



# Development of Standards and Guidelines for Healthcare Surge during Emergencies

## Supplies, Pharmaceuticals, and Equipment

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

### Introduction

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

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

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

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

### Supplies, Pharmaceuticals, and Equipment (SP&E)

Supplies, Pharmaceuticals, and Equipment will focus on the supply chain flow to highlight the process of how these materials are utilized during a surge. This area is vital in understanding the process for obtaining and distributing supplies, pharmaceuticals, and equipment to provide the greatest amount of good to the most people while taking into account laws, regulations, and statutes.

This document is divided into the following two sections. The First section focuses on the licensing, liability, and regulatory implication issues relating to supplies, pharmaceuticals, and equipment. This section lays out the potential issues that may arise during a surge and provides the current guidelines around these issues.

The Second section focuses on the management of the supply chain including the acquisition, storage, staging, and distribution of supplies, pharmaceuticals, and equipment. First this section addresses the acquisition of supplies, pharmaceuticals, and equipment and highlights the uniqueness in acquiring or procuring the needed materials. The distinct needs at each operational level from the local level to the state and federal levels are considered to appreciate how all of the organizational levels must interact and work together. Considerations for storing supplies, pharmaceuticals, and equipment are then addressed. Recommendations are made for efficient set up or staging of the

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supply areas in a prearranged fashion so the materials can be used in an efficient manner. The last part of the supply chain management section focuses on the deployment of or the distribution of resources. It considers how scarce resources need to be distributed and focuses on some of the legal requirements when distributing and dispensing pharmaceuticals at existing healthcare facilities, alternate care sites, and licensed dispensing sites.

### **Liability, Licensing and Regulatory Implications of Supplies, Pharmaceuticals, and Equipment Related to Surge**

*This section provides an understanding of liability, licensing, and regulatory implications related to surge for supplies, pharmaceuticals, and equipment. There are potential situations where regulatory implications around the use, delivery, distribution, and administration in this area. This section highlights specific advanced planning mechanisms that have been implemented for the purpose of encouraging the emergency provision of care to affected patients and areas. It provides answers to questions such as “can standards be flexed for using expired medications during a surge?” and “are there waivers for requirements that may be implausible to meet under certain circumstances?”*

The California State Board of Pharmacy plays a large role in the function of pharmacists who play an intricate role in patients receiving needed medications. In a recent response to the potential of a surge, the California State Board of Pharmacy created a Disaster Response Policy Statement in January 2007 to ensure proper preparation and an effective response to any local, state, or national disaster. The purpose of the policy statement and potential waivers as part of section 4062, subdivision (b) is to encourage pharmacists to do everything possible to do the most good for the largest amount of people.

This policy highlights that in the event of declared disaster or emergency, the Board expects utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances. This takes into account what would be otherwise normal operating procedures that may not be able to be addressed during a surge such as record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements and other standard pharmacy practices and duties that may interfere with the most efficient response to those affected.

In the event of the waiver, the State of California Board of Pharmacy would communicate this information to the Office of Emergency Services (OES) for them to distribute the information. Information would also be posted on their website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) and communicated via phone @ (916) 574-7900.

The Board expects licensees to apply their judgment and training to provide medication to patients in the best interests of the patients with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board expects that the highest standard of care possible will be provided, and once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

The following are potential liability and regulatory compliance issues that may arise during a surge. Each issue’s compliance requirements are addressed.

#### **Use of Expired Medications**

Approved drugs are tested for stability and the expiration dates are based on those tests. However, most drugs remain stable far beyond the expiration date, sometimes ten times as long. The manufacturers have no incentive to test stability for longer periods of time; shorter expiration dates mean higher drug turnover, and testing stability for longer periods of time is expensive. So, they generally don’t try to establish longer expiration dates, even if there is data showing that the drug is stable for much longer than they state in their new drug applications.

