for integrated planning, and provides some strategies to increase surge capacity. Integrated community planning will allow for the rapid and effective deployment of resources in a well-defined surge response system.

2.1 Healthcare Surge Defined

A healthcare surge, as referenced in this guide, specifically relates to a catastrophic emergency that overwhelms the healthcare delivery system. For purposes of planning a response to a surge in California, “healthcare surge” means the following:

A healthcare surge is proclaimed in a local jurisdiction when an authorized local official, such as a local health officer or other appropriate designee,³ using professional judgment determines, subsequent to a significant emergency or circumstances, that the healthcare delivery system has been impacted, resulting in an excess in demand over capacity in hospitals, long-term care facilities, community care clinics, public health departments, other primary and secondary care providers, resources and/or emergency medical services. The local health official uses the situation assessment information provided from the healthcare delivery system partners to determine overall local jurisdiction/Operational Area medical and health status.

Healthcare surge is **not** the frequent emergency department overcrowding experienced by healthcare facilities (for example, Friday/Saturday night emergencies). It is also not a local casualty emergency that might overcrowd nearby facilities but have little to no impact on the overall healthcare delivery system.

As defined above, a healthcare surge will directly impact a provider's ability to acquire and manage resources under their normal procedures. At the point that a surge situation is proclaimed for the jurisdiction or Operational Area, all healthcare providers must be integrated into a unified incident command management structure under SEMS/NIMS that coordinates the movement of patients, establishes priorities and allocates scarce resources, services and supplies among the healthcare providers. In this situation, the needs of all healthcare providers will be integrated into a single consolidated incident action plan that will result in optimum patient care for the community.

To accomplish this, an authorized local official, or designee, will notify healthcare facilities that the Unified Command has been established and provide a contact within the Operations Section of the Unified Command for coordination of patient movement and requests for resources, services and supplies.



2.2 Healthcare Surge Capacity

2.2.1 Developing Community-Based Surge Capacity

The concepts, ideas and content in this section are based on guidance from other States' healthcare surge plans and references from a report by The CNA Corporation, *Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources during Large-Scale Emergencies*, August 2004.

Currently, patient care during emergencies or disasters is provided primarily at community-based hospitals, integrated healthcare systems, private physicians' offices and other point-of-service medical facilities. The successful delivery of care during a catastrophic surge will be based on the healthcare system's preparedness planning and capacity. This approach to response during a healthcare surge focuses on a population-outcome perspective as well as maximizing the use of resources available.

According to the CNA report: "Research has shown that most individual healthcare facilities possess limited surge supplies, personnel and equipment, and that vendors or anticipated 'backup systems' for these critical assets are often shared among local and regional healthcare facilities. This 'double counting' of resources diminishes the ability to meet individually projected surge demands across multiple institutions" during a healthcare surge.

Community partners, therefore, must collaboratively develop plans for increasing capacity. This does not preclude or diminish the need for individual healthcare facilities to have a comprehensive emergency management plan/program that addresses mitigation, preparedness, and response and recovery activities. However, efforts must extend beyond optimizing internal emergency management plans and focus on integrating with other healthcare and non-healthcare assets in the community, both public and private. For example, communities should consider developing memoranda of understanding for transfer of patients from hospitals to skilled nursing facilities. Various existing healthcare facilities should be included in community planning efforts to identify their role during a healthcare surge.

Similarly, during a pandemic influenza, home healthcare will play a critical role in the continuum of healthcare delivery. Community-based planning to define the role of home healthcare and availability of personnel to support such care will enable communities to better respond to an outbreak. Community-based planning will allow existing healthcare resources in the public and private sectors as well as other non-healthcare assets to be optimally leveraged.

One of the challenges in increasing a community's healthcare surge capacity is integrating medical clinics, private physicians' offices, and other healthcare and non-healthcare assets. It is important to recognize that many community healthcare assets do not have the management infrastructure or personnel necessary to establish complex processes for incident preparedness and response.



Community-based healthcare surge capacity is composed of healthcare facilities and non-healthcare facilities promoting effective communications and consistent information sharing with local government. While the community assets retain their management autonomy during a healthcare surge response, they coordinate and participate in information and asset sharing. A critical component of community-based healthcare surge response is sharing of personnel, facilities, equipment, or supplies. Public entities share resources through mutual aid, whereas private entities can do so by establishing memoranda of understanding or contracts prior to an emergency event. Understanding how to access resources through the SEMS/NIMS process is critical for healthcare facilities to be able to successfully participate in community-based response plans.

2.2.2 Community Participants

An important element of the community-based capacity is inclusion and integration of public and private partners in the community. The following table gives examples of community members to consider for community-based planning:

Community Planning Participants Checklist

	Community Participant	Potential Role
Local, State, and federal organizations		
<input type="checkbox"/>	Law enforcement, fire, and coroner	Emergency first responders, security, enforcement of quarantine/isolation orders, fatality management
<input type="checkbox"/>	Local emergency medical services agencies	Local implementing arm of the Emergency Medical Systems Agencies
<input type="checkbox"/>	Local federal offices	Personnel, planning
<input type="checkbox"/>	Local public health	Public health planning, personnel, technical assistance
<input type="checkbox"/>	Local State offices	Personnel, planning
<input type="checkbox"/>	National Guard and military establishments	Transportation and infrastructure support, security, enforcement
Volunteer organizations		
<input type="checkbox"/>	Community Emergency Response Teams (CERT)	Volunteers
<input type="checkbox"/>	Medical Reserve Corps (MRC)	Volunteers
<input type="checkbox"/>	Neighborhood Emergency Response Teams (NERT)	Volunteers



	Community Participant	Potential Role
<input type="checkbox"/>	Red Cross/Salvation Army and other nonprofit organizations	Volunteers and supplies aid
Commercial organizations and business partners		
<input type="checkbox"/>	Area airports	Transportation, facilities
<input type="checkbox"/>	Board of Realtors	Coordination of additional space for healthcare facilities
<input type="checkbox"/>	Chambers of commerce	Business community support
<input type="checkbox"/>	Communication companies (e.g., private cell, two-way radio, broadcast television)	Communication needs
<input type="checkbox"/>	Major employers and business community, especially big-box retailers (e.g., Costco, Sam's Club)	Essential supplies and services
<input type="checkbox"/>	Mortuaries	Burial and cremation services
<input type="checkbox"/>	Private security firms	Security services
<input type="checkbox"/>	Public works and local utility companies	Critical infrastructure
<input type="checkbox"/>	Restaurants, caterers, party supply stores	Facilities, food, supplies
Community organizations		
<input type="checkbox"/>	City unified school districts and community colleges	Alternate care sites, personnel/services, supplies
<input type="checkbox"/>	Faith-based organizations	Facilities, volunteers, supplies, translation
<input type="checkbox"/>	Public transportation	Transportation
<input type="checkbox"/>	Nursery schools/preschools	Facilities, personnel, child care
<input type="checkbox"/>	Veterinary shelters/pet boarding and care	Pet care for workers/evacuees
Other partners		
<input type="checkbox"/>	Miscellaneous services	Financial, accounting, general services

The Community Planning Participants Checklist above can also be found on page 80 of the Foundational Knowledge Manual, Section 9: Foundational Knowledge Operational Tools.



2.2.3 Role of Hospitals

Disaster response involves many different community resources—from police and fire to medical providers, engineers and transportation and housing experts. The hospital plays a crucial role in this larger picture. It is the epicenter of medical care delivered to those who are injured. Running a hospital is an enormously complex task under the best of circumstances; preparing a hospital for a disaster is infinitely more complicated. During a surge event, hospitals will have to convert quickly from their current care capacity to surge capacity to handle the maximum patient load possible.

The Joint Commission's Environment of Care standards provide the following guidance and criteria for standards for community-based surge capacity. These standards are applicable to accredited facilities and will become effective January 1, 2008.

- EC.4.11: The organization plans for managing the consequences of emergencies.

An emergency at a healthcare organization or in its community can suddenly and significantly affect demand for its services or its ability to provide those services. The organization's emergency management program defines a comprehensive approach to identifying risks and mobilizing an effective response within the organization and in collaboration with essential response partners in the community.

- EC.4.12: The organization develops and maintains an emergency operations plan.

A successful response relies upon planning around the management of six critical areas: communications; resources and assets; safety and security; staffing; utilities; and clinical activities. While the emergency operations plan can be formatted in a variety of ways, it must address these six critical functions to serve as a blueprint for managing care and safety during an emergency.

Some emergencies can escalate unexpectedly and strain not only the organization but the entire community. An organization cannot mitigate risks, plan thoroughly, and sustain an effective response and recovery without preparing its staff and collaborating with the community, suppliers and external response partners. Such an approach will aid the organization in developing a scalable response capability and in defining the timing and criteria for decisions involving sheltering in place, patient transfer, facility closings, or evacuation.

- EC.4.14: The organization establishes strategies for managing resources and assets during emergencies.

During emergencies, healthcare providers that continue to provide care, treatment and services to their patients must sustain essential resources, materials and facilities. The emergency operation plan should identify how resources and assets will be solicited and



acquired from a range of possible sources, such as vendors, neighboring healthcare providers, other community organizations, State affiliates or a regional parent company.

The organization establishes processes to collaborate with healthcare providers outside of the community in the event of a regional or prolonged disaster that requires resources and assets from outside the immediate geographic area.

The organization establishes processes to receive and care for evacuees from other communities consistent with the organization's role in the State or local emergency operations plan.

2.2.4 Role of Clinics, Long-term Care Facilities and Other Non-Hospital Providers

Under normal conditions, community clinics, long-term care facilities and other non-hospital providers play a significant role in delivering healthcare to the communities they serve. Considered integral components along the healthcare delivery continuum, these providers often serve rural and underserved communities, provide transitional care from the acute care setting to home and offer patients alternatives to inpatient hospital care.

During a healthcare surge, these providers can play a critical role in the delivery of healthcare and it is important to integrate them into the overall surge planning activities.

Key considerations during the planning phase include:

- Non-hospital facilities, including clinics and outpatient surgery centers, are equipped to respond to a variety of health related needs. A referral network which includes these providers will allow a triage response that enables patients with the least severe injuries to be directed to non-hospital facilities or freestanding outpatient surgery centers, with the most severe cases getting triaged to the acute care setting. When possible, patients can be directed to the most appropriate level of care, creating additional access at high demand hospitals.
- Certain emergencies, such as a biological agent release, may be prolonged in duration and generate patients who can be safely evaluated in these settings, thus relieving some of the burden on larger healthcare facilities. (The CNA Corporation, *Medical Surge Capacity and Capability: A Management System for Integrating Medical and Health Resources During Large-Scale Emergencies*, August 2004)
- Urgent care centers, dialysis clinics, and other non-hospital facilities also provide essential medical services and should be considered when developing a disaster response. Increasingly, licensing, accreditation, and funding agencies require community clinics to develop disaster response plans and perform hazard vulnerability assessments. Following a catastrophic disaster, all of these facilities have several potential response roles and responsibilities including protecting staff and patients.



Non-hospital providers can serve in additional capacities during a disaster response. Alternative roles for non-hospital providers include:

- Stabilizing casualties who are injured prior to transfer to a more appropriate level of care
- Providing continuity of care to the ambulatory or resident patient base
- Creating a healthcare surge capacity resource for the treatment of stable, low-priority incident and/or non-incident patients
- Creating a venue to establish specialty disaster services, such as blood donation stations, worried well centers, and mental health services
- Providing assistance with recruiting medical personnel or volunteers to augment staff at other healthcare facilities or service sites
- Supporting community medical response through language services and outreach and information dissemination to limited-English proficient and isolated communities
- Rapidly restoring functions to provide services to its usual patient population

2.2.5 Surge Capacity Strategies for Healthcare Facilities

According to a report by Health Systems Research Inc., *Altered Standards of Care in Mass Casualty Events*, an Agency for Healthcare Research and Quality (AHRQ) publication, April 2005, and the recommendations of an expert panel on inpatient and outpatient healthcare surge capacity, *Guidelines for Managing Inpatient and Outpatient Surge Capacity*, State of Wisconsin, November 2005, if a healthcare facility determines it is experiencing a healthcare surge, it may use the following guidelines to assess, prepare, and mobilize to meet the need for increased patient care capacity:

- Rapidly discharge Emergency Department and other outpatients who can continue their care at home safely
- Cancel elective surgeries and procedures, with reassignment of surgical staff members and space
- Reduce the usual use of imaging, laboratory testing, and other ancillary services
- Transfer patients to other institutions in the State, interstate region, or nationally
- Facilitate the use of home-based care for patients in cooperation with public health and home care agencies
- Group like-patient types together to maximize efficient delivery of patient care
- Expand critical care capacity by placing select ventilated patients on monitored or step-down beds; use pulse oximetry (with high/low rate alarms) in lieu of cardiac monitors; or rely on ventilator alarms (which should alert for disconnect, high pressure, and apnea) for ventilated patients, with spot oximetry checks



- Convert single rooms to double rooms or double rooms to triple rooms if possible
- Designate wards or areas of the facility that can be converted to negative pressure or isolated from the rest of the ventilation system for cohorting contagious patients; or use these areas to cohort those healthcare providers caring for contagious patients to minimize disease transmission to uninfected patients
- Use cots and beds in flat space areas (e.g., classrooms, lobbies) within the hospital for non-critical patient care
- Avert elective admissions at hospitals and discharge patients to rehabilitation or a long-term care facility or to home healthcare
- Use Obstetrics as a “clean” unit (no infectious patients should be placed in Obstetrics), and fill this unit with other “clean” patients as a last resort
- Treat any unit used for immuno-suppressed patients in the same way as the Obstetrics unit and, thus, do not count the unit as inpatient healthcare surge capacity beds
- Do not consider nursery beds as potential inpatient healthcare surge capacity beds even for infants, since these beds are used only for neonates younger than 28 days. If an infant with an infectious disease or with trauma is admitted, place the infant in pediatrics

Facilities need to identify wings, areas and spaces that could be opened and/or converted for use as patient/inpatient treatment areas. These potential treatment areas include such areas or spaces as:

- Outpatient clinics
- Waiting rooms
- Wings previously used as inpatient areas that can be reopened
- Conference rooms
- Physical therapy gyms
- Medical office buildings
- Temporary shelters on facility premises (including parking lots and cots in tents)

Facilities should establish a hierarchy among areas as to which would best and first be used as patient/inpatient healthcare surge capacity treatment areas. This selection of areas to be used for healthcare surge capacity can best take place when the facility has an understanding of the intensity of the incident and the resulting number of healthcare surge patients that it may receive. Collaboration and the establishment of alert protocols with the emergency operations center, emergency medical services, and first responders will provide facilities with the necessary information to implement the appropriate number of outpatient/inpatient healthcare surge capacity.



3. Emergency Preparedness and Response in California

3.1 California Emergency Services Act⁴

The California Emergency Services Act recognizes the State's responsibility to mitigate the effects of natural, manmade or war-caused emergencies which result in conditions of disaster or in extreme peril to life, property and the resources of the State, and generally to protect the health and safety and preserve the lives and property of the people of the State.⁵ To ensure adequate preparations to deal with emergencies, the Emergency Services Act confers emergency powers upon the Governor and upon the chief executives and governing bodies of political subdivisions of the State, provides State assistance for the organization of local emergency response programs and creates the Office of Emergency Services within the Office of the Governor.

The Emergency Services Act recognizes the need to assign emergency functions to State agencies and to coordinate and direct the emergency actions of those agencies. It provides for the rendering of mutual aid by the State and its political subdivisions to carry out the purposes of the Emergency Services Act. Further, the Emergency Services Act establishes State policy that all State emergency services functions are coordinated as far as possible with the comparable functions of its political subdivisions, the federal government, other States and private agencies of every type to make the most effective use of all staff, resources and facilities for dealing with any emergency that may occur.

3.2 State Emergency Plan

The Governor is responsible for coordinating the State Emergency Plan and programs necessary for the mitigation of the effects of an emergency. The Governor is also responsible for coordinating the preparation of local plans and programs, and for seeing that they are integrated into and coordinated with the State Emergency Plan and the plans and programs of the federal government (and of other States) to the fullest possible extent.⁶ By law, the State Emergency Plan is in effect in each political subdivision of the State, and the governing body of each political subdivision is obligated to take whatever action may be necessary to carry out its provisions.⁷

As part of the State plan, the Governor can assign to a State agency any activity necessary for the mitigation of the effects of an emergency related to the existing powers and duties of the agency, including interstate activities. Such an assignment makes it the duty of the agency to undertake and carry out that activity on behalf of the State.⁸

In accordance with the State Emergency Plan, the Governor can plan for the use of any private facilities, services, and property and, when necessary, and when in fact used, provide for payment for that use under the terms and conditions as may be agreed upon.⁹ This planning authorization is consistent with the Governor's power, described above, to commandeer property and personnel.¹⁰



3.3 The Concept of Mutual Aid

Mutual aid is a concept under which separate jurisdictional or organizational units share and combine resources in order to accomplish their mutual goals.

The Emergency Services Act recognizes that, during emergencies, the rendering of mutual aid by State government, including all its departments and agencies, and its political subdivisions will be necessary to mitigate the effects of the emergency. Public agencies are authorized by law to enter into joint powers agreements, and these agreements can be for the purposes of providing assistance to each other.¹¹ However, given the number of cities and counties in the State, it would be impractical to require jurisdictions to have separate agreements with other jurisdictions in the event of an emergency.

Accordingly, one purpose of the Emergency Services Act is to make it unnecessary for public agencies to execute written agreements to render aid to areas stricken by an emergency.¹² It accomplishes this goal by authorizing State and local public agencies to exercise mutual aid powers in accordance with the California Disaster and Civil Defense Master Mutual Aid Agreement, and local plans, ordinances, resolutions and agreements.¹³ The Master Mutual Aid Agreement was made and entered into by and between the State of California, its various departments and agencies, various political subdivisions, municipal corporations, and other public agencies. Each government entity, as signatory to the agreement, agrees to assist each other during an emergency without expectation of reimbursement.

A key element of the agreement states the following: “It is expressly understood that the mutual aid extended under this agreement and the operational plans adopted pursuant thereto shall be available and furnished in all cases of local peril or emergency and in all cases in which a State of Extreme Emergency has been proclaimed.”

The Master Mutual Aid Agreement requires that each party develop a plan providing for the effective mobilization of all its resources and facilities, both public and private, to cope with any type of disaster.¹⁴ Under the Emergency Services Act, a duly adopted and approved emergency plan is deemed to satisfy this requirement.¹⁵

As previously discussed, the Governor is authorized to divide the State into mutual aid regions for the more effective application, administration, and coordination of mutual aid and other emergency-related activities.¹⁶ A mutual aid region is part of the State, not local, emergency services structure and is established to facilitate the coordination of mutual aid and other emergency operations within an area of the State consisting of two or more county Operational Areas.¹⁷ Currently, California is divided into six mutual aid regions for general mutual aid coordination.¹⁸ Each mutual aid region consists of designated counties/Operational Areas.

Within each mutual aid region, there may be a Regional Disaster Medical and Health Coordinator, who is appointed by the directors of Emergency Medical Services Authority and CDPH.¹⁹ The job of the Regional Disaster Medical and Health Coordinator during an



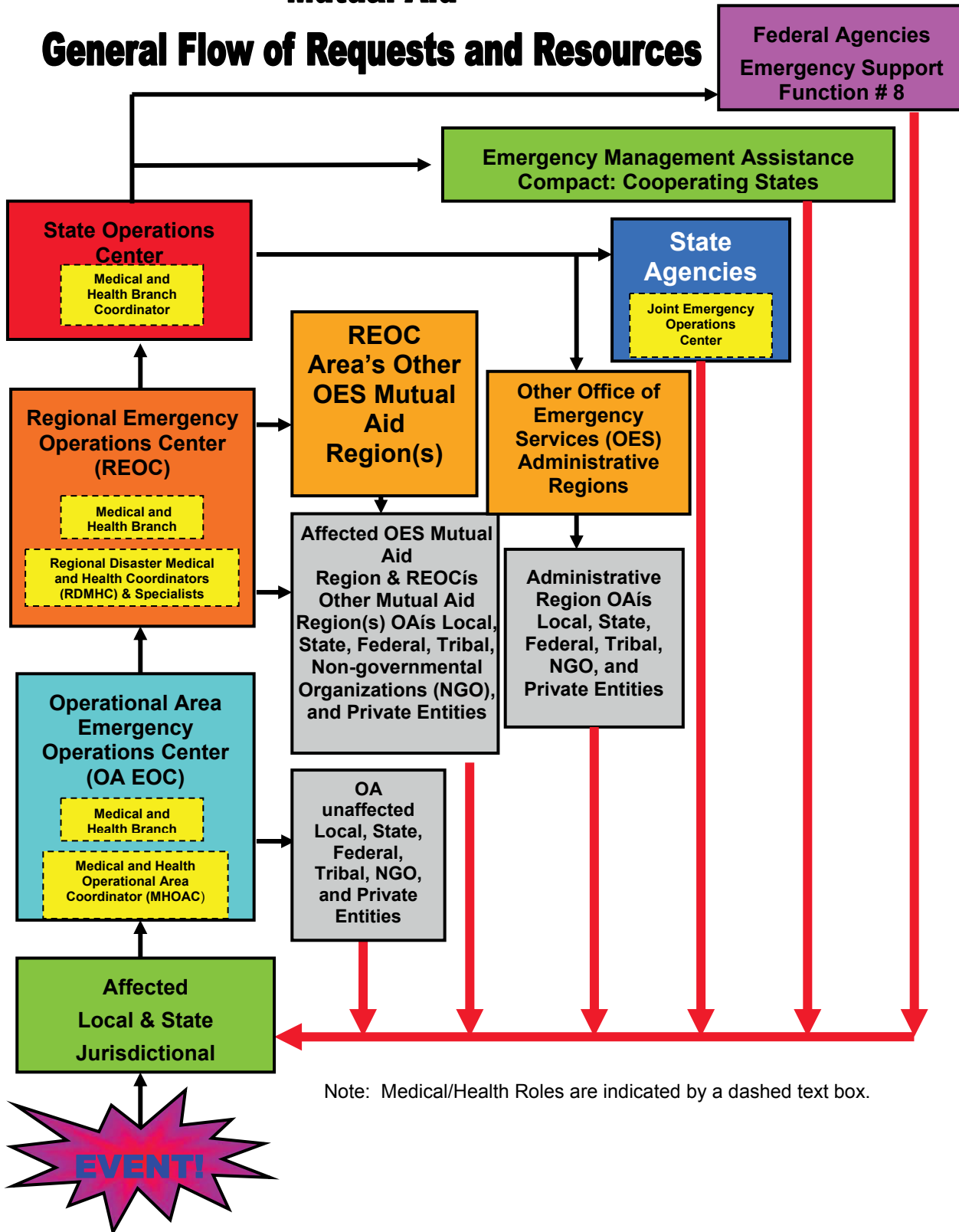
emergency is to coordinate the acquisition of requested medical or public and environmental health mutual aid in an affected region to deliver to the area affected by the disaster through the SEMS/NIMS structure. The Regional Disaster Medical and Health Coordinator must either be a county health officer, a county coordinator of emergency services, an administrator of a local Emergency Medical Services agency, or a medical director of a local Emergency Medical Services agency. In a proclaimed emergency and at the request of Emergency Medical Services Authority, CDPH or the Office of Emergency Services, a Regional Disaster Medical and Health Coordinator in an unaffected region may also coordinate the acquisition of requested mutual aid resources in his or her region.²⁰

Mutual aid is not limited to aid between jurisdictions in California. The Governor may also enter into reciprocal aid agreements or compacts, mutual aid plans, or other interstate arrangements for the protection of life and property with other States and the federal government, either on a Statewide or a political subdivision basis.²¹ The Emergency Management Assistance Compact is the primary legal tool that all states use to immediately send and receive emergency personnel and equipment during a major disaster. The State has also entered into the Interstate Civil Defense and Disaster Compact²² and can also seek federal mutual aid by requesting a presidential declaration of an emergency or major disaster under the provisions of the Stafford Act.²³ A presidential declaration makes federal assistance programs available, depending on the level of the declaration, as outlined in the Federal Response Plan, which includes contributions from several federal agencies and nongovernmental organizations, such as the American Red Cross. The mutual aid process is described in the following chart which shows that requests for mutual aid rise through the levels (i.e., Operational Area Emergency Operations Center, Regional Emergency Operations Center and State Operations Center) and resources flow back down to the affected local and State jurisdictional agencies and affected healthcare facilities.



