

Introduction

The healthcare supply chain is complex. It supports patient care on a daily basis by producing and delivering medications as well as products ranging from gloves and gowns to diagnostics, to pharmaceuticals and biomedical equipment, to medical and surgical supplies, and blood products.

Around the world, the healthcare supply chain is confronted with countless challenges every day. Production and delivery issues can cause shortages on a routine basis. During disasters or other catastrophic events, the healthcare supply chain can experience multiple distinct strains depending on the nature of the event and the impact on manufacturing, warehousing, or delivery infrastructure.

The commercial supply chain has a lot of experience and knowledge on how to navigate and mitigate some of these challenges. Establishing opportunities for the public and private sector to learn from each other for improved public health response and recovery in the future benefits everyone.

Purpose: This document provides an overview of the emergency planning and response considerations for healthcare supply chain owners, operators, and end users, as well as insights for healthcare coalitions (HCCs) working with healthcare supply chain partners on preparedness, response, and recovery. It is not intended to be a comprehensive listing but aims to capture **key changes** during serious or catastrophic events, compared to steady-state supply chain operations, as well as planning and response contingencies.



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Healthcare Supply Chain Operations

The healthcare supply chain involves the flow of numerous product types from manufacturer to patient and requires the participation of various stakeholders who work in concert to achieve the goal of meeting patient care needs.

Healthcare supply chain stakeholders include:

- Manufacturers
- Distributors
- Providers
- Patients
- Healthcare coalitions
- Federal programs¹

Descriptions of each stakeholder, their roles in the supply chain, and a few key vulnerabilities to plan for are included on the next few pages.

Under steady-state conditions, the complex processes that make up the supply chain are nearly invisible due to steady-state production and delivery of healthcare products. Healthcare supply chain stakeholders adhere to their daily roles and standard operating procedures.

The following infographic displays the normal operations and activities of healthcare supply chain stakeholders and key vulnerabilities for each stakeholder.

Although the healthcare supply chain is largely owned and operated by the private sector, several federal offices and agencies have a role in supporting the continuity of supply chain operations during emergencies and events that could impact healthcare operations and have established partnerships with key components of the supply chain in order to accomplish this. Appendix C outlines some of the key federal partners roles "at-a-glance" that are consistent with the purpose of this particular document.



Healthcare Supply Chain Under Normal Operations



Manufacturers

Plants for production and research, labs, biologists, and vaccinologists

Role in Supply Chain

- Research and develop new products
- Create and manufacture medical products (branded and generic pharmaceuticals, medical, and surgical supplies)
- Monitor and respond to shortages
- Produce disposable and durable products, medications, electrolytes, dialysis products, sterilization and medical gases, and IV fluids

Key Vulnerabilities:

- Raw materials/ production disruption
- Spike in demand outpaces production
- Limited number of vendors for needed products
- Damage to factory/ utilities
- Overseas production vulnerability



Distributors

Wholesale distributors and logistic partners (including third-party logistics)

Role in Supply Chain

- Deliver medicines and supplies from manufacturers to providers and healthcare facilities
- 92% of prescription drug sales are handled by distributors
- Screen suppliers to reduce the risk of fraudulent or unsafe product entering the market.

Key Vulnerabilities:

- Access and re-entry to disaster-affected facilities/areas
- Secure transportation need
- Spikes in customer orders
- Road damage/ infrastructure damage
- Product shortage(s)
- Impacts to labor force and transportation



Providers

Hospitals, pharmacies, emergency medical services agencies, dialysis centers, urgent care facilities, assisted living facilities, and long-term care facilities

Role in Supply Chain

- Receive medicines and products from distributors
- Prescribe and dispense medicines and products to patients
- Use products in hospitals/healthcare facilities



Patients

Consumers, patients, and communities

Role in Supply Chain

- Unique medical needs that require specific products
- Influence the demand for medicines and products
- Care for and use products according to directions/labeling (e.g., refrigerate)

Key Vulnerabilities:

- Lack of redundancy in vendors and suppliers
- Limited substitutes
- Product shortages; just-in-time inventory; medical surge
- Pharmacy/healthcare infrastructure impacts
- Inadequate supplies for demand; hoarding

Key Vulnerabilities:

- Difficulty finding options to meet patient's needs
- Insurance issues
- Cost/limited ability to stockpile medicines and medical products
- Utilities failures
 Access delivery/
 transportation issues



The Healthcare Coalition Role in Supply Chain Operations

Healthcare coalitions (HCCs) play a key role linking public sector response agencies, including emergency management agencies and public health departments, and private healthcare facilities that serve as points of service. HCCs are key stakeholders and while not direct components of the supply chain, they may be able to act as a coordination point between multiple vendors/suppliers and healthcare facilities to address supply disruptions. During normal operations, HCCs play an important role in working with members on supply chain readiness and response planning.