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Certain drug products have been qualified for shelf life extension through the Shelf Life Extension Program (SLEP), which is sponsored by the Department of Defense (DOD) and performed by the FDA. The SLEP is sponsored by the DOD because of the substantial savings to the government from extending the shelf life of certain antibiotics and other drug products that are stored in Federal stockpiles in large quantities under controlled conditions and are of strategic importance. Absent some approved shelf-life extension for specific drugs, the only way to determine the potency of drug stocks is to test. This is not a requirement that can be flexed by state law from a regulatory perspective.

Any restrictions on pharmacists dispensing expired drugs could be waived by the Pharmacy Board. An emergency proclamation changing the standard of care could also provide some protection.

### Off – Label Drug Use

If a drug is being used for off-label use, it means that the drug is approved by Federal Drug Administration (FDA), but the physician is using the drug for a use other than the one for which FDA gave the approval. The Federal Food, Drug & Cosmetic Act, Chapter V, Subchapter A, sec. 501(a) (2) (B) [21 USC 351] looks at the quality and purity characteristics of medications which are standards the FDA creates. Subsequent to a drug's approval, researchers often notice that the drug has other beneficial uses. Based on this published research, clinicians may prescribe the drug for this other use whether in a surge or not. Over time, use of the drug for this off-label use can become common practice, and be considered within the standard of care in the community.

There is no statutory or regulatory prohibition against off-label use of a drug by a physician. Consequently, pharmacists may dispense pharmaceuticals without being out of compliance.

The only limitation on such off-label use is the law of medical malpractice. The more a drug is used for off-label purposes, the lower the likelihood that such use will be considered a breach of the standard of care owed to the patient.

A proclamation of an emergency could include a provision making the standard of care the prevention of the greatest loss of life, which could allow some off label uses even if not generally accepted by the medical community, but consistent with the goal of saving a life.

### Distribution and/or Dispensing of Pharmaceuticals by non-licensed Pharmacists

During a surge, there is a possibility that there will not be a licensed Pharmacist on-site to dispense pharmaceuticals. The California Business and Professions Code, Section 4051 states that "it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter." To address this, the California State Board of Pharmacy may waive application of any provisions of this chapter or the regulations adopted if, in the Pharmacy Board's opinion, the waiver will aid in the protection of public health or the provision of patient care during a declared federal, state, or local emergency as noted in California Business and Professions Code, Section 4062(b)

### Out – of State Licensed Pharmacists, Intern Pharmacists and/or Pharmacy Technicians

The California State Board of Pharmacy encourages that persons outside of California will assist the residents of California. In the event of a declared disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California, but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California.

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Nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state are encouraged to ship medications to pharmacies, health professionals or other wholesalers in California.

### Licensing of Dispensing Sites and Alternate Care Sites

All designated dispensing sites are required to have a license to dispense medications. A pharmacist needs to acknowledge the receipt of the delivery of pharmaceuticals. A pharmacist's educational background and experience should be utilized in this situation to understand if the appropriate medications have been delivered in the correct quantities so they can then utilize the pharmaceuticals in the most efficient manner.

### Furnishing Medications without a Prescription

During a surge, there may be limited time to receive a prescription from a Physician. Therefore Section 4062, subdivision (a) states that a Pharmacist may in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state or local emergency, to further the health and safety of the public. This section states that a record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible.

Mass Dispensing During a Surge - **To be reviewed for further analysis.**

Preferential prices of Pharmaceuticals - **To be reviewed for further analysis.**

Current Applicable Legislation, Statute, Law

a) Abbott Laboratories v. Portland Retail Druggists Ass'n Inc., 425 U.S. 1, 96 S.Ct. 1305, 47 L.Ed.2d 537 (1976)

b) The Prescription Drug Marketing Act (PDMA) of 1987, Section VI. Sales Restrictions for Hospitals, Health Care Entities, and Certain Charitable Organizations

### Supplies and Equipment Liability

#### The Use of Supplies and Equipment beyond the Manufacturers Recommended Use

The Federal Food, Drug & Cosmetic Act, Chapter V, Subchapter E, Sec. 564 [21 USC 360bbb-3] - 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 (referred to in this section as an "emergency use").