Mutual Aid

General Flow of Requests and Resources





3.4 State Department of Public Health

CDPH²⁴ is designated as the lead for the public health agency of the medical and health services operations set forth in the State Emergency Plan and participates with the Emergency Medical Services Authority in carrying out medical responsibilities.^{25, 26} CDPH is the lead planning organization for the State's emergency response for pandemic influenza. CDPH is also the agency with licensure and certification responsibility for acute care hospitals and other health-related facilities.²⁷ During the early stages of an incident when acute care hospitals are reaching the limits of their capacity, healthcare facility administrators may contact the Licensing and Certification Division of CDPH in their region to obtain waivers of specific regulatory requirements.²⁸

3.5 Emergency Medical Services Authority

The Emergency Medical Services Authority²⁹ is required by law to respond to any medical disaster by mobilizing and coordinating emergency medical services mutual aid resources to mitigate health problems.³⁰ The State Emergency Plan designates the Emergency Medical Services Authority as the lead State agency for the medical response to an emergency.³¹ Generally, any attendant in a publicly or privately owned ambulance must possess evidence of specialized training as set forth in the emergency medical training and educational standards for ambulance personnel established by the Emergency Medical Services Authority.³² However, this requirement does not apply in any state of emergency declared under the Emergency Services Act when it is necessary to fully utilize all available ambulances in an area and it is not possible to have the ambulance operated or attended by persons with the qualifications required by the Emergency Medical Services Authority.³³

3.6 Governor's Office of Emergency Services

The Office of Emergency Services is established in the Governor's Office.³⁴ The Governor is required to assign all or part of his powers under the Emergency Services Act to the Office of Emergency Services,³⁵ but cannot delegate to the Office of Emergency Services his authority to issue orders and regulations.³⁶ During a state of emergency or a local emergency, the director of the Office of Emergency Services is responsible to coordinate the emergency activities of all State agencies in connection with such emergency.³⁷ The director does so through the State Operations Center and Regional Emergency Operations Centers.

The Office of Emergency Services has established three administrative regions: the Southern Region, the Coastal Region and the Inland Region.³⁸ These administrative regions coordinate emergency management in the six mutual aid regions created by the Governor (see Section 3.3: The Concept of Mutual Aid).



3.7 Role of the Governor

The Governor is given broad powers under the Emergency Services Act. Some powers granted to the Governor have been previously discussed, for example, the power to make, amend and rescind orders and regulations having the force and effect of law,³⁹ to suspend regulatory statutes and regulations,⁴⁰ and the power to use and commandeer property and personnel.⁴¹ In addition, the Governor has powers which are specific to the type of emergency proclaimed.⁴² For example, during a state of emergency, the Governor has authority over all agencies of State government and the right to exercise all police power vested by law in the State within the area designated.⁴³ Also during a state of emergency, the Governor can direct all State government agencies to utilize and employ State personnel, equipment, and facilities for the performance of any and all activities designed to prevent or alleviate actual and threatened damage due to the emergency, and can direct them to provide supplemental services and equipment to political subdivisions to restore any services which must be restored in order to provide for the health and safety of the citizens of the affected area.⁴⁴

In carrying out his/her responsibilities under the Emergency Services Act, the Governor is assisted by the California Emergency Council.⁴⁵ Among other duties, the California Emergency Council must consider, recommend and approve orders and regulations that are within the province of the Governor to promulgate.⁴⁶ This would include orders and regulations to suspend regulatory requirements or to alter standards of care.

The Governor is also assisted by the Emergency Response Team for State Operations,⁴⁷ whose task is to improve the ability of State agencies to resume operations in a safe manner and with a minimum of delay if their operations are significantly interrupted by a business interruption.⁴⁸

3.8 Local Emergency Plans and Local Disaster Councils

Most emergencies begin at the local level. Section 3.9 defines the SEMS structure, which begins at the local level, and discusses the role of local government as it relates to healthcare surge.

The Emergency Services Act defines “emergency plans” to mean those official and approved documents which describe the principles and methods to be applied in carrying out emergency operations or rendering mutual aid during emergencies. These plans include such elements as continuity of government, the emergency services of governmental agencies, mobilization of resources, mutual aid, and public information.⁴⁹ During a state of emergency, outside aid must be rendered in accordance with approved emergency plans, and public officials are required to cooperate to the fullest extent possible to carry out such plans.⁵⁰



3.8.1 Disaster Councils

Cities and counties are authorized to create disaster councils by ordinance.⁵¹ If created, the disaster council is responsible for developing emergency plans.⁵² The plans must meet any condition constituting a local emergency or state of emergency, including, but not limited to, earthquakes, natural or manmade disasters specific to that jurisdiction, or state of emergency, and the plans must provide for the effective mobilization of all of the resources within the political subdivision, both public and private.⁵³

A primary motivation for organizing a disaster council is that the disaster council can register disaster service workers. Under the Emergency Services Act, the Office of Emergency Services is authorized to adopt regulations for the classification and registration of disaster service workers.⁵⁴ The regulations provide that a disaster service worker is a person registered either with the Office of Emergency Services, a State agency authorized to register disaster service workers, or a disaster council.⁵⁵ Registered disaster service workers can be afforded workers' compensation benefits and liability protections for their acts and omissions during an emergency. If a volunteer is registered with an unaccredited disaster council, the volunteer arguably is not a disaster service worker for purposes of workers' compensation coverage.

It is the legal duty of each organizational component, officer and employee of each political subdivision of the State to render all possible assistance to the Governor and to the director of the Office of Emergency Services in mitigating the effects of an emergency. Local public official emergency powers are subordinate to any emergency powers exercised by the Governor.⁵⁶

3.9 Standardized Emergency Management System

SEMS is a system for managing the response to multi-agency and multi-jurisdictional emergencies in California.⁵⁷ This system integrates the National Incident Management System (NIMS), the Incident Command System, and the support and coordination system developed under SEMS. All State agencies are required to use SEMS to coordinate multiple jurisdiction or multiple agency emergency and disaster operations.⁵⁸ Every local government agency, in order to be eligible for any funding of response-related (i.e., personnel) costs under disaster assistance programs, must also use SEMS to coordinate multiple jurisdiction or multiple agency emergency and disaster operations.⁵⁹ This means that local emergency plans must also incorporate SEMS, assuming the local government wants to be reimbursed for emergency personnel costs.

SEMS recognizes five organizational levels for response. The levels are listed below in the order in which they become involved in the response:

1. Field – where diverse local response organizations (law enforcement, fire, public health) use their own resources to carry out tactical decisions and activities



2. Local – where local governments, for example, cities, counties and special districts, manage and coordinate the emergency response and recovery
3. Operational Area– the entity consisting of all political subdivisions within a county that coordinates resources, the provision of mutual aid, emergency response and damage information
4. Regional – manages and coordinates resources and information among Operational Areas in a geographic area
5. State –responsible for statewide resource allocation; if State resources are inadequate, this level is integrated with federal agency resources

SEMS embraces the concept of mutual aid.⁶⁰ It should be emphasized that under the Emergency Services Act, unless the parties to a mutual aid agreement expressly provide otherwise, the responsible local official in whose jurisdiction an incident requiring mutual aid has occurred remains in charge at such incident, including the direction of personnel and equipment provided through mutual aid.⁶¹ Thus, the fact that higher organizational levels become involved in coordinating resources and information does not mean that officials at that higher level take charge of the incident.

SEMS addresses the concept of emergency communications by supporting networks to ensure that all levels of government can communicate during a disaster. Two systems have been established:

1. The Response Information Management System – an electronic data management system that links emergency management offices throughout California
2. The Operational Area Satellite Information System – a portable, satellite-based network that provides communication when land-based systems are disrupted

In addition, there are discipline-specific communications systems, such as the California Health Alert Network. The California Health Alert Network is the emergency alert and notification system used by CDPH and many emergency preparedness stakeholders and partners associated with public health. The California Health Alert Network contains both an alerting system that provides rapid notification of emergencies to public health stakeholders and partners and a highly secure web-based document repository used for the creation and collaboration of information pertaining to preparation and/or response to various incidents or emergencies.

3.9.1 Incident Command System

SEMS is based on the concept of the Incident Command System⁶² which organizes emergency management during an incident response through eight core concepts:

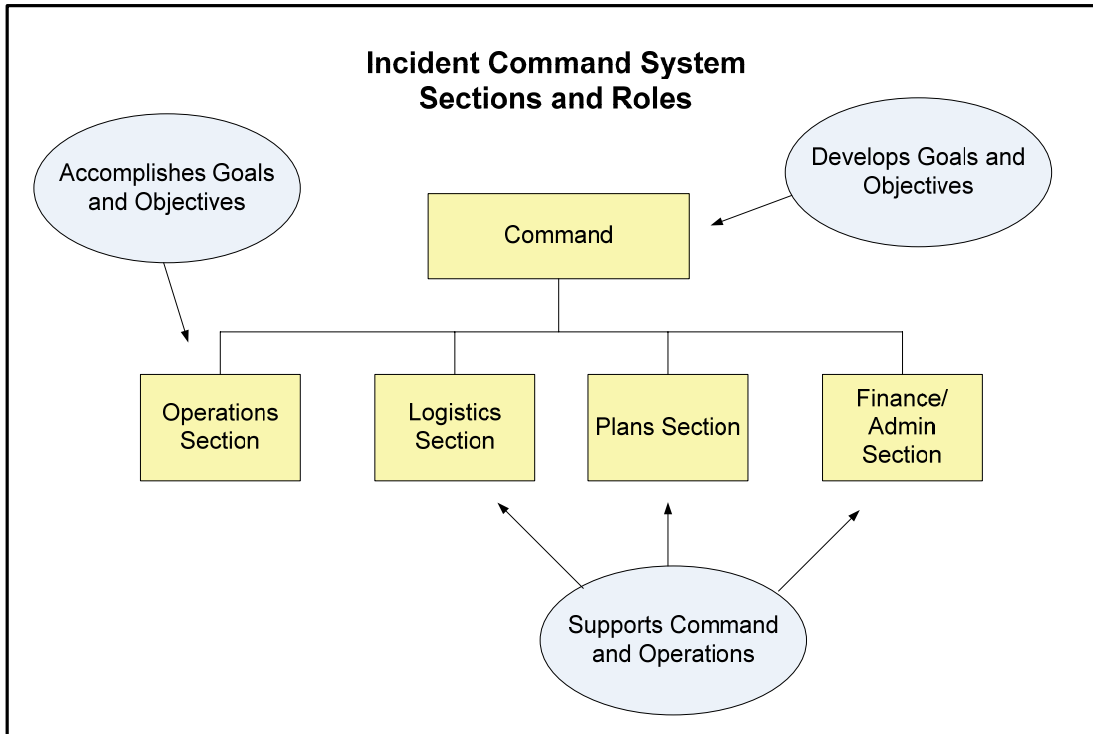
1. Common terminology: the use of similar terms and definitions for resource descriptions, organizational functions, and incident facilities across disciplines



2. Integrated communications: the ability to send and receive information within an organization, as well as externally to other disciplines
3. Modular organizations: response resources are organized according to their responsibilities during the incident. Assets within each functional unit may be expanded or contracted based on the requirements of the event
4. Unified Command structures: multiple disciplines and response organizations work through their designated managers within the Incident Command System to establish common objectives and strategies that prevent conflict and duplication of effort
5. Manageable span of control: the response organization is structured so that each supervisory level oversees an appropriate number of assets such that effective supervision is maintained. The Incident Command System defines this as supervising no more than three to seven entities
6. Consolidated action plans: a single, formal documentation of incident goals, objectives, strategies, and major assignments that are defined by the incident commander or by Unified Command
7. Comprehensive resource management: system processes to describe, maintain, identify, request, and track all resources within the system during an incident
8. Pre-designated incident facilities: assignment of locations where expected critical incident-related functions will occur

The Incident Command System recognizes that every response, regardless of size, requires five management functions be performed:

1. Management – the function of setting priorities and policy direction and coordinating the response
2. Operations – the function of taking responsive actions based on policy
3. Planning/Intelligence – the function of gathering, assessing and disseminating information
4. Logistics – the function of obtaining resources to support operations
5. Finance/Administration – the function of documenting and tracking the costs of response operations



The primary person in charge at field level is the Incident Commander. During the initial phases of an event, or for a very small event, this person will fulfill all necessary roles. As the event size or scope increases, the Incident Commander will expand the Incident Command System and identify chiefs for each of the sections.

As part of any event involving emergency management, local government agencies will use the Incident Command System as the method to organize and direct the field level tactical activities of the incident. This system has built-in flexibility that allows for any type of emergency. As an incident expands in scope, the Incident Command System expands and adapts with it. For additional information, refer to the California Office of Emergency Services website: <http://www.oes.ca.gov/Operational/OESHome.nsf/1?OpenForm>, click on “Update SEMS/NIMS”.

3.9.2 Unified Command

Unified Command is a management concept under the Incident Command System that occurs when there is more than one agency with jurisdictional responsibility (for example, public health, law enforcement, and fire) for the emergency or when emergency incidents expand across multiple political boundaries. Agencies work through the designated members of the Unified Command located at an Incident Command Post to establish a common set of objectives and strategies and a single Incident Action Plan.



The 1999 Westley Tire Fire in Stanislaus County, an example of Unified Command and response, involved multiple jurisdictions, each with specific responsibilities for abatement of the emergency. What started as a large number of tires on fire led to a multitude of emergencies, including an adjacent wildfire threatening hundreds of acres of vegetation, traffic flow problems on Interstate 5 involving miles of backed-up traffic, environmental pollution from toxic runoff into a creek creating a threat to drinking water and fish and game, and an air quality problem from the plume of smoke entering the populated areas downwind. Each emergency involved different local, regional and state agencies.

3.9.3 Multi-Agency Coordination Group

Multi-agency coordination groups establish policies and set priorities for management of the emergency response. It includes representation from governmental agencies with responsibilities to mitigate the impact of an emergency. The policies and priorities set by the multi-agency coordination groups direct the operational activities of the Unified Command. The principle functions and responsibilities of the multi-agency coordination group typically include:

1. Ensuring situational awareness and resource status information among responsible agencies
2. Establishing priorities for resources between incidents in concert with the Incident Command or Unified Command involved
3. Acquiring and allocating resources required by incident management personnel in concert with the priorities established by the Incident Command or Unified Command
4. Anticipating and identifying future resource requirements
5. Coordinating and resolving policy issues arising from the incident(s)
6. Providing strategic coordination as required

3.9.4 Operational Area Management

The Operational Area, defined in the Emergency Services Act, is a required concept of SEMS.⁶³ The Operational Area consists of a county and all political subdivisions within the county area, and serves as an intermediate level of the State emergency response organization.⁶⁴ The governing bodies of each county and the political subdivisions in the county are authorized to organize and structure their Operational Area. An Operational Area is used by the county and the political subdivisions comprising the Operational Area for the coordination of emergency activities and to serve as a link in the communications system during a state of emergency or a local emergency.⁶⁵ The responsibility for facilitating the activities of an Operational Area Emergency Operations Center during emergencies is



assigned to each county government within the State. However, upon agreement, a city government may assume the functions of an Operational Area Emergency Operations Center. In addition to the Operational Area, political subdivisions within a county may have their own Emergency Operations Center.

Under SEMS, an Operational Area Emergency Operations Center does not manage the emergency operations of any single government entity, but exists as an organization to facilitate the emergency management coordination of all government entities within the Operational Area.

The Operational Area Emergency Operations Center must be distinguished from department operations centers. Under SEMS, a department operations center is an emergency operations center used above the field level by a specific discipline (e.g., flood operations, fire, medical, hazardous material) or a governmental unit (e.g., Department of Public Works or Department of Health).⁶⁶ There may be as many department operations centers as there are public agencies involved in the response above the field level.

3.9.5 Operational Area's Medical and Health Disaster Plans

Each Operational Area may appoint a Medical Health Operational Area Coordinator who may be the local health officer, local emergency medical services director, or an appropriate designee. The Medical Health Operational Area Coordinator or designee is responsible for the development of a medical and health disaster plan for the provision of medical and health mutual aid for the Operational Area. The medical and health disaster plan must comply with the framework established by SEMS.⁶⁷

At a minimum, the Operational Area's medical and health disaster plan should include the following components relevant to healthcare surge:

- Assessment of immediate medical needs of the Operational Area
- Coordination of disaster medical and health resources
- Coordination of patient distribution and medical evaluations
- Coordination with inpatient and emergency care providers
- Coordination of out-of-hospital medical care providers
- Coordination and integration with fire agencies' personnel, law enforcement, resources and emergency fire pre-hospital medical services
- Coordination of providers of non-fire based pre-hospital emergency medical services
- Coordination of the establishment of temporary field treatment sites
- Health surveillance and epidemiological analyses of community health status
- Provision or coordination of mental health services
- Provision of medical and health public information protective action recommendations



- Investigation and control of communicable disease⁶⁸

During a medical or health disaster, the Medical Health Operational Area Coordinator or designee is responsible for implementing this plan and coordinating with the Regional Disaster Medical Health Coordinator on the acquisition of resources or the movement of patients to other jurisdictions.

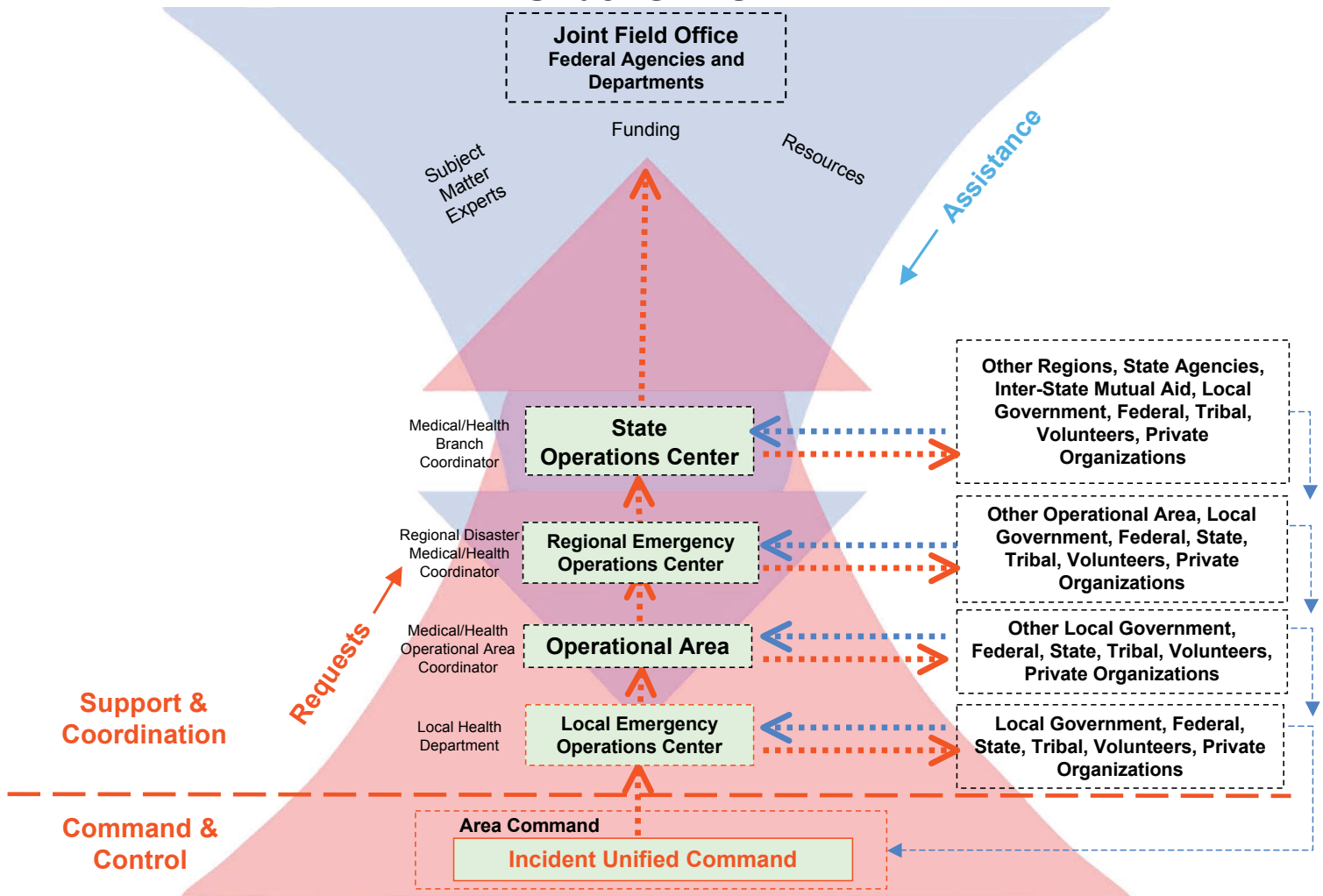
The Governor's Office of Emergency Services website, <http://www.oes.ca.gov>, provides specific information regarding Operational Area planning.