By serving as a coordination and information-sharing hub, HCCs can: encourage best practices in communicating and engaging with supply chain components, standardize and provide guidance on activities that impact supply chain operations during emergency events, and provide opportunities for supply chain components and coalition members to train and exercise with one another. HCCs can also play a role in helping healthcare facilities share information and coordinate strategies in their area to cope with specific supply shortages (e.g., medication, equipment, dialysis solutions).

HCCs serve as a unifier of healthcare preparedness and response activities across a community – working to link the disaster preparedness and response plans to provide care and protect public health in their area. All HCCs should be able to act as information-sharing hubs for distributors and providers and have the ability to share product and delivery information and strategy. For HCCs with a broader role in emergency response, primary activities may include tracking impediments to product delivery, resource request management and brokering, and monitoring operational status and needs of healthcare facilities within the HCC.

Supply Chain Hazards, Threats, and Vulnerabilities

The healthcare supply chain is dependent on many variables including raw material availability, machinery and parts, workforce, standards compliance, delivery methods, contracts and regulatory requirements, and underlying critical infrastructure systems such as power, telecommunications systems, and transportation (including vehicle and roadway, airport, railroad, and port components). When one element is compromised there can be cascading effects up and down the supply chain. Disruptions to systems can thus be caused by factors *internal* to the supply chain or by *external* hazards, underlying vulnerabilities, and threats that can directly impact every level of the supply chain. These external factors are the focus of this document. Examples include the following:

- Natural disasters While hazards vary from region to region, natural disasters have the potential to disrupt the healthcare supply chain in all parts of the world. Thus, a natural disaster in a foreign country may have profound impact on domestic medical supplies. Common domestic hazards include hurricanes, snowstorms, tornadoes, flooding, wildfires, and earthquakes. All phases and components of the chain may be affected regardless of any advance notice and may require assistance with response and recovery efforts.
- **Human-caused disasters** These hazards also vary and can include cyber-attacks, acts of terrorism, and unintentional events like an oil spill, damage or impacts to goods during delivery accidents, or even unforeseen equipment breakdown.
- **Public health threats** Biological threats can impact the healthcare supply chain by creating both dramatically increased and sustained demand for products, especially medical supplies. These events include disease outbreaks (of both commonly occurring and emerging diseases) and biological attacks.



Supply chain implications for public health-centric events differ from those of a natural hazard in that public sector partners – via public health officials (state, local, and federal, including the Strategic National Stockpile [SNS]) – can play a significant role in supply chain operations through activation of programs, language included in emergency declarations, Emergency Use Authorizations (EUA), public messaging, and more. Vendors for commonly needed products during these events, including vaccines and personal protective equipment (PPE), are often limited. Depending on the nature of the event, demand for these products can far exceed production capacity.

Supply Chain Vignette: Federal Response

At the height of the response to the COVID-19 pandemic, FEMA's Supply Chain Task Force worked with private sector healthcare distributors to establish Project Airbridge. The initiative helped address shortages of PPE by flying products from overseas to the US, instead of the more traditional movement by sea. Throughout Project Airbridge, FEMA, working with ASPR and private sector manufacturers and distributors, expedited delivery of millions of N-95 respirators, face shields, gloves, and other protective equipment to the US.

Steady-State Supply Chain Challenges

To meet patient care demands, all stakeholders should focus on mitigating the supply chain hazards, threats, and vulnerabilities unique to their area while identifying key actions that will enhance resilience during incidents. Some impacts can be greatly reduced through integrated mitigation and planning. Working with providers in the community and distributors to forecast ordering for different scenarios, including emergencies, can help set use and delivery expectations and plans and highlight areas where back up options are required.