It may be possible, through an emergency declaration changing the overall standard of care, to use equipment in a manner not recommended if the purpose is to save the life, and still receive compensation. This may not preclude liability lawsuits, but it could lessen the likelihood of a successful claim.

As for employees, and particularly with regard to Personal Protective Equipment (PPE), the liability would be for workers compensation benefits. The Labor Code requires that every employer furnish

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and use safety devices and safeguards, and adopt and use practices, means, methods, operations, and processes which are reasonably adequate to render such employment and place of employment safe and healthful.

Liability for Non-Governmental Organizations (NGOs) for the distribution of medical and health supplies

There is potential for the state, regional areas and local healthcare facilities to have the need to utilize NGOs to access medical and health supplies. Because this may not be part of the normal process there can be concerns around liability. An NGO can be held liable in negligence just as any other organization. The liabilities for the distribution of medical and health supplies can be either regulatory (i.e., criminal), or civil (e.g., for damages).

Regulatory liabilities would arise where the item distributed is subject to regulatory controls and the NGO acts in violation of those controls, e.g., prescription drugs. Those controls could be waived by the Board of Pharmacy under section 4062(b) of the Business & Professions Code.

Civil liability for NGOs during a declared emergency would depend upon whether the NGO was functioning as a disaster service organization, i.e., all of its employees are functioning as disaster service workers. If so, the employee's would be immune to liability under Civil Code section 1714.5.

Also, the Governor could issue orders that require NGOs to carry out certain functions, and they would not have liability under Civil Code section 1714.6

## Supply Chain Management of Supplies, Pharmaceuticals, and Equipment

*This section defines how each of the supply chain processes relates to supplies, pharmaceuticals, and equipment. It attempts to clearly lay out the process for acquiring, storing, staging, and deploying materials at each of the operational levels and what the triggers are for accessing the next operational level. Lastly, this section makes recommendations on what types of supplies, pharmaceuticals, and equipment should be on hand at existing healthcare facilities and in stockpiles to be adequately prepared for a surge.*

There are current processes that exist for healthcare facilities to access, procure, store and distribute supplies, pharmaceuticals, and equipment. Each step of the supply chain is impacted in a different manner. During a surge, those processes may change and there needs to be an organized process that is understood so that each of the operational levels can obtain potentially scarce resources in a timely manner. Preliminary work was conducted to define the supply chain during surge and how it relates to supplies, pharmaceuticals, and equipment.

Key Terms:

- **Supplies:** Durable and consumable goods which are essential in carrying out the treatment of a patient's illness or injury.
- **Pharmaceuticals:** Any prescription medications and/ or over - the counter drugs administered to persons to diagnose, treat, or prevent disease or other abnormal conditions.
- **Equipment:** Fixed and portable equipment used for diagnosis, treatment, monitoring and direct care of individuals
- **Access:** Acquisition of supplies, pharmaceuticals, and equipment from various sources via procurement, stockpiles, caches, and other sources.
- **Procurement:** To be defined.
- **Storage:** The task of appropriately maintaining a supply of pharmaceuticals, supplies, and equipment that is readily accessible.
- **Distribution:** To be defined.

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### Chain of Command / Communication Structure

Authority / Key Roles and Responsibilities – The acquisition of materials is governed by SEMS. From a supplies, pharmaceuticals, and equipment perspective, the roles of those who determine *where* the needed materials can be accessed and *when* the next organization level needs to be utilized will be identified.

Field → Local → Operational Area → Regional → State

From each level of the Standardized Emergency Management System (SEMS) structure (see the five SEMS organizational levels above) the lead and supporting roles will be identified so those accessing the system can understand the chain of command so the proper process is followed.