3.9.6 Resource Requesting and Assistance under SEMS

SEMS is designed to foster the coordination of public and private sector resources at all levels of its structure. As such, requests for resources flow upward from the local level to the federal level and assistance to meet these request flows downward from the federal level to the local level. To facilitate the request and assistance for resources, it is imperative that each coordination level above the requesting level be contacted in order to effectively supply and account for available resources. The diagram below depicts this flow of request and assistance for resources using SEMS during catastrophic emergencies.



Flow of Requests and Assistance During Large Scale Incidents Under SEMS



3.10 Persons Responsible for Local Emergency Healthcare Response

Thus far, the roles of the following State officials and agencies and, to some extent, regional levels in emergency preparedness and response have been discussed. The following sections discuss the roles of local officials.

3.10.1 Local Governing Body

The local governing body can be either the county board of supervisors or a city council. These bodies are authorized to proclaim a “local emergency.”⁶⁹ By ordinance, they may also designate an official who can proclaim local emergencies.⁷⁰ During a proclaimed local



emergency, political subdivisions of the State have full power to provide mutual aid to any affected area in accordance with local ordinances, resolutions, emergency plans, or agreements,⁷¹ and State agencies are authorized to provide mutual aid in accordance with mutual aid agreements or upon direction from the Governor.⁷²

The local governing body is also authorized during a local emergency to promulgate orders and regulations necessary to provide for the protection of life and property, including orders or regulations imposing a curfew within designated boundaries where necessary to preserve the public order and safety.⁷³

3.10.2 Local Health Officer

Each county is required to appoint a health officer.⁷⁴ The county health officer is responsible to enforce and observe, in the unincorporated territory of the county, the orders and ordinances of the board of supervisors pertaining to the public health and sanitary matters, orders – including quarantine and other regulations – prescribed by CDPH and statutes relating to public health.⁷⁵

There is similar authority for the appointment of city health officers.⁷⁶ However, most cities contract with the county health officer to provide local public health services.⁷⁷ Thus, in most counties, the county health officer has jurisdiction throughout the county.

Both city and county health officers are authorized, regardless of whether an emergency is declared, to take measures as may be necessary to prevent the spread, or the occurrence of additional cases, of any communicable disease that he or she reasonably believes may exist within his or her jurisdiction.⁷⁸ This includes the power to quarantine and isolate persons, animals or places, conduct investigations and examinations, and to disinfect where necessary to protect public health.⁷⁹ The local health officer can also require, during an outbreak of disease or when an outbreak appears imminent, that healthcare providers disclose their inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products that may be used for the prevention of, or may be implicated in, the transmission of communicable disease.⁸⁰

In addition, during any state of war emergency (defined by Government Code Section 8558(a)), state of emergency (defined by Government Code Section 8558(b)), or local emergency (defined by Government Code Section 8558(c)), a local health officer is authorized to take any preventive measure within his or her jurisdiction that may be necessary to protect and preserve the public health from any public health hazard. For purposes of this authorization, the term “preventive measure” means abatement, correction, removal or any other protective step that may be taken against any public health hazard that is caused by a disaster and affects the public health.⁸¹

In some jurisdictions, the local health officer is authorized by the governing body to declare a local emergency.⁸² All local health officers may also declare a local health emergency



whenever there is an imminent and proximate threat of the introduction of any contagious, infectious or communicable disease, chemical agent, non-communicable biologic agent, toxin or radioactive agent in the jurisdiction or any area thereof affected by the threat to the public health.⁸³ However, such a declaration does not carry all the implications of a “local emergency.” The immunity granted to hospitals, physicians and other medical professionals under Government Code Section 8659 is implicated.⁸⁴ Otherwise, the declaration authorizes the exercise of mutual aid,⁸⁵ allows the exchange of health information, and authorizes the determination of the cause of the emergency.⁸⁶

When an incident first arises, the local health officer may issue an order authorizing first responders to immediately quarantine exposed individuals that may have been exposed to biological, chemical, toxic, or radiological agents and that could spread to others. Such an order lasts only two hours, but may be sufficient time to allow the local health officer to reach the scene of the incident and to issue more comprehensive orders if needed.⁸⁷

3.10.3 County Director of Emergency Services

Counties may appoint a county director of emergency services. In absence of this, by virtue of his or her office, the county sheriff serves in this role.⁸⁸ The county director of emergency services has all the duties prescribed by State law and executive order, the California Disaster and Civil Defense Master Mutual Aid Agreement, mutual aid operational plans, and by county ordinances and resolutions.⁸⁹

3.10.4 Local Emergency Medical Services Agency/Medical Director

Each county is authorized to develop an emergency medical services program. Each county developing such a program must designate a local emergency management services agency. It may be the county health department or a separate agency established and operated by the county. It may also be an entity with which the county contracts or a joint powers agency created for the administration of emergency medical services by agreement between counties.⁹⁰

Every local emergency management services agency shall have a full- or part-time licensed physician and surgeon as medical director to provide medical control and to assure medical accountability throughout the planning, implementation and evaluation of the emergency management services system.⁹¹

3.10.5 County Director of Environmental Health

Some counties have separated the public health and environmental health responsibilities of the local health officer by creating a comprehensive environmental health agency.⁹² During a local emergency or a state of emergency, the county director of environmental health may be responsible for the coordination of emergency response under his or her jurisdiction. However, during a health emergency declared by the board of supervisors, or a county health



emergency declared by the local health officer, the local health officer shall have supervision and control over all environmental health and sanitation programs and personnel employed by the county during the state of emergency.⁹³

3.10.6 Medical Health Operational Area Coordinator

Each Operational Area may appoint a Medical Health Operational Area Coordinator. The Medical Health Operational Area Coordinator may be the local health officer and the county emergency medical services coordinator acting jointly, or a separate person appointed by these officials. The responsibilities of the Medical Health Operational Area Coordinator or appropriate Operational Area designee include coordinating with inpatient and emergency care providers, assessment of medical needs, and coordinating disaster medical and health resources.⁹⁴ These responsibilities are performed in compliance with the local emergency plan. The Medical Health Operational Area Coordinator or designee also coordinates with the Regional Disaster Medical Health Coordinator for resources within the designated region. The Regional Disaster Medical Health Coordinator generally delegates this coordination activity to the Regional Disaster Medical Health Specialist.

3.10.7 Healthcare Facility Incident Command System

In order to organize emergency response within a healthcare facility, it is recommended that each facility establish an Incident Command System. For example, many hospitals have adopted the Hospital Incident Command System (HICS). The Incident Command System can be scaled to meet the needs of the emergency. During an emergency, only the necessary incident command functions are activated.

At the point that a surge situation is proclaimed for the jurisdiction or Operational Area, all healthcare providers must be integrated into a unified incident command management structure under SEMS that coordinates the movement of patients, establishes priorities and allocates scarce resources, services and supplies among the healthcare providers. In this situation, the needs of all healthcare providers will be integrated into a single consolidated incident action plan that will result in optimum patient care for the community. The facility incident command will request resources through the Unified Command of the Operational Area.

To accomplish this, an authorized local official, or designee, will notify healthcare facilities that the Unified Command has been established and provide a contact within the Operations Section of the Unified Command for coordination of patient movement and requests for resources, services and supplies.

3.10.8 County Coroner

Each county in California has a sheriff/coroner, a coroner or a medical examiner.⁹⁵ His or her duty is to manage the remains of deceased persons within the county, their personal effects, if



necessary,⁹⁶ and to inquire into the causes of death under specified circumstances.⁹⁷ In a catastrophic emergency also involving mass fatalities, this officer serves as the Operational Area Coroner Mutual Aid Coordinator.⁹⁸ The State is divided into seven coroners' mutual aid regions, and each region has a Coroner's Regional Mutual Aid Coordinator.

Each Operational Area coroner/medical examiner is advised to develop local contingency plans to deal with mass fatality emergencies, including those involving chemical, biological and radiological contamination of human remains. These plans should also address issues such as storage capacity for human remains, and disposition of remains, including cremation, isolated burial, mandatory mass disposition, and return to family.⁹⁹

3.11 Progression of Healthcare Response through Surge

When a catastrophic emergency occurs, healthcare facilities will activate emergency operations plans and mobilize under their individual Incident Command Systems to manage the actual or anticipated influx of patients and the increased resource demands. If conditions within the hospital are sufficiently strained, the hospital may consult with CDPH Licensing and Certification to determine if specific requirements related to staffing and patient management can be flexed to maximize the hospital's response capabilities. If circumstances become overwhelming, the hospital can divert inbound ambulances, if possible, and transfer patients who have been medically screened and deemed stable for transfer to other hospitals, other healthcare facilities or Alternate Care Sites established by local governmental authorities.

Under the SEMS/NIMS structure, once the impact of an emergency is sufficient to impact multiple emergency response disciplines (law enforcement, fire, public health), a Unified Command organization will be established close to the incident to manage the tactical operations of mitigating the response. Under these conditions, the specific healthcare provider's logistical functions within its Incident Command System would place the facilities resource requests through the Unified Command. The Unified Command, through its Logistics Section, would request the resources that are needed for all healthcare facilities through the SEMS structure. All resource requests (i.e., pharmaceuticals, medical supplies and staff) are prioritized through the Multi-agency Coordination Group which includes representation from all affected response disciplines and political subdivisions.

If the Operational Area needs resources from outside the area, a request for mutual aid, made through its Emergency Operations Center, can be sent to the Office of Emergency Services Regional Emergency Operations Center. Typically, medical and health requests flow from the Medical Health Operational Area Coordinator to the Regional Disaster Medical Health Coordinator. The Regional Disaster Medical Health Coordinator, in coordination with the Regional Emergency Operations Center, would attempt to acquire the needed resources within the region.

If resources are unavailable in the region, the Regional Emergency Operations Center would notify State Operations Center which would coordinate with the CDPH/Emergency Medical



Services Authority Joint Emergency Operation Center to obtain additional resources, through the following process:

- The State Operations Center would coordinate with unaffected regions to obtain resources. Regional Disaster Medical Health Coordinators from unaffected regions will be utilized to coordinate the acquisition of requested resources and mutual aid on behalf of the affected region.
- CDPH and the Emergency Medical Services Authority would then attempt to fill the request at the State level from resources under their control.
- If the request(s) cannot be filled from within the State, the State Operations Center would contact other states and/or the Federal Emergency Management Agency to request deployment of federal resources.

The Governor can determine that, despite all the mutual aid provided and the immunities available to professionals and facilities providing emergency care, extraordinary measures must be taken to suspend regulatory statutes under Government Code Section 8571 in order to enable providers of medical care to render emergency aid to individuals who otherwise would not receive it. In addition, the Governor could issue orders and regulations to modify standards of care or to commandeer property and personnel, consistent with the Emergency Services Act's goal of preserving lives.

3.12 Termination of the Emergency

A local emergency proclaimed by a designated local official terminates by operation of law after seven days, unless the proclamation has been ratified by the local governing body.¹⁰⁰ If a local emergency has been proclaimed by the local governing body, the governing body must review the need for continuing the local emergency at its regularly scheduled meetings until the emergency is terminated.¹⁰¹ The governing body must proclaim the termination of the local emergency at the earliest possible date that conditions warrant.¹⁰²

Similarly, the Governor must proclaim the termination of a state of emergency at the earliest possible date that conditions warrant.¹⁰³ All of the powers granted to the Governor under the Emergency Services Act for a state of emergency terminate upon the proclamation.¹⁰⁴ Thus, to the extent that the Governor has suspended regulatory statutes or altered standards of care by regulation, those suspensions and alterations would automatically end when the Governor proclaims the termination of the state of emergency.



4. The Exercise of Extraordinary Powers during a Healthcare Surge

4.1 Regulatory Standards as Potential Obstacles to Mitigating Medical Disasters

In a medical or health disaster, suspension of healthcare-related regulatory statutes and regulations could be used to increase the capacity of providers to render medical services which, under normal standards, might not be available. Most medical care in California is delivered by providers in the private sector that are highly regulated through a myriad of laws including licensure and certification requirements. Under normal circumstances, a failure to comply with these requirements can result in criminal, administrative, and/or civil liabilities. However some requirements may impede the ability to deliver care and may need to be flexed to facilitate the provision of care.

Up until this point, the focus of the emergency response is the acquisition of requested aid. However, a disaster could be so severe that resources statewide are exhausted. For example, it is conceivable that a pandemic influenza could cause a medical and health disaster in every Operational Area of the State, with no Operational Area having resources to share because all jurisdictions are utilizing every available resource to mitigate the disaster within their Operational Areas. Further, it may not be possible in all circumstances to deliver requested medical aid to an affected Operational Area in a timely fashion. For example, a severe-magnitude earthquake in the San Francisco Bay region could make roads and bridges into the area impassable, while at the same time causing a healthcare surge within that Operational Area.

The Emergency Services Act (Government Code Section 8550, et seq.) authorizes the Governor during a “state of emergency” to suspend any regulatory statute, or statute prescribing the procedure for conduct of State business, or the orders, rules, or regulations of any State agency, where the Governor determines and declares that strict compliance would in any way prevent, hinder, or delay the mitigation of the effects of the emergency.¹⁰⁵ The authority to suspend statutes is unique to the Governor. Local governing bodies and officials acting under a proclaimed local emergency do not have this power.

The Emergency Services Act also authorizes the Governor to make, amend, and rescind orders and regulations necessary to carry out the provisions of the Emergency Services Act, and further provides that the orders and regulations have the force and effect of law.¹⁰⁶

The suspension of regulatory statutes and regulations can have several consequences. During the period of the proclaimed emergency and suspension, the suspended statutes and regulations have no force and effect. Consequently, regulatory and law enforcement agencies cannot penalize persons for failing to comply with the statute or regulation. Further, the statute or regulation cannot provide a basis for finding negligence as a matter of law, which can lessen the potential for civil liability should a person, be unintentionally harmed by emergency response activities. The absence of specific regulatory restraints can remove barriers for



persons to act beneficially to mitigate the effects of the emergency and generally to protect the health and safety and preserve the lives and property of the people of the State without fear of subsequent criminal, administrative or civil liability. Not all requirements, however, are indispensable under all circumstances to protect the consumer. For example, during a healthcare surge, California Occupational Safety and Health Administration will work with the Safety Officer at facilities in the Regional or Operational Area Emergency Operations Center to assist with achieving compliance with occupational safety standards and regulations.

4.2 Immunities from Liability Available in an Emergency

Several statutes provide qualified immunity to persons rendering aid and healthcare facilities providing care during an emergency. These immunity provisions instruct the courts not to impose liability in specified emergency circumstances. Thus, if the immunity applies, there can be no liability. This, in turn, may reduce the need for a suspension of regulatory requirements because the immunity already contemplates that the standard of care is dependent upon available resources.

Immunities available by law for emergency care must first be examined before examining more closely the authority and procedures for suspending regulatory statutes or promulgating emergency orders and regulations, or what regulatory statutes or State agency orders, rules or regulations, if suspended, would assist in the mitigation of the effects of a medical and health emergency.

4.2.1 Healthcare Services during a Proclaimed Emergency

Government Code Section 8659 under the Emergency Services Act states that any physician or surgeon (whether licensed in this State or any other State), hospital, pharmacist, nurse, or dentist who renders services during any state of emergency, a state of war emergency, or a local emergency at the express or implied request of any responsible State or local official or agency is immune from liability for any injury sustained by any person by reason of such services, regardless of how or under what circumstances or by what cause such injuries are sustained.¹⁰⁷ The immunity provided under the Emergency Services Act does not apply “in the event of a willful act or omission.”

It has been argued that the phrase “willful act or omission” completely negates the immunity, because every act undertaken by a health facility or professional to render services during an emergency is willful, that is, the product of a deliberate choice. However, there does not appear to be any case to support such an interpretation of Government Code Section 8659. To the contrary, cases interpreting Business and Professions Code Section 2395, the “Good Samaritan” statute for physicians, which contains an identical exclusion for a “willful act or omission,” have repeatedly supported the application of immunity, notwithstanding very deliberate actions on the part of the defendants in those cases to treat their patients. For example, in *Burciaga v. St. John’s Hospital*,¹⁰⁸ a pediatrician summoned under emergency circumstances to the delivery room administered suction and applied oxygen to an infant in



respiratory distress, then secured transfer of the infant to a neonatal unit in a different hospital. The pediatrician was found to be immune, despite the fact that the child allegedly suffered permanent neurological damage and cerebral palsy. Similarly, in *Bryant v. Bakshandeh*,¹⁰⁹ a urologist who was summoned to assist in the catheterization of an infant patient prior to surgery, but despite repeated attempts was unable to do so due to complications, was also found to be immune, even though the child subsequently died.

As a general rule, the purpose of statutory construction is to ascertain the intent of the Legislature so as to effectuate the purpose of the law.¹¹⁰ The clear purpose of the Government Code Section 8659 is to encourage providers of medical care to render emergency aid to individuals who otherwise would not receive it. To construe Government Code Section 8659 to exclude any deliberate attempt to render emergency aid would completely defeat the statute's apparent purpose. Although it remains unclear precisely what the Legislature intended by the words "willful act or omission," it seems obvious that it did not intend that the qualification would negate the purpose of the statute altogether.

The immunity provided by Government Code Section 8659 is distinctive in other ways. Unlike the immunity provided by the Good Samaritan statute for physicians, the services rendered do not need to be emergency care. It appears sufficient that the care was rendered at the express or implied request of an authorized official. Also, unlike the immunity provided to disaster service workers under the Emergency Services Act, providers of care do not need to be registered disaster services workers in order to receive the immunity. The facility or professional simply needs to fall within one of the licensure categories described in the statute and render care at the express or implied request of an authorized official.

4.2.2 Emergency Care at the Scene of an Emergency

Business and Professions Code Section 2395 provides immunity from civil damages to physicians for acts and omissions in rendering emergency care in good faith at the scene of an emergency. The statute specifically includes, but is not limited to, the emergency departments of hospitals in the event of a medical disaster within the meaning of the phrase "the scene of an emergency." The phrase "medical disaster" specifically refers to a duly proclaimed state of emergency or local emergency declared pursuant to the Emergency Services Act. It applies to acts or omissions which occur after the declaration of a medical disaster and those which occurred prior to such declaration but after the commencement of such medical disaster.

Similar provisions exist for nurses,¹¹¹ dentists,¹¹² licensed vocational nurses,¹¹³ physician's assistants,¹¹⁴ any person providing on-scene emergency care,¹¹⁵ physicians providing instructions to Emergency Medical Technicians-IIs or paramedics,¹¹⁶ law enforcement and emergency response personnel providing on-scene emergency care,¹¹⁷ and public entities and emergency rescue personnel providing emergency care¹¹⁸ if acting in good faith.¹¹⁹ The immunity will not apply if the person is grossly negligent.¹²⁰



4.2.3 Failure to Obtain Informed Consent under Emergency Conditions

The right to give or withhold consent to medical treatment is well established in California.¹²¹ In a medical emergency, however, prompt medical treatment may be provided without first obtaining informed consent if treatment is necessary to prevent deterioration or aggravation of a patient's condition and the patient is unconscious and unable to consent, or has no surrogate decision maker. Under this exception, only the emergency condition may be treated. Since informed consent is patient specific—a patient experiencing an emergency medical condition—this exception is based on individual assessments and not, in and of itself, on a mass casualty situation with an overwhelming number of patients requiring treatment.

Physicians and surgeons are also immune from civil damages for injuries in emergency situations in their office or in a hospital on account of a failure to obtain fully informed consent where the (1) patient was unconscious and (2) lack of informed consent was due to the provider's reasonable belief that a medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient or a person authorized to give such consent for the patient.¹²²

4.2.4 Lawfully Ordered Services by Disaster Service Workers

In an emergency, additional staff will be needed. Persons providing services may be public employees redirected to emergency response efforts or volunteers registered with State or local disaster councils.¹²³ The Office of Emergency Services is required to develop a plan for State and local governmental agencies to utilize volunteer resources during a state of emergency proclaimed by the Governor.¹²⁴ Whether a public employee or a volunteer, a person providing disaster relief is referred to as a "disaster service worker."¹²⁵ All State and local public employees are, by law, disaster service workers.¹²⁶ Disaster service workers are covered, to the extent funds are available, by workers' compensation for injuries sustained in the course of training for or providing relief work.¹²⁷ Volunteer disaster service workers are not compensated, but may be reimbursed for expenses.¹²⁸

Disaster service workers are entitled to the same immunities as public employees.¹²⁹ If performing services during a proclaimed disaster under the Emergency Services Act, disaster service workers are also immune from civil damages on account of personal injury to or death of any person or damage to property resulting from any act or omission in the line of duty, except one that is willful.¹³⁰

Some volunteers will be medical professionals, who will staff casualty stations, establish and operate medical and public health field units or assist in hospitals, outpatient clinics, and other medical and public health installations.¹³¹ These persons would have access to qualified immunity other than for willful acts and omissions.