Usual system vulnerabilities (upstream and downstream) may include:

- Industrial and personnel Work stoppages, fluctuating transportation costs or fuel supply issues, geopolitical events, sabotage, market forces, and technological failures may have negative effects impacts on components of the supply chain, especially those companies responsible for processing and manufacturing.
- Operational These can include production or supply problems such as lack of raw materials, lack of packaging materials, lack of machine parts, regulatory actions (including product recalls), compressed manufacturing timeframes, product liability challenges, just-in-time ordering processes, sterility issues, contamination issues, disparate data systems, product cycles (obsolescence), and data silos between suppliers and providers.
- Just-in-case or low unit of measure programs Healthcare providers often rely on these programs from their distributors. These programs keep costs down for
 providers and allow them to reduce labor costs, time, and space required to stock and rotate medical products. While these programs are efficient, they can also lead
 to fragile supply-demand relationships, especially during emergencies. For example, Region V for Kids conducted an assessment to identify changes made to their
 supply chain resilience plans during the COVID-19 pandemic.
 - » Just-in-time (JIT) inventory delivery means distributors are servicing provider customers almost daily in order to keep minimal stock (or "par" levels) at the facility.
 - » In low-unit-of-measure (LUM) programs, distributors are the central source of product for facilities and will deliver to the specific departments on demand. In these programs, distributors "break down" product to the "each." (The "each" is the unit that is used on the patient. For example, distributors may take a box of 100 individually packaged items, break it down, and deliver 5.)



- » Hospitals relying on JIT and LUM strategies can be vulnerable to both increased demand for supplies due to patient surges of patients and/or delayed delivery as a result of the effect of the disaster on distributors. The <u>Disaster Available Supplies in Hospitals (DASH) tool</u> can help hospitals determine what materials they should have immediately available to address the needs of infectious, trauma, and burn emergencies.
- Consumer or provider brand (or product) preference for usual medications, equipment, or consumer distrust of novel medications/ vaccines.

Pre-Event, Response, and Recovery Considerations

The following sections provide pre-event, response, and recovery considerations for various components of the healthcare supply chain. High-level considerations for HCCs are captured at the end of each section and in a separate table in Appendix A.

Supply Chain Vignette: Collaboration to Ease Drug Shortages

Manufacturers, distributors, group purchasing organizations (GPOs), and providers worked together to reduce the impact of the recent intravenous (IV) solution shortage. This shortage added costs and sometimes necessitated a change in site of care. In some cases, patients had to stay in the hospital where IV solutions were more likely to be available, rather than being transferred to less-costly home care settings. Through ongoing collaboration, suppliers and their clinical clients were able to ensure that available product was sent where it was needed most. Providers also found ways to make substitutions when necessary and identified ways to reduce product waste such as eliminating the use of IV bags in kits if they were not essential.

— HIDA, Supply Chain Collaborative Newsletter (June 2019)



Manufacturers

Manufacturers create products – including pharmaceuticals, medical, and surgical supplies – using raw materials on-site in manufacturing plants and labs. As a part of the manufacturing process, these companies identify and develop needed products, determine quantities necessary to meet demand, acquire raw materials, conduct safety trials, and obtain regulatory approvals as required, and then make and package products for distribution. Manufacturing is a diverse and complex discipline, and the field is made up of countless different stakeholders, including brand and generic pharmaceutical manufacturers, medical supply and device manufacturers, and scores of others. International sources of raw materials and manufacturing sites are common. The following considerations and mitigation and response strategies capture high-level themes common across the different types of manufacturers.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Identify hazards, vulnerabilities, and threats – In particular, events that could result in potential shortages in critical supplies (e.g., PPE, medications, medical devices) or damage to a production facility. Raw materials disruptions – A variety of events, including natural hazards, can disrupt manufacturer access to quality raw materials. Production disruptions – These can include small-scale disruptions, such as a facility fire or machine breakdown, and larger-scale disruptions, such as a natural disaster in the area. This can also be due to staffing shortages after a disaster, work stoppage actions, or during an epidemic or pandemic. Product shortages – Shortages in production can occur for a variety of reasons – availability of raw materials, demand outweighing supply, and more. Anticipate common supply needs – Sustained demand for select products is common during disease outbreaks. For example, during the H1N1 outbreak of 2009 and COVID-19 pandemic, demand for PPE, including N95 respirators, increased drastically. 	 Use the ASPR TRACIE <u>Disaster Available Supplies in Hospitals (DASH) Tool</u> to estimate supplies needed immediately after an incident. Design business continuity and disaster recovery plans around hazards, vulnerabilities, and threats identified in hazard vulnerability analysis (HVAs) and risk assessments. Ensure redundant production capacity or alternate vendors. Ensure business continuity plans clearly identify alternate materials sources and delivery methods and routes based on predicted hazards when available. In addition, develop plans for redundant production capabilities (e.g., identification of plants and facilities that can scale production when needed). Comply with U.S. Food and Drug Administration (FDA) requirements for product shortage notification. Verified information on shortages is publicly available on the FDA website. Forecast product demand using historical events (e.g., past flu seasons) and reviewing/revising formularies with distributors and providers. Also determine when products with low production/use might be in high demand if primary products in the marketplace are in shortage.