The Medical Health Operations Area Coordinator (MHOAC) is highlighted in this section because their role is vital in ensuring the proper chain of command for the proper access and distribution of supplies, pharmaceuticals, and equipment. Currently this role is responsible for coordinating all mutual aid. Because of the importance of this position, the following are recommendations:

1. A requirement for this role to be pre-identified.
2. A requirement for this role to have standardized training across California.

Triggers – Key points when the next organizational level of the SEMS structure is engaged relating to Supplies, Pharmaceuticals, and Equipment is engaged.

### Pharmaceuticals at the Field, Local, Operational Area and Regional Level

The proper types and quantities of pharmaceuticals are essential to be able to handle a surge.

Recommendations will be made on the specific pharmaceutical types that should be on hand at an existing facility or that should be part of a stockpile or cache. These specific recommendations will be based on potential anticipated emergency situations that include biological, radiological, and chemical disasters. This includes antidotes for radiological and chemical situations, Vaccines, and Anthrax treatment (this is not a comprehensive list). The list will organize by columns including: strength, route of administration, package size, wholesaler item #, of patients expected to be treated, doses needed per patient day, days of therapy required, total doses required, and # of packages to stock.

Every facility has a unique surge capacity and this needs to be taken into consideration when determining the quantity of pharmaceuticals that need to be on hand. Quantity calculation tools will be referenced for use to help state and regional planning, existing healthcare facilities and Alternate Care Sites (ACSs) to determine the appropriate amount of pharmaceuticals that are needed to handle surge capacity.

Also, an understanding of what pharmaceuticals are kept at the local level and what is kept at the state level need to be identified so existing healthcare facilities and licensed dispensing sites are aware of all potential resources in the case of a surge.

### Supplies / Equipment at the Field, Local, Operational Area and Regional Level

Recommendations will be made on the specific types of supplies that should be on hand at an existing facility or that should be part of a stockpile or cache. These specific recommendations will be based on potential anticipated emergency situations that include biological, radiological, and chemical disasters. The lists will identify types of supplies and equipment (e.g. bandages, dressings, surgical supplies, orthopedic supplies, airway management supplies, infection control supplies, Personal