4.2.5 Facilities Used as Mass Care Centers

Civil Code Section 1714.5 provides immunity from liability for disaster service workers as well as an owner or operator including a public agency that owns or maintains any building or premises which is used as a mass care center, first-aid station, temporary hospital annex or other necessary facility for mitigating the effects of an emergency. The immunity is from liability to any person who has entered to seek refuge, treatment, care or assistance, while in or upon the premises, for injuries sustained as a result of the condition of the building or premises, or as the result of any act or omission, or as a result of the use or designation of the premises as a mass care center, first-aid station, temporary hospital annex or other necessary facility for emergency purposes. The only exclusions from immunity are the willful acts of the owner or occupant or their employees.¹³²

4.2.6 Health Facilities with Inadequate Resources

By law, emergency services and care must be provided to any person upon request for any condition in which the person is in danger of loss of life, serious injury or illness at any health facility licensed by the State that maintains and operates an emergency department to provide emergency services to the public when the health facility has appropriate facilities and qualified personnel available to provide the services or care.¹³³ A medical screening examination and stabilization of an emergency medical condition is required.¹³⁴ However, the health facility and its employees, including any physician, surgeon, dentist, clinical psychologist and podiatrist, are immune from liability in any action arising out of a refusal to render emergency services or care if the refusal is based on the determination, exercising reasonable care, that the person is not suffering from an emergency medical condition or that the health facility does not have the appropriate facilities or qualified personnel available to render those services.¹³⁵

4.2.7 Hospital Rescue Teams

For purposes of the immunity provision, a “rescue team” is a special group of physicians and surgeons, nurses, and employees of a health facility who have been trained in cardiopulmonary resuscitation and have been designated by the health facility to attempt, in cases of emergency, to resuscitate persons who are in immediate danger of loss of life.¹³⁶ So long as good faith is exercised, no act or omission of any rescue team established by any healthcare facility, or operated by the federal or state government, a county, or by the Regents of the University of California, done or omitted while attempting to resuscitate any person who is in immediate danger of loss of life shall impose any liability upon the health facility, the officers, members of the staff, nurses, or employees of the healthcare facility, including, but not limited to, the members of the rescue team, or upon the federal or state government or a county.



4.2.8 Violation of Statute or Ordinance under Emergency Orders

As previously discussed, violation of a statute can provide the basis for a claim of negligence as a matter of law. In an emergency, however, it is a misdemeanor to refuse or willfully neglect to obey any lawful order or regulation promulgated or issued under the Emergency Services Act.¹³⁷ Such orders and regulations may compel a person to violate a statute. Consequently, the law also provides that the violation of any statute or ordinance shall not establish negligence as a matter of law where the act or omission involved was required to comply with any regulation, directive, or order of the Governor promulgated under the Emergency Services Act.¹³⁸ In addition, a person cannot be prosecuted for a violation of any statute or ordinance when the violation was required in order to comply with any regulation, directive, or order of the Governor.¹³⁹

4.3 Suspension of Regulatory Statutes to Expand Availability of Care

For purposes of the following discussion, it is assumed that the Governor has determined that, despite all the aid provided and the immunities available to healthcare facilities and professionals providing emergency care, extraordinary measures must be taken to suspend regulatory statutes as permitted under Government Code Section 8571 in order to facilitate or encourage providers of medical care to render emergency aid to individuals who otherwise might not receive it.¹⁴⁰ Whether this point is ever achieved may depend upon several factors that cannot be predicted. For example, some organized health systems may have a contractual responsibility to provide medical care to their members even under disaster conditions, and therefore may be willing to provide care to their members despite a perceived increased risk of liability. There may also be good reasons, from the standpoint of maintaining goodwill in the community, for a healthcare facility to do everything within its power following a disaster to provide the medical care services needed by the community. Many of the immunities discussed in the preceding sections would apply, and these immunities may be sufficient to justify the provision of services despite degraded circumstances. In addition to the immunity protections, the standard of care expected under normal circumstances would shift to what a reasonable person would do under the disaster circumstances.

Nevertheless, there may be reluctance on the part of healthcare facilities or professionals to render assistance because of the circumstances and resulting uncertainty about immunity or compliance with existing regulatory requirements. It is likely that these healthcare facilities and professionals will continue to provide care as best they can under the circumstances; however, some healthcare professionals could refuse to provide care because they are unable to provide healthcare services at a level normally consistent with ordinary care. There is no general statutory or regulatory requirement that healthcare professionals be available to provide care to the public under all circumstances.¹⁴¹ Indeed, this accounts for the existence of the Good Samaritan laws discussed above.¹⁴² Thus, given the highly regulated nature of healthcare delivery and uncertain consequences for providing care in disaster situations, a Governor's suspension of regulatory requirements may be required to facilitate the willingness and ability to render emergency aid.



4.4 Commandeering of Facilities and Personnel

During a declared state of emergency, the Governor is authorized to commandeer or utilize any private property or personnel as deemed necessary in carrying out the responsibilities hereby vested in him or her as chief executive of the State.¹⁴³ The power to commandeer exists only under a state of emergency, and may only be exercised by the Governor or an authorized designee. It is not available under a local emergency.¹⁴⁴ It must also be distinguished from more commonly used methods, such as contracts and agreements, to obtain necessary resources.



5. Standard of Care

This section defines standard of care during a healthcare surge and discusses the implications of this definition.

5.1 Standard of Care Defined

The "standard of care" in California is based on what a reasonably prudent person with similar knowledge and experience would do under similar circumstances. Standard of care is a legal concept that requires licensed healthcare personnel, when caring for patients, to adhere to the customary skill and care that is consistent with good medical (or other healthcare) practice. As such, it is dependent to a certain degree on the type of provider and their respective scope of practice each provider is licensed or authorized to provide. The standard of care provides a framework to identify and evaluate objectively the professional responsibilities of licensed personnel, and permits individual licensed personnel to be rationally evaluated to ensure that is safe, ethical and consistent with the professional practice of the licensed profession in California.¹⁴⁵ Standard of care encompasses the diagnosis and treatment of patients and the overall management of patients.¹⁴⁶ For the purposes of this document:

The standard of care during a healthcare surge is defined as the utilization of skills, diligence and reasonable exercise of judgment in furtherance of optimizing population outcomes that a reasonably prudent person or entity with comparable training, experience or capacity would have used under the circumstances.



6. Recommended Approach for Healthcare Surge Monitoring

The recommended approach for healthcare surge monitoring provides a standard method to measure the movement away from “normal” operations to surge on the local, regional and State levels. This guideline assists healthcare personnel in understanding the progression of a healthcare surge from normal day-to-day operations to a situation where Operational Area, regional, State, and/or federal resources are needed in order to address the increased demand for healthcare.

As discussed in Section 2.1, a healthcare surge is proclaimed in a jurisdiction when an authorized local official, such as a local health officer or other appropriate designee,¹⁴⁷ using professional judgment, determines, subsequent to a significant emergency or circumstances, that the healthcare delivery system has been impacted, resulting in an excess in demand over capacity in hospitals, community care clinics, public health departments, other primary and secondary care providers, resources and/or emergency medical services. The local official uses the situation assessment information provided from the healthcare delivery system partners to determine overall local medical and health status.

6.1 Surge Monitoring Guidelines

During a healthcare surge, the authorized local official will use color-coded descriptors to designate the status of the local healthcare jurisdiction/Operational Area's healthcare delivery system. Healthcare surge status does not necessarily connote a specific emergency proclamation, but represents the condition of the healthcare delivery system in a continuum from normal daily operations to a significant healthcare surge. The designations of the color descriptors will be made by the authorized local official using their professional judgment and will provide other Operational Areas, the Regional Disaster Medical Health Coordinator and/or Regional Disaster Medical Health Specialist, and State agencies a clear understanding of the local healthcare status. There are five levels of local surge:

- **GREEN:** Local system is operational and in usual day-to-day status. No assistance required.
- **YELLOW:** Most healthcare assets within the local jurisdiction are experiencing a surge and are able to manage the situation within their organizational frameworks. No assistance required.
- **ORANGE:** The healthcare assets in the local jurisdiction require the participation of additional healthcare assets within the jurisdiction to contain the situation.
- **RED:** Local jurisdiction is not capable of meeting the demand for care, and assistance from outside the local jurisdiction/Operational Area is required.
- **BLACK:** Local jurisdiction not capable of meeting the demand for care, and significant assistance from outside the local jurisdiction/Operational Area is required.



Surge Monitoring Guidelines Table

	Local Surge Emergency					Regional Level Surge	Statewide Surge Level
Surge Level	Green	Yellow	Orange	Red	Black		
Enabling Authorities	Regulatory/ Accrediting Agency Waiver	Regulatory/ Accrediting Agency Waiver	Regulatory/ Accrediting Agency Waiver/ Local Emergency Declaration	Local Emergency Declaration	Local Emergency Declaration	State of Emergency Declaration	Federal Emergency Declaration

The chart above illustrates the relationship between the level of healthcare surge and enabling authorities to implement relative surge response activities. The chart includes the five levels of a local surge emergency, as well as a regional level healthcare surge and statewide level healthcare surge.

The Surge Monitoring Guidelines above can also be found on page 82 of the Foundational Knowledge Manual, Section 9: Foundational Knowledge Operational Tools.



7. Suspension of Specific State and Federal Laws and Regulations during a Healthcare Surge

It is inevitable that, during a healthcare surge, individuals providing healthcare services in licensed healthcare facilities and Alternate Care Sites may be unable to fully adhere to statutes, regulations and professional standards of practice relating to patient rights and professional ethics, including obtaining informed consent; honoring advance healthcare directives; communicating with healthcare agents, surrogates and next of kin; providing services to special needs populations; and honoring cultural preferences and rituals in the process disposing of human remains. As such, it is anticipated that the legal requirements concerning such rules will be waived or suspended by government authorities.

The Governor may suspend those regulatory requirements perceived to be an obstacle to the emergency response effort. The suspension would be implemented through an executive standby order of the Governor. Standby orders are directions issued by the Governor that make, amend, or rescind certain state laws that prescribe the conduct of state business that may in any way prevent, hinder, or delay the mitigation of the effects of the emergency. A standby order must be approved by the Emergency Council and then issued during a proclaimed state of emergency. In some cases, standby orders delegate the authority to suspend requirements to a specific State official, for example the director of the Office of Emergency Services, CDPH or the Emergency Medical Services Authority may be given additional authority.

The proclamation of a state of emergency alone is not sufficient to effectuate a suspension of regulatory requirements, unless those requirements have a provision enabling their automatic activation upon such a proclamation. The proclamation would need to include a standby order or the Governor would need to issue a separate executive order issuing the standby order.

It should be emphasized that until such a standby order is issued subsequent to a declaration of a state of emergency, no regulatory requirement is suspended (except to the extent that the regulatory agency has waived enforcement).¹⁴⁸ Therefore, medical providers must ascertain the existence and scope of the declared state of emergency, and extent and applicability of any suspension of regulatory requirements.

A regulatory statute can only be waived or suspended during a State of Emergency upon a determination and declaration by the Governor. Government Code Section 8571 states that that a regulatory statute is one designated to protect public health and safety. The intent of such statutes is to accomplish government's objective by mandating certain affirmative acts. Although criminal sanctions are relied upon, the primary purpose of the statute is regulation rather than punishment or correction. (See *People v. Davis* (2005) 126 Cal.App.4th 1416, 1434-35.)

Pursuant to Government Code Section 8571, the Governor can suspend such regulatory statutes, or statutes prescribing the procedure for the conducting of State business, or the



orders, rules, or regulations of any State agency where the Governor, or authorized designee, determines and declares that strict compliance with the statute, order, rule or regulation would in any way prevent, hinder or delay the mitigation of the effects of the emergency. For example, existing law mandates reporting requirements for various statistics, situations or responses. Under a declared emergency, it will be difficult if not impossible to continue to manage certain reporting requirements while mobilizing a mass casualty response. The Governor has the ability to suspend or modify certain reporting requirements to redirect resources to the casualty response during the duration of the declared emergency.

In addition to this broad authority, the Governor may also request a Federal disaster declaration or relief by Federal agencies of specific compliance requirements during the declared disaster. The Federal government may also waive or temporarily suspend certain federal requirements in order to facilitate healthcare operations and response during a declared disaster.

The tables below highlight specific State and federal laws as well as other regulatory activities that govern healthcare operations that may require suspensions during a state of emergency. It is important to recognize that the Governor will determine whether or not to suspend each statute at the time of each emergency. Regardless of the emergency and the authority of the Governor to suspend the statute, there are some statutes that are unlikely to be suspended due to the nature of the requirement. For further information on these topics, see Reference Manual, Section 3: Surge Regulations and Compliance Legal Matrix.

Table 1: State Statutes/Regulations

State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Public Health Reporting Requirements		
Cancer Registry Reporting – Health and Safety Code Section 103885, et seq.	Any healthcare facility providing therapy to cancer patients shall report each case of cancer to the State or the authorized representative in a format prescribed by the State. In addition, any healthcare professional diagnosing or providing treatment for cancer patients shall report each cancer case to the State or the authorized representative except for those cases directly referred to a treatment facility or those previously admitted to a treatment facility for diagnosis or treatment of that instance of cancer.	The cancer registry reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Burns & Smoke Inhalation Reporting – Health and Safety Code Section 13110.7	The director of every burn center (defined as an intensive care unit in which there are specially trained physicians, nursing and supportive personnel and the necessary monitoring and therapeutic equipment needed to provide specialized medical and nursing care to burned patients) which examines, treats, or admits a person with a burn or smoke inhalation injury or a person who suffers a burn-related death shall file a report with the State Fire Marshal describing the injury or death at the end of the examination or treatment or at the time the patient is discharged from the burn center or at the time of the patient's death.	The burn and smoke inhalation injury registry reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.
Disease Reporting – Health and Safety Code Section 120130	CDPH shall establish a list of reportable diseases and conditions and shall include the urgency of reporting each disease and condition. The list of reportable diseases and conditions may include both communicable and noncommunicable diseases. The list may include those diseases that are either known to be, or suspected of being, transmitted by milk or milk-based products. The list shall also include, but not be limited to, diphtheria, listeria, salmonella, shigella, streptococcal infection in food handlers or dairy workers, and typhoid. The list may be modified at any time by CDPH, after consultation with the California Conference of Local Health Officers.	Disease reporting is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Disease Reporting –17 CCR 2500(b) and (c)	It shall be the duty of every healthcare professional, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed in this statute, to report to the local health officer for the jurisdiction where the	Disease reporting is a regulatory statute. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	patient resides. Where no healthcare professional is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed in this statute may make such a report to the local health officer for the jurisdiction where the patient resides. In addition, the administrator of each healthcare facility, clinic, or other setting where more than one healthcare professional may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.	
Birth Reporting – Health and Safety Code Section 102400	Each live birth shall be registered with the local registrar of births and deaths for the district in which the birth occurred within 10 days following the date of the event.	The birth reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Death Reporting – Health and Safety Code Section 102775	Each death shall be registered with the local registrar of births and deaths in the district in which the death was officially pronounced or the body was found, within eight calendar days after death and prior to any disposition of the human remains.	The death reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Office of Statewide Health Planning and Development Reporting Requirements – Health and Safety Code Section 128765, et seq.	The Office of Statewide Health Planning and Development reporting requirements include summary level information related to individual healthcare facilities as well as aggregate patient data. This information, with the exception of discharge and encounter data, is to be compiled and reported on a timely basis and made publicly available. The public report shall include an executive summary, written in plain English to the maximum extent practicable, a discussion of findings,	The Office of Statewide Health Planning and Development reporting requirement is a regulatory statute. This reporting requirement can be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	conclusions, and trends concerning the overall quality of medical outcomes, including a comparison to reports from prior years, for the procedure or condition studied by the report.	
Health Facility Administration Reporting Requirements		
Transfers of Patients; Violations – Health and Safety Code Section 1317.4	All hospitals shall maintain records of each transfer made or received for a period of three years. All hospitals making or receiving transfers shall file with the State department annual reports on forms prescribed by the department which shall describe the aggregate number of transfers made and received according to the person's insurance status and reasons for transfers. A failure to report may result in civil penalties.	The hospital patient transfer record-keeping and reporting requirement is a regulatory statute with underlying regulations. This section can, however, be waived under Government Code Section 8571.
Unusual Occurrence Reports – 22 CCR 70737 and 22 CCR 71535	All cases of reportable diseases are required to be reported to the local health department. Any occurrence, including an epidemic outbreak, poisoning, fire, major accident, disaster, or other catastrophe or unusual occurrence threatening the welfare, safety or health of patients, personnel or visitors to healthcare facilities shall be reported as soon as reasonably practical to local health officials.	Unusual occurrence reporting is a regulatory statute. This regulation can be waived under Government Code Section 8571.
Medication Errors Reporting – Business and Professions Code Section 4125; 16 CCR 1711	Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.	The medication error reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Occupational Illness & Injury Reporting – Labor Code Section 6409; 8 CCR 14003	Every physician who attends any injured employee shall file a complete report of every occupational injury or occupational illness to the employee with the employer, or if insured, with the employer's insurer, on forms prescribed for that purpose by the Division of Labor Statistics and Research. A portion of the form shall be completed by the injured employee, if he or she is able to do so, describing how the injury or illness occurred. The form shall be filed within five days of the initial examination.	The occupational illness reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.
Work-Related Fatalities Reporting – 8 CCR 342	Work-related fatalities reporting is an occupational safety and health regulation that requires employers to immediately report any employee serious injury, illness or death that occurred as a result or at a place of employment. In the aftermath of a disaster, this regulation requires, whenever possible, that a report of the incident be made within 24 hours of occurrence.	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.
Criminal Activity Reporting Requirements		
Child Abuse & Neglect Reporting – Penal Code Section 11164, et seq.	The intent and purpose of this statute is to protect children from abuse and neglect. In any investigation of suspected child abuse or neglect, all persons participating in the investigation of the case shall consider the needs of the child victim and shall do whatever is necessary to prevent psychological harm to the child victim.	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.
Elder & Dependent Abuse Reporting – Welfare and Institutions Code Section 15600, et seq.	The Legislature recognizes that elders and dependent adults may be subjected to abuse, neglect, or abandonment and that this State has a responsibility to protect these persons. Healthcare practitioners,	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	care custodians, clergy members, and employees of county adult protective services agencies and local law enforcement agencies are required to report known or suspected cases of abuse of elders and dependent adults and to encourage community members in general to do so. Reports shall include information on the numbers of abuse victims, circumstances surrounding the act of abuse, and other data which will aid the State in establishing adequate services to aid all victims of abuse in a timely, compassionate manner.	
Violence against Hospital Personnel – Health and Safety Code Section 1257.7	Any act of assault or battery that results in injury or involves the use of a firearm or other dangerous weapon against any on-duty hospital personnel shall be reported to the local law enforcement agency within 72 hours of the incident. Any other act of assault or battery against any on-duty hospital personnel may be reported to the local law enforcement agency within 72 hours of the incident.	The violence against hospital personnel reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Violence against Community Healthcare Worker – Labor Code Section 6332	Every employer shall keep a record of any violence committed against a community healthcare worker and shall file a copy of that record with the Division of Labor Statistics and Research in the form and detail and within the time limits prescribed by the Division of Labor Statistics and Research.	The violence against community health worker reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Suspicious Injury Reports – Penal Code Section 11160, et seq., Penal Code Section 11161, et seq.	The suspicious injury reporting requirement requires that healthcare professionals providing medical services for a physical condition which may have resulted from a suspicious act, including an injury that resulted from an assault, be reported immediately.	The suspicious injury reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
General Acute Care Hospital Requirements		
Nurse Staffing Ratio – 22 CCR 70217	Hospitals shall provide staffing by licensed nurses within the scope of their licensure in accordance with the nurse-to-patient ratios outlined in 22 CCR 70217. Licensed nurse means a registered nurse, licensed vocational nurse and, in psychiatric units only, a licensed psychiatric technician. No hospital shall assign a licensed nurse to a nursing unit or clinical area unless that hospital determines that the licensed nurse has demonstrated current competence in providing care in that area and has also received orientation to that hospital's clinical area sufficient to provide competent care to patients in that area. Licensed nurse-to-patient ratios represent the maximum number of patients that shall be assigned to one licensed nurse at any one time. "Assigned" means the licensed nurse has responsibility for the provision of care to a particular patient within his/her scope of practice.	22 CCR 70217 may be flexed in the event of a "healthcare emergency which creates an unpredictable or unavoidable occurrence at unscheduled or unpredictable intervals." The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.
Conversion of Space for Other Uses – 22 CCR 70805	Space approved for specific uses at the time of licensure shall not be converted to other uses without the written approval of the CDPH.	The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.
General Acute Care Hospitals; Limitation to Licensed Beds – 22 CCR 70809	No hospital shall have more patients or beds set up for overnight use by patients than the approved licensed bed capacity except in the case of justified emergency when temporary permission may be granted by the CDPH Director or assigned designee. Beds not used for overnight stay such as labor room beds, recovery beds, beds used for admission screening or beds used for diagnostic purposes in X-ray or laboratory departments are not included in the approved licensed	The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	bed capacity. Patients shall not be housed in areas which have not been approved by CDPH for patient housing and which have not been granted a fire clearance by the State Fire Marshal.	
Out of Scope Supplemental Services – 22 CCR 70301	Any licensed general acute care hospital desiring to establish or conduct, or that holds out, represents or advertises by any means the provision of a supplemental service, shall obtain prior approval from CDPH or a special permit if required by 22 CCR 70351. (See below for specific information related to 22 CCR 70351.)	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Out of Scope Special Services – 22 CCR 70351	Any licensed general acute care hospital desiring to establish or conduct, or that holds out, represents or advertises by any means, the performance of a special service shall obtain a special permit from CDPH. The following supplemental services are also special services for which a special permit is required: basic emergency medical service, burn center, cardiovascular surgery service, chronic dialysis unit, comprehensive emergency medical service, psychiatric unit, radiation therapy service, renal transplant center.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Clinical Staff and Personnel Requirements: Physician		
Physician, Inactive – Businesses and Professions Code Section 702	The holder of an inactive healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an active license or certificate is required.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Physician, Retired – Business and Professions Code Section 2439	The holder of a retired license may not engage in the practice of medicine or the practice of podiatric medicine.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Practice Outside Federal Facility – Business and Professions Code Section 715, 718	<p>Unless otherwise required by federal law or regulation, no board which licenses physicians, surgeons or podiatrists may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies:</p> <p>(a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.</p>	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Clinical Staff and Personnel Requirements: Pharmacists		
Pharmacist, Inactive – Business and Professions Code Section 702	The holder of an inactive healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an active license or certificate is required.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Pharmacist, Out-of-State – Business and Professions Code Section 900	The holder of an out-of-state healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	active license or certificate is required.	
Pharmacists, Consultation Requirements – Business and Professions Code Section 4051	A pharmacist may authorize the initiation of a prescription and otherwise provide clinical advice or information or patient consultation if: (1) the clinical advice or patient consultation is provided to a healthcare professional or to a patient; (2) the pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice; (3) Access to the information described in paragraph (2) is secure from unauthorized access and use.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.
Clinical Staff and Personnel Requirements: Dentists		
Practice Outside Federal Facility – Business and Professions Code Section 715	Unless otherwise required by federal law or regulation, no board which licenses dentists may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies: (a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.	
Clinical Staff and Personnel Requirements: Nurses		
Practice Outside Federal Facility – Business and Professions Code Section 715	<p>Unless otherwise required by federal law or regulation, no board which licenses nurses may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies:</p> <p>(a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.</p>	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Pharmaceutical Requirements		
Prescription Drugs – Business and Professions Code Section 4051	It is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug unless he or she is a pharmacist.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.
Requirement for Prescription to Dispense Prescription Drugs – Business and Professions Code Section 4059	A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.

Table 2: Federal Statutes/Regulations

Federal statutes and regulations cannot be waived or suspended by the Governor. However, during a catastrophic disaster, the Governor may make a request to the federal Secretary of Health and Human Services requesting waiver of specific federal statutes and regulations.

Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Health Information Portability and Accountability Act (HIPAA)		
Requirement to Obtain Patient Consent to Speak with Family or Friends - 45 CFR 164.510	This federal regulation under HIPAA allows healthcare providers to disclose health information to a patient's relatives during a disaster, but makes a qualified requirement that the healthcare providers obtain the patient's consent.	The Health and Human Services Secretary may waive the consent requirement under 42 USC Section 1320b-5(b)(7)(A).
Requirement to Honor Opt-Out Request Obtain for Facility Directory - 45 CFR 164.510	This federal regulation under HIPAA allows healthcare providers to disclose health information to maintain a directory of individuals who are being treated in its facility, but makes a qualified requirement that the healthcare providers obtain the patient's consent.	The Health and Human Services Secretary may waive the consent requirement under 42 USC Section 1320b-5(b)(7)(A).



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Requirement to Distribute Notice - 45 CFR 164.520; 42 USC Section 1320b-5(b)(7)(B)	This HIPAA regulation requires covered entities to provide to patients with notice of privacy practices. There is an exception for emergency treatment situations, when notice of privacy practices must be provided as soon as reasonably practical.	The Health and Human Services Secretary is authorized to waive any existing laws under authority at 42 USC Section 130b 5.
Patients Right to Request Privacy Restrictions and Confidential Communications - 45 CFR 164.522; 42 USC Section 1320b-5(b)(7)(C)	This regulation provides patients with the right to request privacy protection for protected health information, including permitted disclosures. Restricted protected health information may be disclosed to a healthcare provider for emergency treatment, but the covered entity must request that the healthcare provider not further use or disclose the information.	The Health and Human Services Secretary may waive the requirement under 42 USC Section 130b 5.
Vaccine Adverse Reaction Reporting Requirements		
Reporting adverse reactions to vaccinations - 42 USC Section 300aa-25 (List of vaccines applicable to this federal statute can be found in the Vaccine Injury Table under 42 USC Section 300aa-14(b))	Each healthcare provider and vaccine manufacturer shall report to the Secretary of Health and Human Services: (a) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the table or within such longer period as is specified in the table or section, (b) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and (c) such other matters as the Secretary may by regulation require.	This requirement is based on federal law and cannot be waived by the Governor. However, the Governor may request that the Health and Human Services Secretary waive the vaccine adverse reaction reporting requirements (pandemic flu only) under 42 USC Section 247d. 42 USC Section 247d gives the Secretary of Health and Human Services the authority to take appropriate action to respond to a public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.
Health Facility Administration & Reporting Requirements		
Safe Medical Device Reporting – 21 USC Section 360	Safe medical device reporting requires that device-related adverse events be reported to the US Food and Drug Administration (FDA) and	This requirement is based on federal law and cannot be waived by the Governor. However, the Governor may request that the Health and



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	the device manufacturer, if appropriate. This section also requires that facilities maintain records of adverse events on-site for a two year period.	Human Services Secretary waive the safe medical device reporting requirements under 42 USC Section 247d. 42 USC Section 247d gives the Secretary of Health and Human Services the authority to take appropriate action to respond to a public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.
Healthcare Facilities and Requirements Regarding Patient Transfers		
Emergency Medical Treatment and Active Labor Act (EMTALA) - 42 USC 1395dd	The Emergency Medical Treatment and Active Labor Act governs when and how a patient may be refused treatment or transferred from one hospital to another when he is in an unstable medical condition.	This requirement is based on federal law and cannot be waived by the Governor. However, the Governor may request that the Health and Human Services Secretary waive the EMTALA requirements under 42 USC Section 1320b-5.
Supplies & Equipment Usage During States of Emergency		
The Use of Supplies and Equipment beyond the Manufacturer's Recommended Use - 21 USC 360bbb-3	The Secretary of Health and Human Services may, under appropriate conditions determined by the Secretary of Health and Human Services, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.	Authorization for Medical Products for Use in Emergencies subdivision states that the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device or biological product intended for use in an actual or potential emergency.
Funding Sources		
Medicare - Social Security Act Title XVIII, 42 USC Section 1395, et seq.	Compliance with Medicare administration requirements under 42 USC Section 1395, et seq., by healthcare facilities and professionals is required for	During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicare administrative requirements of Title XVIII under 42



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	reimbursement of healthcare services provided to Medicare patients.	<p>USC Section 1320b-5 and 42 USC Section 5141.</p> <p>The waiver will grant healthcare providers that provide healthcare services to Medicare patients during a declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.</p>
Medicaid - Social Security Act Title XIX, 42 USC Section 1396, et seq.	Compliance with administration requirements under 42 USC Section 1396, et seq., by healthcare facilities and professionals is required for reimbursement of healthcare services provided to Medicaid patients.	<p>During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicaid administrative requirements of Title XIX under 42 USC Section 1320b-5 and 42 USC Section 5141.</p> <p>The waiver will grant healthcare providers that provide healthcare services to Medicaid patients during a declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.</p>
State Children's Health Program - Social Security Act Title XXI, 42 USC Section 1397aa, et seq.	Compliance with administration requirements under 42 USC Section 1397aa, et seq. by healthcare facilities and professionals is required for reimbursement of healthcare services provided to State Children's Health Program patients.	<p>During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicare administrative requirements of Title XIX under 42 USC Section 1320b-5 and 42 USC Section 5141.</p> <p>The waiver will grant healthcare providers that provide healthcare services to State Children's Health Program patients during the declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.</p>



Table 3: Other Reporting Requirements

In addition to State and federal laws, there are also various accreditation agencies, such as Joint Commission, that provide guidance on emergency planning for healthcare organization but are not under State or federal authority to waive or suspend.

Joint Commission Reporting Requirements	Description of Reporting Requirements	Emergency Provisions
Joint Commission Sentinel Event Reporting – The Joint Commission Manual PI.1.10, 2.20, 3.10	Accredited organizations are expected to identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.	<p>This reporting requirement is imposed by the Joint Commission. Joint Commission requirements are standards that measure hospital quality of care during normal times. They do not have the force of law or regulations and cannot be waived by the Governor or Secretary of Health and Human Services.</p> <p>Compliance with Joint Commission reporting requirements will be an independent hospital decision that may be based on the impact of the healthcare surge on hospital operations and its ability to comply based on redirected healthcare resources.</p>

The Tables of Specific State and Federal Laws and Regulations and their Emergency Provisions during a Healthcare Surge depicted above can also be found on page 84 of the Foundational Knowledge Manual, Section 9: Foundational Knowledge Operational Tools.

For additional information on the level of declarations needed to invoke statutory or regulatory flexibility, see the Statutory and Regulatory Flexibility under Emergency Declarations Table provided on page 101 of the Foundational Knowledge Manual, Section 9: Foundational Knowledge Operational Tools. This table provides further details related to the authorized agency or entity with authority to flex the regulatory, statutory or accreditation requirements under emergency declarations.



8. Transitioning From Individual Care to Population-Based Care

During a healthcare surge, the delivery of care will shift from individual-based to population-based outcomes. This transition will challenge healthcare providers as they struggle to understand the consequences of their actions. This section discusses healthcare surge-related ethical principles, caring for special-needs populations, guidelines for population-based outcome and scarce resource allocation.

8.1 Healthcare Surge-Related Ethical Principles

When a physician graduates from medical school, he or she swears to an oath that embodies the ethics and ideals of Hippocrates, the acknowledged father of modern medicine. Translated from the traditional Greek version, the Hippocratic Oath States that a physician should “above all, do no harm” to the patients he or she serves. An excerpt from this oath reads, “I will remember that I remain a member of society, with special obligations to all my fellow human beings.” In the current state of medicine, each licensed provider of care has an overarching obligation to treat every individual patient to the best of his or her abilities.

During catastrophic emergencies the demand for medical care may exceed available resources to deliver that care. Healthcare surge capacity planning for environments with limited resources must therefore consider a departure from the individual patient-based outcomes that physicians have been long conditioned to uphold in favor of an approach that saves the most lives. In other words, “clinicians will need to balance the obligation to save the greatest possible number of lives against that of the obligation to care for each single patient.”¹⁴⁹ To the fullest extent possible, this migration of a provider’s obligation from individual responsibility to population outcome should adhere to the longstanding principles of ethical practice. Those rendering care must be informed of surge status in their community so that they can adjust their practices accordingly.

Much planning has been undertaken at the federal, State and local levels to enhance healthcare surge capacity in response to a large-scale emergency resulting in mass casualties. In August 2004, AHRQ convened a panel of experts drawn from the fields of bioethics, emergency medicine, disaster management, health administration, law and public health. The deliberations of this panel led to a report, *Altered Standards of Care in Mass Casualty Events*, which outlines a number of important issues and policy recommendations. In March 2006, the New York State Task Force on Life and the Law, at the request of the New York State Department of Health, convened a workgroup to consider clinical and ethical issues in the allocation of mechanical ventilators in an influenza pandemic.



The following principles have been adapted from the Public Health Leadership Society's *Principles of the Ethical Practice of Public Health*.¹⁵⁰

Principle No. 1: The authorized local official has an ethical obligation to utilize all readily accessible information in a responsible way and in a timely manner in making a determination that a healthcare surge situation exists. The health and medical aspects of system response to a healthcare surge should be coordinated and informed by consideration of ethics.

It is essential that the communication regarding a healthcare surge is accurate and uniform throughout the area affected by the healthcare surge. This principle combines the thought leadership behind the Public Health Leadership Society's *Principles of the Ethical Practice of Public Health* and AHRQ's *Altered Standards of Care in Mass Casualty Events*.

Principle No. 2: To the fullest extent possible under the circumstances of a healthcare surge, the authorized local health official and those working under his or her direction and authority should provide those in the community with accurate information pertaining to the nature of the healthcare surge and the responses to it with reasonable frequency.

To further ensure adherence to this principle, the following points should be kept in mind:

- Moving to a population-based set of treatment protocols represents a radical departure from patient-based decision making. It is essential that efforts be made well in advance of a healthcare surge to generate public understanding and acceptance for the change.
- Messages should be as consistent and timely as possible at all stages.
- Official health and medical care messages should be delivered to the public through public media by the local health officer (or other local physician (e.g., hospital or medical group chief of staff) whom the public perceives to have knowledge of the emergency and the area), the California State public health officer, a representative of the Centers for Disease Control and Prevention, or the United States Surgeon General, depending on the level of communication necessary.
- Spokespersons at all levels (local, State, regional, federal) should coordinate their messages.
- Modes of communication should be tailored to the type of information to be communicated, the target audience for which it is intended and the operating condition of media outlets which may be directly affected. Attention to the need to use languages other than English and the use of alternative communication channels outside of usual media outlets are examples of specific concerns. Also, specificity and details within messages should vary by target population (affected area versus neighboring area versus the rest of the State).



While the first two principles above speak to the declaration of a healthcare surge and the communication that must result, the next principles address the important issues that healthcare facilities and workers must face and the difficult decisions required of them. The next principle is adapted from AHRQ's *Altered Standards of Care in Mass Casualty Events*.¹⁵¹

Principle No. 3: In planning for a healthcare surge, healthcare personnel should aim to maintain functionality of the healthcare system and to deliver a quality of care that is optimal under current circumstances. Those persons involved in formulating and implementing the response to a healthcare surge should pursue the goal of preserving as many lives as possible. In pursuit of this goal, those persons should strive, to the fullest extent possible, to respect individual rights and community norms, including, but not limited to, the following circumstances:

- In establishing and operationalizing an adequate framework for the delivery of care
- In determining the basis on which scarce resources will be allocated

The goal of saving as many lives as possible is thus infused with an aim to respect the individual rights of the patient wherever and whenever possible. While apparently contradictory, it describes the ethical challenge of providing care during a healthcare surge. At a time when resources are scarce and time is compromised, reasonable exercise of clinical judgment must still come into play when making decisions.

While the ethical challenge of principle No. 3 rests on the shoulders of those implementing the response during a healthcare surge, principle No. 4 emphasizes the responsibility of the healthcare community as a whole.

Principle No. 4: Reasonable accommodations should be made for the personal needs and commitments of those healthcare and other personnel responding to the healthcare surge.

Examples of the reasonable accommodations that should be made include the provision of housing, food, transportation, child care/pet care or mental health support needed by healthcare and other personnel in order to effectively respond to a healthcare surge.

8.2 Caring for Populations with Special Needs

Caring for populations with special needs during a healthcare surge poses many challenges. Community-based organizations should be involved in the planning, response and recovery of healthcare surge emergency.

When discussing emergency preparedness, the following groups could be considered to have special needs: infants and small children under age three, women who are pregnant, elderly people (age 65 and older), the obese, the bedridden, mentally ill, those with cognitive disorders, those with medical conditions (e.g., heart disease, diabetes, high blood pressure),



those requiring life-saving medications (e.g., for high blood pressure, depression, insomnia), individuals with drug or alcohol addictions, those with mobility constraints, non-ambulatory, those under extreme working conditions, the poor, socially isolated, and non-English speakers who may not have access to information.¹⁵²

When planning for a healthcare surge, it is essential that the special needs of several groups be taken into consideration. These needs may vary and include, but are not limited to:

- Communicating disaster information in a variety of languages; having translators available at intake centers
- Providing mental health assessment resources within the healthcare setting
- Delivering emergency food, healthcare and counseling
- Providing alternative housing for displaced persons
- Providing shelter facilities with appropriate support services
- Providing alternate means of decontamination for babies and other non-ambulatory persons or those unable to sufficiently decontaminate themselves due to developmental or mobility limitations
- Ensuring vulnerable persons such as those with physical limitations have services for an effective recovery
- Addressing long-term recovery issues
- Recognizing and incorporating cultural and/or religious beliefs into the delivery of services

In *Meeting the Needs of Vulnerable People in Times of Disasters: A Guide for Emergency Managers*, the Office of Emergency Services recommends involving organizations and services designed to serve groups with special needs.¹⁵³

"Community-based organizations provide a direct link to the local communities and the vulnerable people that CBOs [community-based organizations] serve." Community-based organizations can provide valuable assistance in emergency management because they:

- Have pre-established networks for delivering services
- Have access to communities the government may not be able to reach
- Understand the needs of their clients with special needs
- Have the ability to respond quickly to local issues
- Enhance the cultural competency of government to meet needs
- Have the ability to often provide information to people in their own languages

An individual's underlying medical condition, such as a physical or development disability, may affect his or her survivability, and therefore may impact the acceptable criteria for resource allocation among patients that are listed in Section 8.4: Scarce Resource Allocation. However, community-based organizations bring expertise in delivering services to accommodate people



and communities with language, cultural, and accessibility needs. The most effective way to provide the greatest good to the greatest number of individuals with special needs is to have community-based organizations active in the response and recovery plan. It is suggested that memoranda of understanding with community-based organizations be established in planning for a healthcare surge.

8.3 Guidelines to Promote Population-Based Outcomes

Healthcare professionals should adhere to the standards established by existing laws and the core values and principles of public health ethics during a healthcare surge and should depart from those core values and principles only when the nature and extent of the healthcare surge precludes full adherence to them. To the extent possible, both healthcare facilities and Alternate Care Sites should inform all patients that pre-established patient rights may be waived or changed during a healthcare surge. For a listing of current patient rights laws, refer to the Reference Manual, Section 11: Current Patient Resource Guide.

Under normal conditions, a healthcare professional employs appropriate health and medical resources and responses to improve the health status and/or save the life of an individual patient. However, during a healthcare surge, the standard of care will shift from focusing on patient-based outcomes to population-based outcomes. According to a report by Health Systems Research Inc., *Altered Standards of Care in Mass Casualty Events*, (an AHRQ¹⁵⁴ Publication, April 2005), providers should anticipate “a shift to providing care and allocating scarce equipment, supplies and personnel in a way that saves the largest number of lives in contrast to the traditional focus on saving individuals.” Examples of these shifts in care may include:

- "Triage efforts that will need to focus on maximizing the number of lives saved. Instead of treating the sickest or the most critically injured first, triage would focus on identifying and reserving immediate treatment for individuals who have a critical need for treatment and are likely to survive. The goal would be to allocate resources in order to maximize the number of lives saved. Complicating conditions, such as underlying chronic disease, may have an impact on an individual's ability to survive.
- Triage decisions that will affect the allocation of all available resources across the spectrum of care: from the scene to hospitals to alternate care sites. For example, emergency department access may be reserved for immediate-need patients; ambulatory patients may be diverted to alternate care sites (including non-medical space, such as cafeterias within hospitals, or other non-medical facilities) where “lower level” hospital ward care or quarantine can be provided. Intensive or critical care units may become surgical suites and regular medical care wards may become isolation or other specialized response units.
- Needs of current patients, such as those recovering from surgery or in critical or intensive care units; the resources they use will become part of overall resource allocation. Elective procedures may have to be cancelled, and current inpatients may have to be discharged



early or transferred to another setting. In addition, certain lifesaving efforts may have to be discontinued.

- Usual scope of practice standards that will not apply. Nurses and physicians may function outside their specialties. Credentialing of providers may be granted on an emergency or temporary basis.
- Equipment and supplies that will be rationed and used in ways consistent with achieving the ultimate goal of saving the most lives (e.g., disposable supplies may be reused).
- Not enough trained staff. Staff will be scared to leave home and/or may find it difficult to travel to work. Burnout from stress and long hours will occur, and replacement staff will be needed. Some scarce and valuable equipment, such as ventilators, may not be used without staff available that is trained to operate them.
- Delays in hospital care due to backlogs of patients. Patients will be waiting for scarce resources, such as operating rooms, radiological suites, and laboratories.
- Providers may need to make treatment decisions based on clinical judgment. For example, if laboratory resources for testing or radiology resources for x-rays are exhausted, treatment based on physical exam, history, and clinical judgment will occur.
- The psychological impact of the emergency on providers. Short- and long-term stress management measures (e.g., Critical Incident Stress Management programs) are essential for providers and their families.
- Current documentation standards that will be impossible to maintain. Providers may not have time to obtain informed consent or have access to the usual support systems to fully document the care provided, especially if the healthcare setting is damaged by the emergency.
- Backlog in processing fatalities. It may not be possible to accommodate cultural sensitivities and attitudes toward death and handling bodies. Numbers of fatalities may make it difficult to find and notify next of kin quickly. Burial and cremation services may be overwhelmed. Standards for completeness and timeliness of death certificates may need to be lifted temporarily.”

The guidelines included below aim to alleviate, to the extent possible, concern over the liability associated with making such difficult decisions.

Guideline No. 1: Informed Consent during a Healthcare Surge

This guideline was adapted from California Business and Professions Code Section 2397 and applied to a healthcare surge. A healthcare provider is not obligated to obtain informed consent, as that term is defined by applicable facility policy and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge, when any one or more of the following circumstances is present:



- The patient is unconscious, the healthcare provider believes that the service or procedure should be undertaken immediately and the healthcare provider believes the patient's legal representative for healthcare decisions is not immediately available.
- The medical service or procedure is undertaken without the consent of the patient because the healthcare provider believes that the service or procedure should be undertaken immediately and there is insufficient time to fully inform the patient.
- A medical service or procedure is performed on a person legally incapable of giving consent, and the healthcare provider believes that the procedure should be undertaken immediately and there is insufficient time to obtain the information consent of the person authorized to give such consent for the patient.

Healthcare providers are required to document the presence or absence of these circumstances if, and only if, time, circumstances and professional judgment permit such documentation.

Guideline No. 2: Advanced Healthcare Directives during a Healthcare Surge

This guideline was adapted from California Probate Code Section 4734 and 4740 and made applicable to a healthcare surge. Providers should attempt, whenever possible, to accommodate advanced healthcare directives during a healthcare surge. However, a healthcare provider is obligated to inquire about, read or adhere to an advanced healthcare directive, as that term is defined under applicable facility policy, State law and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge if, and only if, all of the following circumstances are present:

- The healthcare provider is aware of the terms of the advanced healthcare directive.
- The healthcare provider believes that accommodating the terms of the healthcare directive will not require time, staff or resources that would otherwise be utilized in the care of other individuals.

Healthcare providers are required to document the presence or absence of these circumstances if, and only if, time, circumstances and professional judgment permit such documentation.

Guideline No. 3: Communicating with Legal Representatives for Healthcare Decisions during a Healthcare Surge

This guideline was adapted from California Probate Code Section 4736. A healthcare provider is not obligated to locate or obtain informed or other consent from a patient's legal representative for healthcare decisions (including but not limited to the parent or guardian of a minor child, a conservator, an agent for healthcare decisions, a surrogate or next of kin) before rendering a healthcare service or procedure during a healthcare surge, unless the following circumstance is present:



- The healthcare provider knows that the legal representative for healthcare decisions is immediately available to the healthcare provider. “Immediately available” means the representative is physically present next to the patient.

Healthcare providers are required to document the presence or absence of these circumstances if, and only if, time, circumstances and professional judgment permit such documentation.

Guideline No. 4: Providing Services to Individuals with Special Needs during a Healthcare Surge

Individuals with special needs have the same rights to healthcare services as individuals who do not have special needs during a healthcare surge. Therefore, the decision by a healthcare provider as to whether an individual should be provided with healthcare services (including but not limited to healthcare services and procedures, pharmaceuticals and accommodations) should be based on the acceptable criteria for resource allocation as set forth in Section 8.4: Scarce Resource Allocation and not on whether the individual meets the definition of an individual with special needs.