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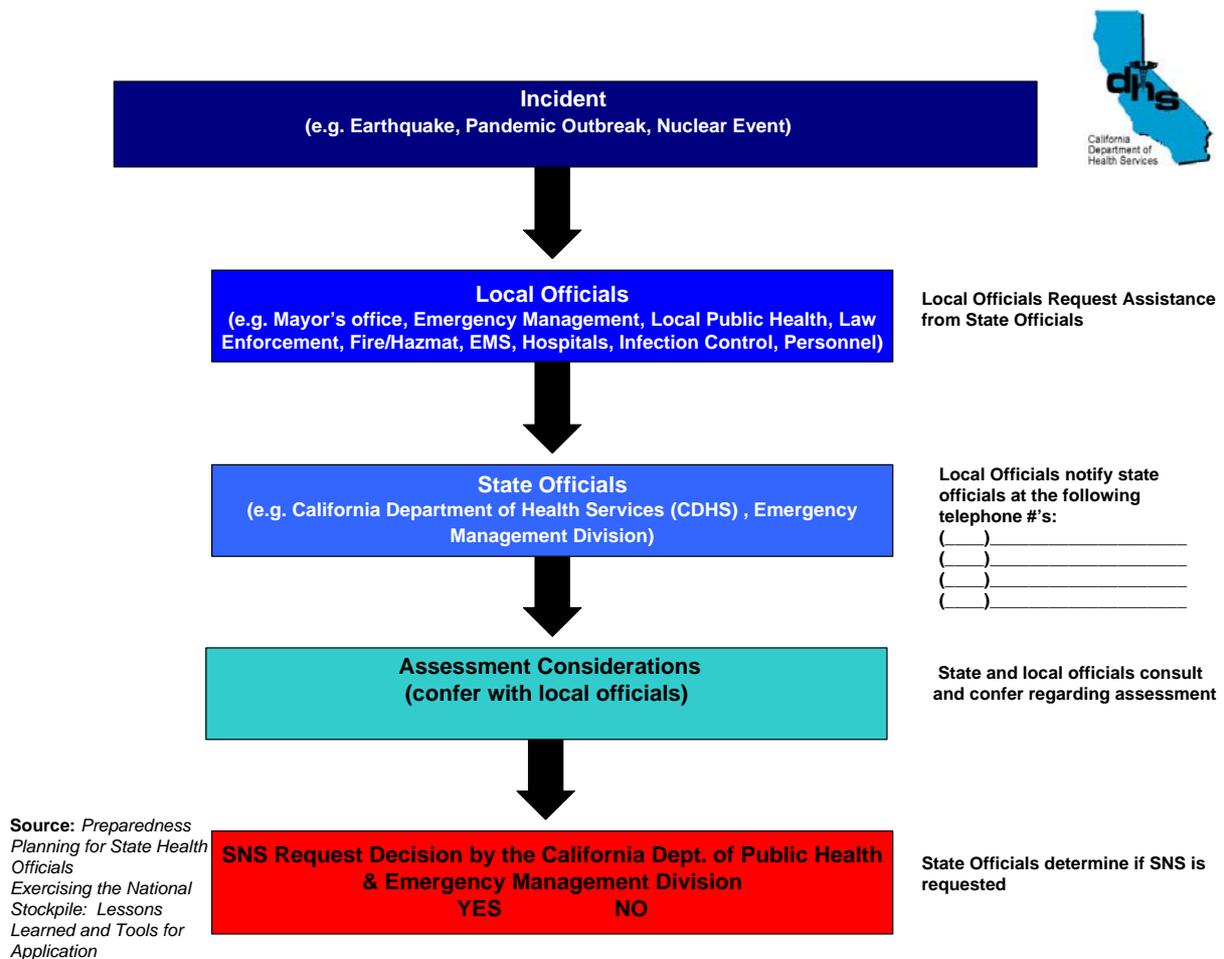
Protective Equipment (PPE). Also the lists will be organized by columns that indicate # of patients expected, package size, # supplies or equipment per box, and # of boxes

As mentioned above, every facility has a unique surge capacity and this needs to be taken into consideration when determining the quantity of supplies and equipment that is needed to be on hand. Quantity calculation tools will be referenced for use to help state and regional planning, existing healthcare facilities and Alternate Care Sites (ACSs) to determine the appropriate amount of supplies and equipment that are needed to handle surge capacity.

### Supplies, Pharmaceuticals, and Equipment at the State and Federal Level

Once the need for supplies, pharmaceuticals, and equipment has reached the state level there is a defined process by the Centers for Disease Control and Prevention (CDC) that identify the appropriate steps to access the Strategic National Stockpile (SNS) and the Pharmaceutical National Stockpile (PNS). The detailed information can be found on the CCDC website at <http://www.bt.cdc.gov/stockpile/index.asp>

To clearly identify the process, a process flow chart will depict the procedure and order of events with websites and telephone numbers for easy point of contact. Tools currently in development include a decision process on accessing the SNS. A sample is below.



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### Storage and Staging of Supplies, Pharmaceuticals and Equipment

Tools currently in development include:

Pharmaceutical Storage Considerations for temperature, labeling, and security

Supplies and Equipment Storage Considerations including temperature, cost, space requirements, maintenance of specific equipment, supplier/vendor requirements, and inventory management.

Supplies, Pharmaceuticals and Equipment Staging: Suggested models for efficient access to needed supplies, pharmaceuticals, equipment in a pre-arranged fashion (e.g. Point of Dispensing Trailers [POD], recommended mobile field supply, pharmaceutical, and equipment set up)

Deployment / Distribution of Supplies, Pharmaceuticals, and Equipment – This area of the Supply Chain Management section is currently being updated with appropriate materials.