Guideline No. 5: Provision and Withdrawal of Care

Decisions as to who should receive care and when care should be withdrawn and/or discontinued should be based on the guidelines set forth in Section 8.4: Scarce Resources Allocation.

- A healthcare provider may determine that an individual will not receive care, or that care currently being provided to an individual will be discontinued or withdrawn, based on the criteria identified in Section 8.4. Examples of care that may be denied or discontinued or withdrawn in order to allocate limited resources, in accordance with the criteria identified in Section 8.4, include but are not limited to ventilator support, antibiotics, hydration and life-sustaining nutritional support, Intensive Care Unit and other facility beds and supplies, and blood.
- When a decision is made to deny or discontinue or withdraw care, palliative care should be offered to the affected individual whenever such palliative care is reasonably available. Palliative care includes, but is not limited to, sedation and supplements to breathing.
- When a decision is made to deny or discontinue or withdraw care, the healthcare provider should, when time and circumstances reasonably permit, clearly document the rationale for the decision on a document that will be retained.

Guideline No. 6: Disposal of Human Remains during a Healthcare Surge

During a healthcare surge, the manner and process for disposing of human remains will be based on directives from State and local healthcare authorities and not on the requests of the



patient in an advanced healthcare directive or requests by the patient's legal representative for healthcare decisions.

8.4 Scarce Resource Allocation

The provision of care in the setting of a large-scale disaster must be a sliding scale of care appropriate to the resource demands of the emergency. Healthcare facilities and providers managing a large excess of demand over supply of services during a healthcare surge will likely need to allocate resources in ways that are unique to the surge emergency.

In 1993, the American Medical Association published *Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources among Patients*,¹⁵⁵ a report that gives guidance to physicians who must make critical allocation decisions due to a naturally limited supply of available resources. Guidelines from this report have been extracted below and made applicable to a healthcare surge environment to give ethical guidance to healthcare facilities and providers for both the acceptable and the inappropriate criteria for making resource allocation decisions during a healthcare surge emergency.

Appropriate Criteria for Resource Allocation	Inappropriate Criteria for Resource Allocation
<ul style="list-style-type: none"> • Likelihood of survival • Change in quality of life • Duration of benefit • Urgency of need • Amount of resources required 	<ul style="list-style-type: none"> • Ability to pay • Provider's perception of social worth • Patient contribution to disease • Past use of resources

8.4.1 Acceptable Criteria for Resource Allocation among Patients

Likelihood of Survival

During a healthcare surge, priority of resource allocation and treatment should be given to patients with a greater likelihood of survival. This is an essential component in maximizing best outcomes and saving the most number of lives.

Change in Quality of Life

The benefit of the population of patients during a healthcare surge will be maximized if treatment is provided to patients who will have the greatest improvement in quality of life. Change in quality of life can be defined by comparing functional status with treatment to functional status without treatment.



Duration of Benefit

The length of time each patient will benefit from treatment is an appropriate consideration in allocating scarce medical resources during a healthcare surge. By giving higher priority to patients who will benefit longer than other patients, scarce resources will be directed to patients who will benefit the most.

Urgency of Need

Prioritizing patients according to how long they can survive without treatment can often maximize the number of lives saved. However, urgency of need should only be applied to patients who have presented themselves during a healthcare surge, not to hypothetical patients that a healthcare facility or provider forecasts receiving. Resources should not be denied to patients because it is anticipated that other patients with more urgent need may soon present.

Amount of Resources Required

In a situation where resources are limited, it will be necessary to treat patients who will need less of a scarce resource rather than patients expected to need more. This will maximize the number of patients who will benefit.

8.4.2 Inappropriate Criteria for Resources Allocation among Patients

Ability to Pay

During a healthcare surge, healthcare facilities and providers should not systematically deny needed resources to patients simply due to their lower economic status.

Perception of Social Worth

A patient's contribution to society, or his or her social worth, should not be a factor in resource allocation decisions during a healthcare surge. A social-worth criterion undermines the focus on the welfare of the patient and prohibits achievement of the overall goal to maximize the best outcome for the greatest number of patients.

Patient Contribution to Disease

This criterion assigns a lower priority to patients whose past behaviors are believed to have contributed significantly to their present need for scarce resources. Examples include heart transplant candidates whose high-fat diets may have contributed to their conditions. Using judgment about patients' morals to allocate healthcare is inappropriate and inconsistent.

Past Use of Resources

It may be argued that, during a healthcare surge, patients who have had considerable access to a scarce medical resources in the past should be given a lower priority than equally needy patients who have, up to the time of the surge, received relatively less of that resource. For instance, a patient could be displaced from an intensive care unit by another patient with the same condition and prognosis but less past access, or a re-transplant patient could be denied



any chance at all of receiving additional organs. Because past use is irrelevant to present need, it should not factor into allocation decisions.

8.4.3 Allocation of Ventilators for Pandemic Influenza

An example of guidelines for scarce resource allocation is the policy on Allocation of Ventilators for Pandemic Influenza issued in draft by the New York State Task Force on Life and the Law in March 2007.¹⁵⁶ The document was developed by clinicians for the New York State Department of Health. The document has been designed as a proposed policy and is open for public comment. It is included in this document as an example of standards that might be implemented during a catastrophic emergency.

The New York State Task Force on Life and the Law stresses that the criteria described below must be seen as guidelines, not standards. "More important than the specifics of any tool (which will require modification based on the emergency) is the establishment of a process for making decisions to limit care so that, in a time of crisis, a mechanism is in place to apply as much science as possible to these decisions and the persons involved are prepared for their roles."¹⁵⁷

Duty to Care

The ethical rationing system for allocation of ventilators must support the fundamental obligation of healthcare professionals to care for patients. While ventilator allocation decisions may involve the choice between life and death, to the fullest extent possible, physicians must strive to ensure the survival of each individual patient. Guidelines must stress the provision of care that is possible when ventilation is not. Patients who do not receive mechanical ventilation must not be disregarded entirely. These patients must receive the next best care under the circumstances, whether it is other forms of curative treatment or palliative care.

Duty to Steward Resources

During a healthcare surge, clinicians will need to balance the obligation to save the greatest possible number of lives against their longstanding responsibilities to care for each single patient. Government and healthcare providers must embrace this obligation to devise a rationing system and be prepared for the ethical tension that will result.

Duty to Plan

Planning is not a recommendation but an obligation. The absence of guidelines would leave important allocation decisions to be made by exhausted providers, which would result in a failure of responsibility toward both patients and providers.



Distributive Justice

The same allocation guidelines should be used across the State. These allocation guidelines must not vary from private to public sector. They need to remain consistent throughout the community at hand. Also, the allocation of ventilators from State and federal stockpiles must take into account the ratio of local populations to available resources, designating appropriate resources for the most vulnerable who are most likely to suffer the greatest impact in any disaster.

Transparency

Any just system of allocating ventilators will require robust efforts to promote transparency. Proposed guidelines should be publicized and translated into different languages as necessary.

Guidelines Related to the Withdrawal/Restriction of Ventilator Support

During a healthcare surge, as the demand for mechanical ventilation increases, the available supply of each facility's ventilators will naturally decrease. To speak to this dilemma, in *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*, Hick et al. published a number of criteria to be used to guide the withdrawal or restriction of ventilator support. Hick et al. recommend that criteria for ventilator allocation should be implemented in a tiered fashion to provide a scalable framework for restriction. Hick's criteria have been listed below as a sample of triage that may occur during a healthcare surge.

- **First-Tier Criteria**

The first tier would eliminate access to ventilators for patients with the highest probability of mortality.

- **Second-Tier Criteria**

If resources continue to decrease during a healthcare surge, the second tier would deny ventilator support to patients with respiratory failure as well as a high use of additional resources. This tier includes patients who have a pre-existing illness with a poor prognosis.

- **Third-Tier Criteria**

When resources continue to decrease, a third tier of criteria would need to be implemented. These criteria lack the specificity of the first two and this may need to be a real-time decision on criteria to be used.

Allocation of Ventilators-Sample Clinical Evaluation

Mechanical ventilators should be allocated to patients during a pandemic based on each patient's clinical evaluation. There are many scoring tools available that should be considered as warranted by the circumstances.¹⁵⁸

The Ontario Health Plan for an Influenza Pandemic (OHPiP) protocol utilizes the Sepsis-related Organ Failure Assessment (SOFA) score to add points to each patient based on objective measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting and blood pressure. A perfect SOFA score, indicating normal function in all six



categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems. The SOFA scale is presented below and the explanation of the variables are as follows:

- PaO₂/FiO₂ indicates the level of oxygen in the patient's blood
- Platelets are a critical component of blood clotting
- Bilirubin is measured by a blood test and indicates liver function
- Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring, including dopamine, epinephrine, and norepinephrine
- The Glasgow coma score is a standardized measure that indicates neurologic function; low score indicates poorer function
- Creatinine is measured by a blood test and indicates kidney function

Sequential Organ Failure Assessment (SOFA) score SOFA Scale

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

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

Adapted from: Ferreira FI, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001; 286(14): 1754-1758.

Patients placed on ventilators before the surge event will also be assessed to see whether they meet criteria for continued use. When a ventilator becomes available and many potential patients are waiting, clinicians may choose the patient with pulmonary failure who has the best chance of survival with ventilator support, based on objective clinical criteria.



Time Trials

The New York State Task Force on Life and the Law recommends that continued use of ventilators will be reviewed and reassessed at intervals of 48 and 120 hours. Patients who continue to meet criteria for benefit or improvement would continue until the next assessment, while those who no longer meet these criteria would lose access to mechanical ventilation.

Guidelines for Ventilator Exclusion

The New York State Task Force on Life and the Law recommends that clinicians assess patients for exclusion guidelines both to determine the appropriateness of the initiation and continuation of ventilator use. Exclusion criteria should focus primarily on current organ function, rather than on specific disease entities. A set of exclusion guidelines is presented below.

Guidelines for Ventilator Exclusion*

- Cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures; trauma-related arrest
- Metastatic malignancy with poor prognosis
- Severe burn: body surface area >40%, severe inhalation injury
- End-stage organ failure:
 - Cardiac: NY Heart Association class III or IV
 - Pulmonary: severe chronic lung disease with FEV1** <25%
 - Hepatic: MELD*** score >20
 - Renal: dialysis dependent
 - Neurologic: severe, irreversible neurologic event/condition with high expected mortality

* Adapted from Ontario Health Plan for an Influenza Pandemic (OHPiP) guidelines

** Forced Expiratory Volume in 1 second, a measure of lung function

*** Model of end stage liver disease



9. Foundational Knowledge Operational Tools

This section includes tools to facilitate healthcare surge planning, management, delivery of care and administrative functions. These tools may be used by healthcare facilities, Alternate Care Sites and healthcare professionals to plan for and respond to catastrophic healthcare emergencies. The tools on the following pages are embedded in the content of the Foundational Knowledge Manual, but have been pulled into a separate section for ease of use and printing.



Tool 1: Community Planning Participants Checklist

Instructions

An important element of the community-based capacity is inclusion and integration of public and private partners in the community. Consider the following table of community members for community-based planning:

	Community Participant	Potential Role
Local, State, and federal organizations		
<input type="checkbox"/>	Law enforcement, fire, and coroner	Emergency first responders, security, enforcement of quarantine/isolation orders, fatality management
<input type="checkbox"/>	Local emergency medical services agencies	Local implementing arm of the Emergency Medical Systems Agencies
<input type="checkbox"/>	Local federal offices	Personnel, planning
<input type="checkbox"/>	Local public health	Public health planning, personnel, technical assistance
<input type="checkbox"/>	Local State offices	Personnel, planning
<input type="checkbox"/>	National Guard and military establishments	Transportation and infrastructure support, security, enforcement
Volunteer organizations		
<input type="checkbox"/>	Community Emergency Response Teams (CERT)	Volunteers
<input type="checkbox"/>	Medical Reserve Corps (MRC)	Volunteers
<input type="checkbox"/>	Neighborhood Emergency Response Teams (NERT)	Volunteers
<input type="checkbox"/>	Red Cross/Salvation Army and other nonprofit organizations	Volunteers and supplies aid
Commercial organizations and business partners		
<input type="checkbox"/>	Area airports	Transportation, facilities
<input type="checkbox"/>	Board of Realtors	Coordination of additional space for healthcare facilities
<input type="checkbox"/>	Chambers of commerce	Business community support
<input type="checkbox"/>	Communication companies (e.g., private cell, two-way radio, broadcast television)	Communication needs



	Community Participant	Potential Role
<input type="checkbox"/>	Major employers and business community, especially big-box retailers (e.g., Costco, Sam's Club)	Essential supplies and services
<input type="checkbox"/>	Mortuaries	Burial and cremation services
<input type="checkbox"/>	Private security firms	Security services
<input type="checkbox"/>	Public works and local utility companies	Critical infrastructure
<input type="checkbox"/>	Restaurants, caterers, party supply stores	Facilities, food, supplies
Community organizations		
<input type="checkbox"/>	City unified school districts and community colleges	Alternate care sites, personnel/services, supplies
<input type="checkbox"/>	Faith-based organizations	Facilities, volunteers, supplies, translation
<input type="checkbox"/>	Public transportation	Transportation
<input type="checkbox"/>	Nursery schools/preschools	Facilities, personnel, child care
<input type="checkbox"/>	Veterinary shelters/pet boarding and care	Pet care for workers/evacuees
Other partners		
<input type="checkbox"/>	Miscellaneous services	Financial, accounting, general services



Tool 2: Surge Monitoring Guidelines

The Surge Monitoring Guidelines provide a standard method to measure the movement away from “normal” operations to surge on the local, regional and State levels. They can be used to assist healthcare personnel in understanding the progression of a healthcare surge from day-to-day operations to a situation where Operational Area, regional, State, and/or federal resources are needed in order to address the increased demand for healthcare.

A healthcare surge is proclaimed in a local health jurisdiction when an authorized local official, such as a local health officer or other appropriate designee,¹⁵⁹ using professional judgment determines, subsequent to a significant event or circumstances, that the healthcare delivery system has been impacted, resulting in an excess in demand over capacity in hospitals, community care clinics, public health departments, other primary and secondary care providers, resources and/or emergency medical services. The local official uses the situation assessment information provided from the healthcare delivery system partners to determine overall local healthcare jurisdiction/Operational Area medical and health status.

Instructions

During a healthcare surge, the authorized local official will use color-coded descriptors to designate the status of the local healthcare jurisdiction/Operational Area's healthcare delivery system. Healthcare surge status does not necessarily connote a specific emergency proclamation, but represents the condition of the healthcare delivery system in a continuum from normal daily operations to a significant healthcare surge. The designations of the color descriptors will be made by the authorized local official using their professional judgment and will provide other Operational Areas, the Regional Disaster Medical Health Coordinator and/or Regional Disaster Medical Health Specialist, and State agencies a clear understanding of the local healthcare status. There are five levels of local surge:

- **GREEN:** Local system is operational and in usual day-to-day status. No assistance required.
- **YELLOW:** Most healthcare assets within the local jurisdiction are experiencing a surge and are able to manage the situation within their organizational frameworks. No assistance required.
- **ORANGE:** The healthcare assets in the local jurisdiction require the participation of additional healthcare assets within the jurisdiction to contain the situation.
- **RED:** Local jurisdiction is not capable of meeting the demand for care, and assistance from outside the local jurisdiction/Operational Area is required.
- **BLACK:** Local jurisdiction not capable of meeting the demand for care, and significant assistance from outside the local jurisdiction/Operational Area is required.



	Local Surge Emergency					Regional Level Surge	Statewide Surge Level
Surge Level	Green	Yellow	Orange	Red	Black		
Enabling Authorities	Regulatory/ Accrediting Agency Waiver	Regulatory/ Accrediting Agency Waiver	Regulatory/ Accrediting Agency Waiver/ Local Emergency Declaration	Local Emergency Declaration	Local Emergency Declaration	State of Emergency Declaration	Federal Emergency Declaration

The chart above illustrates the relationship between the level of healthcare surge and enabling authorities to implement relative surge response activities. The chart includes the five levels of a local surge emergency, as well as a regional level healthcare surge and statewide level healthcare surge.



Tool 3: Tables of Specific State and Federal Laws and Regulations and their Emergency Provisions during a Healthcare Surge

It is inevitable that, during a healthcare surge, individuals providing healthcare services in licensed healthcare facilities and Alternate Care Sites may be unable to fully adhere to statutes, regulations and professional standards of practice relating to patient rights and professional ethics, including obtaining informed consent; honoring advance healthcare directives; communicating with healthcare agents, surrogates and next of kin; providing services to special needs populations; and honoring cultural preferences and rituals in the process disposing of human remains. As such, it is anticipated that the legal requirements concerning such rules will be waived or suspended by government authorities.

The Governor may suspend those regulatory requirements perceived to be an obstacle to the emergency response effort. The suspension would be implemented through an executive standby order of the Governor. Standby orders are directions issued by the Governor that make, amend, or rescind certain state laws that prescribe the conduct of state business that may in any way prevent, hinder, or delay the mitigation of the effects of the emergency. A standby order must be approved by the Emergency Council and then issued during a proclaimed state of emergency. In some cases, standby orders delegate the authority to suspend requirements to a specific State official, for example the director of the Office of Emergency Services, CDPH or the Emergency Medical Services Authority.

The proclamation of a state of emergency alone is not sufficient to effectuate a suspension of regulatory requirements, unless those requirements have a provision enabling their automatic activation upon such a proclamation. The proclamation would need to include a standby order or the Governor would need to issue a separate executive order issuing the standby order.

It should be emphasized that until such a standby order is issued subsequent to a declaration of a state of emergency, no regulatory requirement is suspended (except to the extent that the regulatory agency has waived enforcement). Therefore, medical providers must ascertain the existence and scope of the declared state of emergency, and extent and applicability of any suspension of regulatory requirements.

The following tables highlight specific State and federal laws as well as other regulatory activities that govern healthcare operations that may require suspensions during a state of emergency. It is important to recognize that the Governor will determine whether or not to suspend each statute at the time of each emergency. Regardless of the emergency and the authority of the Governor to suspend the statute, there are some statutes that are unlikely to be suspended due to the nature of the requirement.



Table 1: State Statutes/Regulations

State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Public Health Reporting Requirements		
Cancer Registry Reporting – Health and Safety Code Section 103885, et seq.	Any healthcare facility providing therapy to cancer patients shall report each case of cancer to the State or the authorized representative in a format prescribed by the State. In addition, any healthcare professional diagnosing or providing treatment for cancer patients shall report each cancer case to the State or the authorized representative except for those cases directly referred to a treatment facility or those previously admitted to a treatment facility for diagnosis or treatment of that instance of cancer.	The cancer registry reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Burns & Smoke Inhalation Reporting – Health and Safety Code Section 13110.7	The director of every burn center (defined as an intensive care unit in which there are specially trained physicians, nursing and supportive personnel and the necessary monitoring and therapeutic equipment needed to provide specialized medical and nursing care to burned patients) which examines, treats, or admits a person with a burn or smoke inhalation injury or a person who suffers a burn-related death shall file a report with the State Fire Marshal describing the injury or death at the end of the examination or treatment or at the time the patient is discharged from the burn center or at the time of the patient's death.	The burn and smoke inhalation injury registry reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.
Disease Reporting – Health and Safety Code Section 120130	CDPH shall establish a list of reportable diseases and conditions and shall include the urgency of reporting each disease and condition. The list of reportable diseases and conditions may include both communicable and	Disease reporting is a regulatory statute. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	noncommunicable diseases. The list may include those diseases that are either known to be, or suspected of being, transmitted by milk or milk-based products. The list shall also include, but not be limited to, diphtheria, listeria, salmonella, shigella, streptococcal infection in food handlers or dairy workers, and typhoid. The list may be modified at any time by CDPH, after consultation with the California Conference of Local Health Officers.	
Disease Reporting –17 CCR 2500(b) and (c)	It shall be the duty of every healthcare professional, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed in this statute, to report to the local health officer for the jurisdiction where the patient resides. Where no healthcare professional is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed in this statute may make such a report to the local health officer for the jurisdiction where the patient resides. In addition, the administrator of each healthcare facility, clinic, or other setting where more than one healthcare professional may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.	Disease reporting is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Birth Reporting – Health and Safety Code Section 102400	Each live birth shall be registered with the local registrar of births and deaths for the district in which the birth occurred within 10 days following the date of the event.	The birth reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Death Reporting – Health and Safety Code Section 102775	Each death shall be registered with the local registrar of births and	The death reporting requirement is a regulatory statute. It can therefore be



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	deaths in the district in which the death was officially pronounced or the body was found, within eight calendar days after death and prior to any disposition of the human remains.	waived under Government Code Section 8571.
Office of Statewide Health Planning and Development Reporting Requirements – Health and Safety Code Section 128765, et seq.	The Office of Statewide Health Planning and Development reporting requirements include summary level information related to individual healthcare facilities as well as aggregate patient data. This information, with the exception of discharge and encounter data, is to be compiled and reported on a timely basis and made publicly available. The public report shall include an executive summary, written in plain English to the maximum extent practicable, a discussion of findings, conclusions, and trends concerning the overall quality of medical outcomes, including a comparison to reports from prior years, for the procedure or condition studied by the report.	The Office of Statewide Health Planning and Development reporting requirement is a regulatory statute. This reporting requirement can be waived under Government Code Section 8571.
Health Facility Administration Reporting Requirements		
Transfers of Patients; Violations – Health and Safety Code Section 1317.4	All hospitals shall maintain records of each transfer made or received for a period of three years. All hospitals making or receiving transfers shall file with the State department annual reports on forms prescribed by the department which shall describe the aggregate number of transfers made and received according to the person's insurance status and reasons for transfers. A failure to report may result in civil penalties.	The hospital patient transfer record-keeping and reporting requirement is a regulatory statute with underlying regulations. This section can, however, be waived under Government Code Section 8571.
Unusual Occurrence Reports – 22 CCR 70737 and 22 CCR 71535	All cases of reportable diseases are required to be reported to the local health department. Any occurrence, including an epidemic outbreak, poisoning, fire, major accident, disaster, or other catastrophe or	Unusual occurrence reporting is a regulatory statute. This regulation can be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	unusual occurrence threatening the welfare, safety or health of patients, personnel or visitors to healthcare facilities shall be reported as soon as reasonably practical to local health officials.	
Medication Errors Reporting – Business and Professions Code Section 4125; 16 CCR 1711	Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.	The medication error reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.
Occupational Illness & Injury Reporting – Labor Code Section 6409; 8 CCR 14003	Every physician who attends any injured employee shall file a complete report of every occupational injury or occupational illness to the employee with the employer, or if insured, with the employer's insurer, on forms prescribed for that purpose by the Division of Labor Statistics and Research. A portion of the form shall be completed by the injured employee, if he or she is able to do so, describing how the injury or illness occurred. The form shall be filed within five days of the initial examination.	The occupational illness reporting requirement is a regulatory statute with underlying regulations. It can therefore be waived under Government Code Section 8571.
Work-Related Fatalities Reporting – 8 CCR 342	Work-related fatalities reporting is an occupational safety and health regulation that requires employers to immediately report any employee serious injury, illness or death that occurred as a result or at a place of employment. In the aftermath of a disaster, this regulation requires, whenever possible, that a report of the incident be made within 24 hours of occurrence.	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Criminal Activity Reporting Requirements		
Child Abuse & Neglect Reporting – Penal Code Section 11164, et seq.	The intent and purpose of this statute is to protect children from abuse and neglect. In any investigation of suspected child abuse or neglect, all persons participating in the investigation of the case shall consider the needs of the child victim and shall do whatever is necessary to prevent psychological harm to the child victim.	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.
Elder & Dependent Abuse Reporting – Welfare and Institutions Code Section 15600, et seq.	The Legislature recognizes that elders and dependent adults may be subjected to abuse, neglect, or abandonment and that this State has a responsibility to protect these persons. Healthcare practitioners, care custodians, clergy members, and employees of county adult protective services agencies and local law enforcement agencies are required to report known or suspected cases of abuse of elders and dependent adults and to encourage community members in general to do so. Reports shall include information on the numbers of abuse victims, circumstances surrounding the act of abuse, and other data which will aid the State in establishing adequate services to aid all victims of abuse in a timely, compassionate manner.	The Governor may suspend or waive this regulatory requirement pursuant to authority in the Emergency Services Act.
Violence against Hospital Personnel – Health and Safety Code Section 1257.7	Any act of assault or battery that results in injury or involves the use of a firearm or other dangerous weapon against any on-duty hospital personnel shall be reported to the local law enforcement agency within 72 hours of the incident. Any other act of assault or battery against any on-duty hospital personnel may be reported to the local law enforcement agency within 72 hours of the incident.	The violence against hospital personnel reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Violence against Community Healthcare Worker – Labor Code Section 6332	Every employer shall keep a record of any violence committed against a community healthcare worker and shall file a copy of that record with the Division of Labor Statistics and Research in the form and detail and within the time limits prescribed by the Division of Labor Statistics and Research.	The violence against community health worker reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
Suspicious Injury Reports – Penal Code Section 11160, et seq., Penal Code Section 11161, et seq.	The suspicious injury reporting requirement requires that healthcare professionals providing medical services for a physical condition which may have resulted from a suspicious act, including an injury that resulted from an assault, be reported immediately.	The suspicious injury reporting requirement is a regulatory statute. It can therefore be waived under Government Code Section 8571.
General Acute Care Hospital Requirements		
Nurse Staffing Ratio – 22 CCR 70217	Hospitals shall provide staffing by licensed nurses within the scope of their licensure in accordance with the nurse-to-patient ratios outlined in 22 CCR 70217. Licensed nurse means a registered nurse, licensed vocational nurse and, in psychiatric units only, a licensed psychiatric technician. No hospital shall assign a licensed nurse to a nursing unit or clinical area unless that hospital determines that the licensed nurse has demonstrated current competence in providing care in that area and has also received orientation to that hospital's clinical area sufficient to provide competent care to patients in that area. Licensed nurse-to-patient ratios represent the maximum number of patients that shall be assigned to one licensed nurse at any one time. "Assigned" means the licensed nurse has responsibility for the provision of care to a particular patient within his/her scope of	22 CCR 70217 may be flexed in the event of a "healthcare emergency which creates an unpredictable or unavoidable occurrence at unscheduled or unpredictable intervals." The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	practice.	
Conversion of Space for Other Uses – 22 CCR 70805	Space approved for specific uses at the time of licensure shall not be converted to other uses without the written approval of the CDPH.	The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.
General Acute Care Hospitals; Limitation to Licensed Beds – 22 CCR 70809	No hospital shall have more patients or beds set up for overnight use by patients than the approved licensed bed capacity except in the case of justified emergency when temporary permission may be granted by the CDPH Director or assigned designee. Beds not used for overnight stay such as labor room beds, recovery beds, beds used for admission screening or beds used for diagnostic purposes in X-ray or laboratory departments are not included in the approved licensed bed capacity. Patients shall not be housed in areas which have not been approved by CDPH for patient housing and which have not been granted a fire clearance by the State Fire Marshal.	The Governor may suspend or waive this requirement pursuant to authority in the Emergency Services Act.
Out of Scope Supplemental Services – 22 CCR 70301	Any licensed general acute care hospital desiring to establish or conduct, or that holds out, represents or advertises by any means the provision of a supplemental service, shall obtain prior approval from CDPH or a special permit if required by 22 CCR 70351. (See below for specific information related to 22 CCR 70351.)	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Out of Scope Special Services – 22 CCR 70351	Any licensed general acute care hospital desiring to establish or conduct, or that holds out, represents or advertises by any means, the performance of a special service shall obtain a special permit from CDPH. The following supplemental services are also special services for which a special permit is required: basic emergency	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	medical service, burn center, cardiovascular surgery service, chronic dialysis unit, comprehensive emergency medical service, psychiatric unit, radiation therapy service, renal transplant center.	
Clinical Staff and Personnel Requirements: Physician		
Physician, Inactive – Businesses and Professional Code Section 702	The holder of an inactive healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an active license or certificate is required.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Physician, Retired – Business and Professions Code Section 2439	The holder of a retired license may not engage in the practice of medicine or the practice of podiatric medicine.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Practice Outside Federal Facility – Business and Professions Code Section 715, 718	<p>Unless otherwise required by federal law or regulation, no board which licenses physicians, surgeons or podiatrists may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies:</p> <p>(a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a</p>	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.	
Clinical Staff and Personnel Requirements: Pharmacists		
Pharmacist, Inactive – Business and Professions Code Section 702	The holder of an inactive healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an active license or certificate is required.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Pharmacist, Out-of-State – Business and Professions Code Section 900	The holder of an out-of-state healing arts license or certificate issued pursuant to this statute shall not engage in any activity for which an active license or certificate is required.	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.
Pharmacists, Consultation Requirements – Business and Professions Code Section 4051	A pharmacist may authorize the initiation of a prescription and otherwise provide clinical advice or information or patient consultation if: (1) the clinical advice or patient consultation is provided to a healthcare professional or to a patient; (2) the pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice; (3) Access to the information described in paragraph (2) is secure from unauthorized access and use.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.
Clinical Staff and Personnel Requirements: Dentists		
Practice Outside Federal Facility – Business and Professions Code Section 715	Unless otherwise required by federal law or regulation, no board which licenses dentists may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies:	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	<p>(a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.</p>	
Clinical Staff and Personnel Requirements: Nurses		
Practice Outside Federal Facility – Business and Professions Code Section 715	<p>Unless otherwise required by federal law or regulation, no board which licenses nurses may require a person to obtain or maintain any license to practice a profession or render services in California if one of the following applies:</p> <p>(a) The person practicing a profession or rendering services does so exclusively as an employee of the federal government, and provides medical services exclusively on a federal reservation or at any facility wholly supported by and maintained by the United States government. (b) The person practicing a profession or rendering services does so solely pursuant to a</p>	The Governor may waive or suspend this requirement pursuant to authority in the Emergency Services Act.



State Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
	contract with the federal government on a federal reservation or at any facility wholly supported and maintained by the United States government. (c) The person practicing a profession or rendering services does so pursuant to, or as a part of a program or project conducted or administered by a department, bureau, office, division, or similarly constituted agency of the federal government which by federal statute expressly exempts persons practicing a profession or rendering services as part of the program or project from state laws requiring licensure.	
Pharmaceutical Requirements		
Prescription Drugs – Business and Professions Code Section 4051	It is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug unless he or she is a pharmacist.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.
Requirement for Prescription to Dispense Prescription Drugs – Business and Professions Code Section 4059	A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor.	The Board of Pharmacy, under Business and Professions Code 4062, may waive this requirement if the waiver will aid in the protection of public health or the provision of patient care.



Table 2: Federal Statutes/Regulations

Federal statutes and regulations cannot be waived or suspended by the Governor. However, during a catastrophic disaster, the Governor may make a request to the federal Secretary of Health and Human Services requesting waiver of specific federal statutes and regulations.

Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Health Information Portability and Accountability Act (HIPAA)		
Requirement to Obtain Patient Consent to Speak with Family or Friends - 45 CFR 164.510	This federal regulation under HIPAA allows healthcare providers to disclose health information to a patient's relatives during a disaster, but makes a qualified requirement that the healthcare providers obtain the patient's consent.	The Health and Human Services Secretary may waive the consent requirement under 42 USC Section 1320b-5(b)(7)(A).
Requirement to Honor Opt-Out Request Obtain for Facility Directory - 45 CFR 164.510	This federal regulation under HIPAA allows healthcare providers to disclose health information to maintain a directory of individuals who are being treated in its facility, but makes a qualified requirement that the healthcare providers obtain the patient's consent.	The Health and Human Services Secretary may waive the consent requirement under 42 USC Section 1320b-5(b)(7)(A).
Requirement to Distribute Notice - 45 CFR 164.520; 42 USC Section 1320b-5(b)(7)(B)	This HIPAA regulation requires covered entities to provide to patients with notice of privacy practices. There is an exception for emergency treatment situations, when notice of privacy practices must be provided as soon as reasonably practical.	The Health and Human Services Secretary is authorized to waive any existing laws under authority at 42 USC Section 130b 5.
Patients Right to Request Privacy Restrictions and Confidential Communications - 45 CFR 164.522; 42 USC Section 1320b-5(b)(7)(C)	This regulation provides patients with the right to request privacy protection for protected health information, including permitted disclosures. Restricted protected health information may be disclosed to a healthcare provider for emergency treatment, but the covered entity must request that the healthcare provider not further use or disclose the information.	The Health and Human Services Secretary may waive the requirement under 42 USC Section 130b 5.



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
Vaccine Adverse Reaction Reporting Requirements		
<p>Reporting adverse reactions to vaccinations - 42 USC Section 300aa-25</p> <p>(List of vaccines applicable to this federal statute can be found in the Vaccine Injury Table under 42 USC Section 300aa-14(b))</p>	<p>Each healthcare provider and vaccine manufacturer shall report to the Secretary of Health and Human Services: (a) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa-14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the table or within such longer period as is specified in the table or section, (b) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and (c) such other matters as the Secretary may by regulation require.</p>	<p>This requirement is based on federal law and cannot be waived by the Governor. However, the Governor may request that the Health and Human Services Secretary waive the vaccine adverse reaction reporting requirements (pandemic flu only) under 42 USC Section 247d.</p> <p>42 USC Section 247d gives the Secretary of Health and Human Services the authority to take appropriate action to respond to a public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.</p>
Health Facility Administration & Reporting Requirements		
<p>Safe Medical Device Reporting – 21 USC Section 360</p>	<p>Safe medical device reporting requires that device-related adverse events be reported to the US Food and Drug Administration (FDA) and the device manufacturer, if appropriate. This section also requires that facilities maintain records of adverse events on-site for a two year period.</p>	<p>This requirement is based on federal law and cannot be waived by the Governor. However, the Governor may request that the Health and Human Services Secretary waive the safe medical device reporting requirements under 42 USC Section 247d.</p> <p>42 USC Section 247d gives the Secretary of Health and Human Services the authority to take appropriate action to respond to a public health emergency, including making grants and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder.</p>
Healthcare Facilities and Requirements Regarding Patient Transfers		
<p>Emergency Medical Treatment and Active Labor Act</p>	<p>The Emergency Medical Treatment and Active Labor Act governs when</p>	<p>This requirement is based on federal law and cannot be waived by the</p>



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
(EMTALA) - 42 USC 1395dd	and how a patient may be refused treatment or transferred from one hospital to another when he is in an unstable medical condition.	Governor. However, the Governor may request that the Health and Human Services Secretary waive the EMTALA requirements under 42 USC Section 1320b-5.
Supplies & Equipment Usage During States of Emergency		
The Use of Supplies and Equipment beyond the Manufacturer's Recommended Use - 21 USC 360bbb-3	The Secretary of Health and Human Services may, under appropriate conditions determined by the Secretary of Health and Human Services, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.	Authorization for Medical Products for Use in Emergencies subdivision states that the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device or biological product intended for use in an actual or potential emergency.
Funding Sources		
Medicare - Social Security Act Title XVIII, 42 USC Section 1395, et seq.	Compliance with Medicare administration requirements under 42 USC Section 1395, et seq., by healthcare facilities and professionals is required for reimbursement of healthcare services provided to Medicare patients.	<p>During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicare administrative requirements of Title XVIII under 42 USC Section 1320b-5 and 42 USC Section 5141.</p> <p>The waiver will grant healthcare providers that provide healthcare services to Medicare patients during a declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.</p>
Medicaid - Social Security Act Title XIX, 42 USC Section 1396, et seq.	Compliance with administration requirements under 42 USC Section 1396, et seq., by healthcare facilities and professionals is required for reimbursement of healthcare services provided to Medicaid patients.	During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicaid administrative requirements of Title XIX under 42 USC Section 1320b-5 and 42 USC Section 5141.



Federal Statute/Regulation	Description of Statute/Regulation	Emergency Provisions
		The waiver will grant healthcare providers that provide healthcare services to Medicaid patients during a declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.
State Children's Health Program - Social Security Act Title XXI, 42 USC Section 1397aa, et seq.	Compliance with administration requirements under 42 USC Section 1397aa, et seq. by healthcare facilities and professionals is required for reimbursement of healthcare services provided to State Children's Health Program patients.	<p>During a federal declaration of emergency, the Secretary of Health and Human Services has the authority to waive Medicare administrative requirements of Title XIX under 42 USC Section 1320b-5 and 42 USC Section 5141.</p> <p>The waiver will grant healthcare providers that provide healthcare services to State Children's Health Program patients during the declared emergency reimbursement for services and exemptions from sanctions of noncompliance, absent any determination of fraud or abuse.</p>



Table 3: Other Reporting Requirements

In addition to State and federal laws, there are also various accreditation agencies, such as Joint Commission, that provide guidance on emergency planning for healthcare organization but are not under State or federal authority to waive or suspend.

Joint Commission Reporting Requirements	Description of Reporting Requirements	Emergency Provisions
Joint Commission Sentinel Event Reporting – The Joint Commission Manual PI.1.10, 2.20, 3.10	Accredited organizations are expected to identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.	<p>This reporting requirement is imposed by the Joint Commission. Joint Commission requirements are standards that measure hospital quality of care during normal times. They do not have the force of law or regulations and cannot be waived by the Governor or Secretary of Health and Human Services.</p> <p>Compliance with Joint Commission reporting requirements will be an independent hospital decision that may be based on the impact of the healthcare surge on hospital operations and its ability to comply based on redirected healthcare resources.</p>

Foundational Knowledge



Tool 4: Statutory and Regulatory Flexibility under Emergency Declarations Table

The level of surge coupled with any corresponding government action, such as an emergency declaration (local, State or federal), will determine the amount of statutory and regulatory flexibility. The following table depicts the authorized agency or entity with authority to flex the regulatory, statutory or accreditation requirements. This flexing authority is dependent on the level at which the emergency is declared. In addition to the laws that may require flexing, there are State and federal statutes that allow flexibility without issuance of an emergency declaration.

(+) = Additional Action Required after Emergency Declaration

Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Civil Liability for Negligence	
	x+				Duty to Provide Ordinary Care Civil Code Section 1714	Governor's Standby Order required for Statutory Suspension
					Immunity Statutes	
				x	Physician & Surgeon; Good Faith Emergency Care at Scene (includes ER) Business and Professions Code Section 2395	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility						
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>	Existing Statute/Requirement	Additional Government Action Required
	X (Or Local Emergency Declaration)	X (Or State Emergency Declaration)				
	X (Or Local Emergency Declaration)	X (Or State Emergency Declaration)				
	X (Or Local Emergency Declaration)	X (Or State Emergency Declaration)				
	X (Or Local Emergency Declaration)	X+ (Or State Emergency Declaration)				
					Dentist: No liability for services at request of authorized official during the state of war emergency, a state of emergency, or a local emergency, unless willful act or omission Government Code Section 8659	Governor's Standby Order required for Statutory Suspension (Clinics, long-term care and other healthcare facilities should be included in standby order.)
					Nurse: No liability for services at request of authorized official during the state of war emergency, a state of emergency, or a local emergency, unless willful act or omission Government Code Section 8659	
					Physician: No liability for services at request of authorized official during the state of war emergency, a state of emergency, or a local emergency, unless willful act or omission Government Code Section 8659	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x (Or Local Emergency Declaration)	x (Or State Emergency Declaration)			Pharmacist; No liability for services at request of authorized official during the state of war emergency, a state of emergency, or a local emergency, unless willful act or omission Government Code Section 8659	
	x (Or Local Emergency Declaration)	x (Or State Emergency Declaration)			Disaster Service Worker; No disaster service worker who is performing disaster services ordered by lawful authority during a state of war emergency, a state of emergency, or a local emergency shall be liable for civil damages, unless willful act or omission Civil Code Section 1714.5	
	x (Or Local Emergency Declaration)	x (Or State Emergency Declaration)			There shall be no liability on the part of owner or occupant of building used as mass care center, first aid station, temporary hospital annex, unless willful act or omission Civil Code Section 1714.5	
	x+				Healthcare Providers; Requirement to Comply with Advanced Healthcare Directive Probate Code Section 4733	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
				x	Healthcare Providers - Informed Consent; Not liable for civil damages for injury or death caused in an emergency situation occurring in the licensee's office or in a hospital on account of a failure a patient of the possible consequences of a medical procedure if certain criteria exist Business and Professions Code Section 2397	
	x+				Disposition of Remains; Where person authorized is unavailable within specified time (Under the Emergency Services Act, the authority for disposition of dead bodies would temporarily reside with the government.) Health and Safety Code Section 7100	Governor's Standby Order required for Statutory Suspension
				x	Special Needs Populations; Entitlement to Treatment on Same Basis as the Able-bodied Health and Safety Code Section 1317(b)	
	x+				Emergency Services; Rendering of emergency services to all patients Health and Safety Code Section 1317(a)	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+		x		Medical Records; Maintenance of a medical records system, based upon current standards for medical record retrieval and storage Health and Safety Code Section 1250.05; 22 CCR 70747, 22 CCR 70751	Governor's Standby Order required for Statutory Suspension
					Privacy	
x+	x				HIPAA: Requirement to Obtain Patient Consent to discuss Protected Health Information with family or friends 45 CFR 164.510; 42 USC Section 1320b-5(b)(7)(A)	Emergency Declaration & Department of Health and Human Services Waiver
x+	x				HIPAA: Requirement to Honor Opt Out Request Obtain for Facility Directory 45 CFR 164.510; 42 USC Section 1320b-5(b)(7)(A)	Emergency Declaration & Department of Health and Human Services Waiver
x+	x				HIPAA: Requirement to Distribute Notice 45 CFR 164.520; 42 USC Section 1320b-5(b)(7)(B)	Emergency Declaration & Department of Health and Human Services Waiver

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>	
					Existing Statute/Requirement
x+	x				HIPAA; Patient Right to Request Privacy Restrictions and Confidential Communications 45 CFR 164.522; 42 USC Section 1320b-5(b)(7)(C)
					Emergency Declaration & Department of Health and Human Services Waiver
x+	x				Confidentiality of Medical Information Act*; Requirement to Obtain Patient Consent to disclose medical information California Civil Code 56 et seq. <i>(*Due to overlapping HIPAA requirements, waiver of State confidentiality laws will also require federal waivers.)</i>
					Emergency Declaration & Department of Health and Human Services Waiver
					Public Health/Vital Statistics
					Disease Reporting Health and Safety Code Section 120130; 17 CCR 2500
	x+				Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+				Birth Reporting Health and Safety Code Section 102400	Governor's Standby Order required for Statutory Suspension
	x+				Death Reporting Health and Safety Code Section 102775	Governor's Standby Order required for Statutory Suspension
	x+				Cancer Registry Reporting Health and Safety Code Section 103875, et seq.	Governor's Standby Order required for Statutory Suspension
	x+				Burns & Smoke Inhalation Reporting Health and Safety Code Section 13110.7	Governor's Standby Order required for Statutory Suspension
					Health Facility Administration	
	x+				Transfers of Patients; Violations Health and Safety Code Section 1317.4	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+				Reporting of Inventory of Medical Supplies Health and Safety Code Section 120176	Governor's Standby Order required for Statutory Suspension
	x+		x		Unusual Occurrence Reports 22 CCR 70737, 71535	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+				Reporting of Violence against Hospital Personnel Health and Safety Code Section 1257.7	Governor's Standby Order required for Statutory Suspension
	x+				Reporting of Violence against Community Healthcare Worker Labor Code Section 6332	Governor's Standby Order Statutory Suspension
	x+				Medication Errors Reporting Business and Professions Code Section 4125; 16 CCR 1711	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+				Occupational Illness & Injury Reporting Labor Code Section 6409; 8 CCR 14003	Governor's Standby Order required for Statutory Suspension
	x+				Work-Related Fatalities Reporting 8 CCR 342	Governor's Standby Order required for Statutory Suspension
					Criminal Behavior	
	x+				Suspicious Injury Reports Penal Code Section 11160, et seq.	Governor's Standby Order required for Statutory Suspension
	x+				Child Abuse & Neglect Reporting Penal Code Section 11164, et seq.	Governor's Standby Order required for Statutory Suspension
	x+				Elder & Dependent Abuse Reporting Welfare and Institutions Code Section 15600, et seq.	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+				Gunshot, Knife Wound Reporting Penal Code Section 11161.8	Governor's Standby Order required for Statutory Suspension
	x+				Office of Statewide Health Planning and Development Reporting Requirements Health and Safety Code Section 128765, et seq.	Governor's Standby Order required for Statutory Suspension
					Federal Reporting Requirements	
x+					Vaccine Adverse Reaction Reports 42 USC Section 300aa-14, 25	Department of Health and Human Services Waiver; 42 USC Section 247d
x+					Safe Medical Device Reporting 21 USC Section 360	Determination required by Secretary of Homeland Security, Defense, or Public Health that agent or device is required in an emergency

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Joint Commission Reporting	
			x		Joint Commission Sentinel Event Reporting JCAHO Manual PI.1.10, 2.20, 3.10	
					Mobile Hospitals, Hospital Annexes	
	x+				Acute Care Basic Services Regulations 22 CCR 70100, et seq.	Governor's Standby Order required for Statutory Suspension
	x+				Acute Care Licensing Requirements Health & Safety Code Section 1253	Governor's Standby Order required for Statutory Suspension
x					Clinical Laboratory Improvement Amendments; Receipt and Testing by Certified facility only 42 USC Section 263a	Department of Health and Human Services Waiver; 42 USC Section 247d
	x+				Office of Statewide Health Planning and Development Approval of Plans Health and Safety Code Section 129750, et seq.	Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>	Existing Statute/Requirement
	x+				
	x+				
	x+				
					Mass Care Centers, First-Aid Stations, Shelters
					Clinic Licensing Requirements Health and Safety Code Section 1200, et seq.
					All Facilities
					Structural Safety of Health Facilities Health and Safety Code Section 129680, 129990; 24 CCR 102
					Medical Waste Management Health and Safety Code Section 117600, et seq.
	x+				Fire Safety Code Compliance 19 CCR 1.09

Additional Government Action Required

Governor's Standby Order required for Statutory Suspension

Governor's Standby Order required for Statutory Suspension

Governor's Standby Order required for Statutory Suspension

Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Federal Labor Standards	
x					Duty of Employer to Furnish Workplace Free of Hazards; Comply with Regulations 29 USC Section 654	
x					Emergency action plans 29 CFR 1910.38	
x					Hazardous Materials Regulations 29 CFR 1910.101-126 1910.120 - Hazardous Waste 29 CFR 1910.1000-1450, App. B	
x					Personal Protective Equipment 29 CFR 1910.132-.139 and App. B 1910.132 - General 1910.133 - Eye and Face Protection 1910.134 - Respiratory Protection 1910.136 - Foot Protection 1910.138 - Hand Protection	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility							Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>			
					State Labor Standards		
	x+				Jurisdiction of California OSHA Labor Code Section 6307	Governor's Standby Order required for Statutory Suspension	
	x+				Minimum Labor Standards Labor Code Section 90.5	Governor's Standby Order required for Statutory Suspension	
	x+				Requirement to Provide Safe Workplace Labor Code Section 6400	Governor's Standby Order required for Statutory Suspension	
	x+				Requirement to Provide Safety Devices and Safe Practices Labor Code Section 6401	Governor's Standby Order required for Statutory Suspension	
	x+				Emergency Action Plans 8 CCR 3220	Governor's Standby Order required for Statutory Suspension	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+				Hazardous Waste Management 8 CCR 5192-E	Governor's Standby Order required for Statutory Suspension
	x+				Injury and Illness Prevention Program 8 CCR 3203	Governor's Standby Order required for Statutory Suspension
					Acute Care Hospitals	
	x+		x		Scope of Services 22 CCR 70011	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+		x		Nurse Staffing Ratio 22 CCR 70217	CDPH Waiver Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility						Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+		x		General Acute Care Hospitals; Out of Scope Supplemental Services 22 CCR 70301	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+		x		General Acute Care Hospitals; Out of Scope Special Services 22 CCR 70351	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+				Posting of Policy on Patients' Rights 22 CCR 70707	Governor's Standby Order required for Statutory Suspension
	x+		x		General Acute Care Hospitals; Conversion of Space for other uses 22 CCR 70805	CDPH Waiver Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+		x		General Acute Care Hospitals; Limitation to Licensed Beds 22 CCR 70809	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+				Medical Control at Emergency Scene Health and Safety Code Section 1798.6	Governor's Standby Order required for Statutory Suspension
	x+				Management of Dangerous Persons, Medical hold of persons dangerous to self or others Welfare and Institutions Code Section 5150	Governor's Standby Order required for Statutory Suspension
x					Emergency Medical Treatment and Active Labor Act; Required Examination and Treatment of Emergency Medical Conditions & Women in Labor 42 USC Section 1395dd	Department of Health and Human Services Waiver; 42 USC Section 1320b-5

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility						
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>	Existing Statute/Requirement	
	x+		x		Skilled Nursing Facilities; Scope of Services 22 CCR 72301	Governor's Standby Order required for Statutory Suspension
	x+		x		Skilled Nursing Facilities; Conversion of Space for other uses. 22 CCR 72603	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+		x		Skilled Nursing Facilities; Limitation to Licensed Beds 22 CCR 72607	CDPH Waiver Governor's Standby Order required for Statutory Suspension
					Intermediate Care Facilities	
	x+		x		Intermediate Care Facilities; Scope of Services 22 CCR 73301, 76301, 76853	CDPH Waiver Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
	x+		x		Intermediate Care Facilities; Conversion of Space for other uses 22 CCR 73605	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+		x		Intermediate Care Facilities; Limitation to Licensed Beds 22 CCR 73609	CDPH Waiver Governor's Standby Order required for Statutory Suspension
					Acute Psychiatric Hospitals	
	X+		x		Acute Psychiatric Hospitals; Conversion of Space for other uses. 22 CCR 71605	CDPH Waiver Governor's Standby Order required for Statutory Suspension
	x+		x		Acute Psychiatric Hospitals; Limitation to Licensed Beds 22 CCR 71609	CDPH Waiver Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility							Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>			
					Primary Care Clinics		
	x+		x		Primary Care Clinics; Scope of Services 22 CCR 75026	CDPH Waiver Governor's Standby Order required for Statutory Suspension	
	x+		x		Primary Care Clinics; Conversion of Space for other uses 22 CCR 75072	CDPH Waiver Governor's Standby Order required for Statutory Suspension	
					Correctional Treatment Centers		
	x+		x		Correctional Treatment Centers; Scope of Services 22 CCR 79597	CDPH Waiver Governor's Standby Order required for Statutory Suspension	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Long-Term Care Facilities	
	x				Prohibition on accepting patient if cannot provide adequate care Health and Safety Code Section 1418.6	
					Transportation	
	x+				Ambulance emergency care equipment & supplies 13 CCR 1103.2	Governor's Standby Order required for Statutory Suspension
	x+				Required Course Content; Emergency Medical Technician-I & Emergency Medical Technician-P 22 CCR 100075, 100159	Governor's Standby Order required for Statutory Suspension
					Physicians	
	x+				Physician, Inactive Business and Professions Code Section 702	Governor's Standby Order required for Statutory Suspension
	x+				Physician, Inactive Business and Professions Code Section 902	Governor's Standby Order required for

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
						Statutory Suspension
	x				Physician, Out-of-State Business and Professions Code Section 900	
	x+				Physician, Retired Business and Professions Code Section 2439	Governor's Standby Order required for Statutory Suspension
					Physician, Federal/Military; Practice Outside Federal Facility Business and Professions Code Section 715, Business and Professions Code Section 718	Governor's Standby Order required for Statutory Suspension
x	x+					
					Pharmacists	
	x+				Pharmacist, Inactive Business and Professions Code Section 702	Governor's Standby Order required for Statutory Suspension
	x+				Pharmacists: Only Pharmacist May Dispense Prescription Drugs Business and Professions Code Section 4051	Governor's Standby Order required for Statutory

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
						Suspension
	x+				Pharmacy: Requirement for Prescription to Dispense Prescription Drugs Business and Professions Code Section 4059	Governor's Standby Order required for Statutory Suspension
x	x	x			Pharmacists; Dispensing w/o Prescription Business and Professions Code Section 4062	
x+	x+	x+	x		Pharmacists; Labeling, Employee Ratio, and Consultation Requirements Business and Professions Code Section 4062	Emergency Declaration and Waiver by Pharmacy Board. Governor's Standby Order required for Statutory Suspension

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Dentists, Federal	
x	X+				Practice Outside Federal Facility Business and Professions Code Section 715	Governor's Standby Order required for Statutory Suspension
					Nurses	
	X+				Nurse, Federal; Practice Outside Federal Facility Business and Professions Code Section 715	Governor's Standby Order required for Statutory Suspension
	x	x			Nursing Care, Public Disasters & Epidemics Business and Professions Code Section 2727	
	x	x			Nursing Care, Gratuitous Care by Friends or Family Business and Professions Code Section 2727	

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					Existing Statute/Requirement	Additional Government Action Required
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>		
					Physician Assistants	
	x+	x			Physician Assistant; Practice w/o Supervising Physician Business and Professions Code Section 3502.5	Governor's Standby Order required for Statutory Suspension
					Medi-Cal Billing	
x+	x				Waiver of Documentation Requirement If Permitted by Federal Law Welfare and Institutions Code Section 14115	Emergency Declaration and Department of Health and Human Services Waiver 42 USC Section 1320b-5, 5141
					Federal Funding	
x+	x				Medicare Administrative Conditions for Assistance Title XVIII; Social Security Act 42 USC Section 1395, et seq.	Emergency Declaration and Department of Health and Human Services Waiver 42 USC Section 1320b-5, 5141

Foundational Knowledge



Level of Emergency Declaration and Agency or Entity Authorized to Enable Statutory and Regulatory Flexibility					
<u>Federal Disaster Declaration/ Department of Health and Human Services Waiver</u>	<u>State of Emergency Declaration</u>	<u>Local Emergency Declaration</u>	<u>Regulatory/ Accrediting Agency Waiver</u>	<u>Emergency Flexibility Exist in Law/ No Enabling Action Required</u>	
x+	x				Medicaid Administrative Conditions for Assistance Title XIX; Social Security Act 42 USC Section 1396 et seq.
x+	x				State Children's Health Program; Conditions for Assistance Title XXI; Social Security Act 42 USC Section 1397aa, et seq.
					Emergency Declaration and Department of Health and Human Services Waiver 42 USC Section 1320b-5, 5141
					Emergency Declaration and Department of Health and Human Services Waiver 42 USC Section 1320b-5, 5141



10. Endnotes

- ¹ *Emergency Management Principles and Practices for Healthcare Systems*. The Institute for Crisis, Disaster, and Risk Management (ICDRM) at the George Washington University; for the Veteran's Health Administration, United States Department of Veteran's Affairs. Washington, D.C., June 2006. Available at <http://www1.va.gov/emshq/>
- ² Depending upon the jurisdiction, the designated official may be the director of emergency services, the director or medical director of the local emergency medical services agency, or medical health operational area coordinator. A description of these officials is provided later in this document.
- ³ Depending upon the jurisdiction, the designated official may be the director of emergency services, the director or medical director of the local emergency medical services agency, or medical health Operational Area coordinator. A description of these officials is provided later in this document.
- ⁴ Government Code Section 8550, et seq.
- ⁵ Government Code Section 8550.
- ⁶ Government Code Section 8569.
- ⁷ Government Code Section 8568.
- ⁸ Government Code Section 8595.
- ⁹ Government Code Section 8570.
- ¹⁰ Government Code Section 8572.
- ¹¹ Government Code Section 6502.
- ¹² Government Code Section 8615.
- ¹³ Government Code Section 8617, 8561.
- ¹⁴ California Disaster and Civil Defense Master Mutual Aid Agreement
- ¹⁵ Government Code Section 8615.
- ¹⁶ Government Code Section 8600.
- ¹⁷ Government Code Section 8559(a).
- ¹⁸ California State Emergency Plan, 2005, pp. 8, 10.
- ¹⁹ Health and Safety Code Section 1797.152(a).
- ²⁰ Health and Safety Code Section 1797.152(b).
- ²¹ Government Code Section 8619.
- ²² Government Code Section 178, et seq.
- ²³ Robert T. Stafford Disaster Relief and Emergency Assistance Act, P.L. 93-288, 100-707, and 106-390, 42 USC Section 5121, et seq.
- ²⁴ Health and Safety Code Section 100100, et seq.; effective July 1, 2007, the public health duties of the State Department of Health Services are transferred to the new State Department of Public Health, Health and Safety Code Section 131000, et seq.
- ²⁵ California State Emergency Plan, 2005, p. 58.
- ²⁶ California State Emergency Plan, 2005, p. 56.
- ²⁷ Health and Safety Code Section 1200, et seq.
- ²⁸ Health and Safety Code Section 1276.
- ²⁹ Health and Safety Code Section 1797.100, et seq.
- ³⁰ Health and Safety Code Section 1797.150.
- ³¹ California State Emergency Plan, 2005, p. 58.
- ³² Health and Safety Code Section 1797.160.
- ³³ Ibid.
- ³⁴ Government Code Section 8585.
- ³⁵ Government Code Section 8586.
- ³⁶ Government Code Section 8587.
- ³⁷ Ibid.
- ³⁸ California State Emergency Plan, 2005, pp. 8, 9.
- ³⁹ Government Code Section 8567.
- ⁴⁰ Government Code Section 8571.
- ⁴¹ Government Code Section 8572.
- ⁴² There are three types of emergencies under the Emergency Services Act: state of emergency, state of emergency and local emergency (See Government Code Section 8558).
- ⁴³ Government Code Section 8627.



- 44 Government Code Section 8628.
- 45 Government Code Section 8575, et seq.
- 46 Government Code Section 8579(b)(1).
- 47 Government Code Section 8549.10.
- 48 Government Code Section 8549.13.
- 49 Government Code Section 8560.
- 50 Government Code Section 8616.
- 51 Government Code Section 8610.
- 52 Ibid.
- 53 Ibid.
- 54 Government Code Section 8585.5.
- 55 19 CCR 2570.2
- 56 Government Code Section 8614.
- 57 In a letter dated September 28, 2006, the director of OES certified to the federal Department of Homeland Security the compliance of SEMS with the National Incident Management System (NIMS) for fiscal year 2006.
- 58 Government Code Section 8607(d).
- 59 Government Code Section 8607(e).
- 60 Government Code Section 8607(a)(3); 19 CCR 2415; See *Emergency Management in California*, OES, 2003, p. 8.
- 61 Government Code Section 8618.
- 62 Government Code Section 8607(a)(1); 19 CCR 2401, 2402(l), and 2405.
- 63 Government Code Section 8559(b), 8605, and 8607(a)(4);
- 64 Government Code Section 8559(b), 8605.
- 65 Government Code Section 8605.
- 66 19 CCR 2402(c).
- 67 Health and Safety Code Section 1797.153.
- 68 Health and Safety Code Section 1797.153(c).
- 69 Under the proposed tool, such a declaration could occur at surge levels Orange, Red or Black.
- 70 Government Code Section 8630.
- 71 Government Code Section 8631.
- 72 Government Code Section 8632.
- 73 Government Code Section 8634.
- 74 Health and Safety Code Section 101000.
- 75 Health and Safety Code Section 101030.
- 76 Health and Safety Code Section 101460.
- 77 Health and Safety Code Section 101375.
- 78 Health and Safety Code Section 101175.
- 79 See, generally, *Health Officer's Practice Guide for Communicable Disease Control*, 2007, DPH.
- 80 Health and Safety Code Section 120176.
- 81 Health and Safety Code Section 101040, 101475.
- 82 Government Code Section 8630.
- 83 Health and Safety Code Section 101080.
- 84 Health and Safety Code Section 101085(c).
- 85 Health and Safety Code Section 101085(b).
- 86 Health and Safety Code Section 101085(a)(2), (3).
- 87 Health and Safety Code Section 101080.2(a).
- 88 Government Code Section 26620.
- 89 Government Code Section 26621.
- 90 Health and Safety Code Section 1797.200.
- 91 Health and Safety Code Section 1797.202(a).
- 92 Health and Safety Code Section 101275.
- 93 Health and Safety Code Section 101310.
- 94 Health and Safety Code Section 1797.153.
- 95 See Government Code Section 24000, 24010, and 24300.



- 96 Government Code Section 27460, et seq.
- 97 Government Code Section 27490, et seq. and 27520, et seq.
- 98 Coroners Mutual Aid Plan, OES, 2006, p. 11.
- 99 Coroners Mutual Aid Plan, OES, 2006, p. 16.
- 100 Government Code Section 8630(b).
- 101 Government Code Section 8630(c).
- 102 Government Code Section 8630(d).
- 103 Government Code Section 8629.
- 104 Government Code Section 8629.
- 105 Government Code Section 8571.
- 106 Government Code Section 8567. Local governing bodies have similar authority under a local emergency to enact ordinances, but these ordinances would be subordinate to State statutes, regulations and orders of the governor.
- 107 Government Code Section 8659.
- 108 *Burciaga v. St. John's Hospital* (1986) 187 Cal.App.3d 710.
- 109 *Bryant v. Bakshandeh* (1991) 226 Cal.App.3d 1241
- 110 *Calatayud v. State of California* (1998) 18 Cal. 4th 1057, 1064.
- 111 Business and Professions Code Section 2727.5
- 112 Business and Professions Code Section 1627.5.
- 113 Business and Professions Code Section 2861.5.
- 114 Business and Professions Code Section 3503.5
- 115 Health and Safety Code Section 1799.102.
- 116 Health and Safety Code Section 1799.104.
- 117 Health and Safety Code Section 1799.106.
- 118 Health and Safety Code Section 1799.107.
- 119 Health and Safety Code Section 1799.102, applying to any person outside an emergency room or place where care is usually offered.
- 120 See, e.g. Business and Professions Code Section 2727.5, applying to nurses.
- 121 *Cobbs v. Grant*, 8 Cal. 3d 229.
- 122 Business and Professions Code Section 2397.
- 123 See Government Code Section 204; "The State may require services of persons, with or without compensation: . . . in protecting life and property from fire, pestilence, wreck and flood."
- 124 Government Code Section 8599.
- 125 Government Code Section 3101.
- 126 Government Code Section 3100.
- 127 See Labor Code Section 3600.6, 3211.9-3211.93a, and 4350-4355; 19 CCR 2570, et seq.
- 128 19 CCR 2570.2.
- 129 Government Code Section 8657.
- 130 Civil Code Section 1714.5; the exception here is essentially identical to the Good Samaritan exception for physicians, and the exception to the specific provider immunity in a declared emergency under Government Code Section 8659, discussed above.
- 131 19 CCR 2572.1(j).
- 132 Civil Code Section 1714.5.
- 133 Health and Safety Code 1317(a), see also 42 USC Section 1395dd and corresponding regulations at 42 CFR Section 489 *et seq.*
- 134 *Id.*
- 135 Health and Safety Code Section 1317(c).
- 136 Health and Safety Code Section 1317(g).
- 137 Government Code Section 8665.
- 138 Civil Code Section 1714.6.
- 139 Civil Code Section 1714.6.
- 140 Regulatory statutes vitally affect the interests of private citizens and of the general public. See e.g. 10 CA ADC Section 260.607 (describing what constitutes a regulatory statute).
- 141 There is an immunity from liability for refusal to treat based on a determination that the health facility does not have the appropriate facilities or qualified personnel available to render those services. (Health and Safety Code Section 1317(c)). Hospitals with emergency departments are required under the Emergency Medical Treatment and Labor Act (EMTALA) to provide a screening and stabilization



- within the abilities of the staff and facilities available prior to transferring the patient to another facility. (42 USC Section 1395dd.) This federal requirement can be waived by the Secretary for Health and Human Services under 42 USC Section 1320b-5(b)(3).
- See, e.g., Business and Professions Code Section 1627.5, 2395, 2727.5, 2861.5, and 3503.5.
- Government Code Section 8567b.
- A local health officer may take preventive measures to protect public health, including protective step that may be taken against any public health hazard that is caused by a disaster and affects the public health. This could, in limited circumstances, include control over vaccine distribution, but not commandeering of either the vaccine or personnel to administer it.
- Adapted from Medical Board of California, Division of Licensing, Standard of Care for California Licensed Midwives. *Midwifery Standards of Care* (September 15, 2005). http://www.mbc.ca.gov/MW_Standards.pdf
- Virginia Jury Instructions, Civil Instruction No. 35.000. Steven D. Gravely, Troutman Sanders LLP. *Altered Standards of Care: An Overview*. http://www.vdh.State.va.us/EPR/pdf/Health_and_Medical_Subpanel.pdf
- Depending upon the jurisdiction, the designated official may be the director of emergency services, the director or medical director of the local emergency medical services agency, or medical health Operational Area coordinator.
- Health and Safety Code Section 1276.
- NYS Workgroup on Ventilator Allocation in an Influenza Pandemic, NYS DOH / NYS Task Force on Life & the Law. *Allocation of Ventilators in an Influenza Pandemic: Planning Document - Draft for Public Comment*. New York, 15 March 2007
- Principles of the Ethical Practice of Public Health, Version 2.2 © 2002 Public Health Leadership Society
- Altered Standards of Care in Mass Casualty Events. Prepared by Health Systems Research Inc. under Contract No. 290-04-0010. AHRQ Publication No. 05-0043. Rockville, MD: Agency for Healthcare Research and Quality. April 2005.
- Contingency Plan for Excessive Heat Emergencies: A Supporting Document to the State Emergency Plan, California Governor's Office of Emergency Services, December 2006.
- Meeting the Needs of Vulnerable People in Times of Disaster: A Guide for Emergency Managers. California Governor's Office of Emergency Services, 2000
- The Agency for Healthcare Research and Quality
- Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients. (*Arch Intern Med*. 1995; 155: 29-40). © 1993 American Medical Association.
- NYS Workgroup on Ventilator Allocation in an Influenza Pandemic, NYS DOH / NYS Task Force on Life & the Law. *Allocation of Ventilators in an Influenza Pandemic: Planning Document - Draft for Public Comment*. New York, 15 March 2007
- Hick, J.L., et al; *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*; *Acad Emerg Med* 2006; 13:223-9
- Project Xtreme*. Cross-Training Respiratory Extenders for Medical Emergencies. April 2007. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/prep/projxtreme/>
- Depending upon the jurisdiction, the designated official may be the director of emergency services, the director or medical director of the local emergency medical services agency, or medical health operational area coordinator.