Stage	Considerations	Mitigation and Response Strategies
Response	 Feasibility of surge production – Depending on the event, rapid surges in production may be required. Damage assessment – Depending on the event, manufacturing may be compromised due to direct impact on the plant, loss of utilities, or impaired transportation. Determining the damage, systems affected, and assistance needed is critical to rapidly restore services. 	 Develop business continuity plans that identify and describe means for scaling production, such as reallocating material use and shifting production schedules for products with less demand, shift/workforce changes, raw materials available, machinery, scheduling, and re-tooling. Identify other vendors for same/substitute product; ensure ability to coordinate with and refer to in an emergency. For public health and natural hazard events, manufacturers can use models and experiences from previous events to try to anticipate demand, but production timelines and capacity can limit flexibility to increase production. Expedite approvals from the FDA to import approved products from abroad. Obtain assistance through insurance providers, local, state, and federal emergency management to restore utilities and essential services or other assistance needed to resume production. Work with emergency management to help communicate what the site produces and the consequences of interrupted production prior to an event and during the response phase.
Recovery	 Resume normal operations and, if needed, repair damage. Assess the impact of the event to staff, products, etc. Communicate resumption of normal allocation/delivery/activities. 	 Coordinate with distributors to resume normal delivery. Coordinate, as appropriate, with partners on product availability if event caused a shortage.

Coalitions and Manufacturing

Manufacturing occurs "upstream" in the supply chain. Given HCCs' key role in preparedness, response, and recovery coordination, which occurs further "downstream" in the supply chain, it is not common for HCCs to engage directly with manufacturers. HCCs can – and should – keep current and informed on significant impacts to manufacturing capabilities, such as drug or PPE shortages. HCCs should consider the need to share information and strategies for addressing the shortage between providers in their HCCs as well as potentially coordinate information exchange between distributors and providers.



Distributors

Distributors and logistics partners, including third-party logistics providers, acquire medical supplies from manufacturers and deliver them to providers and healthcare facilities. As part of this complex process, they may repackage, re-label, and ensure special handling for products, such as cold chain products requiring climate-controlled environments. A pharmaceutical distributor is more often referred to as "wholesaler," whereas in the medical product supply chain, the term "distributor" is more often used. For purposes of this document, the term "distributor" is used throughout for consistency and clarity.

It is important to note that the primary pharmaceutical distributor for a healthcare facility will likely be different than the primary medical product distributor for the facility. Additionally, many distributors have a primary healthcare provider market, which means the primary distributor for the local hospital may not be the same as the one providing the same supplies for the nearby nursing home. The medical product distribution center footprint includes over 500 distribution centers across the country with over 76 million sq feet of warehouse space.

Providers have primary distributors for medical products and pharmaceuticals. However, they often have secondary distributors and specialty distributors that may focus on specific surgical procedures or equipment. It is important to understand those specialty products that are only available from a single source.

The pharmaceutical supply chain has three large national/multinational distribution companies that control 90% of the market. The companies, known as the "Big 3," are McKesson, AmerisourceBergen, and Cardinal Health.² There are also several regional companies that may be significant partners, especially in smaller, more rural communities.

The medical product supply chain is more varied with large national companies and regional companies for healthcare facility types or service lines (e.g., homecare). These distributors often have over 5,000 types of products on hand and depending on the product have approximately 20 to 30 days of inventory that reflects normal customer usage/consumption patterns.³ Most urban healthcare centers are within 50 miles of a distribution center and most distributors can deliver within 24 hours of an order.

Pharmaceutical and medical product supply chains may utilize the services of third-party logistic providers (3PLs) such as FedEx, United Parcel Service (UPS), and others depending on their business and service model. 3PLs can minimize costs and allow for local distribution through local companies familiar with the community. 3PLs can also enable more frequent deliveries from regional or local distribution centers (some facilities receive up to 4 deliveries per day.)

Strategic National Stockpile (SNS)

The <u>SNS</u> relies on partnerships with commercial distributors as these companies are already integrated into the market and can effectively move assets from the SNS to <u>medical countermeasures (MCM)</u> dispensing sites with established modes of transport, transportation routes, and accompanying security.

Allocation

When there is a product shortage, distributors may institute allocation practices. Allocation is a contractual obligation between the supplier and distributor that ensures customers get some amount of product based on a percentage of their historical purchasing. It does not take into account surge needs during a public health event which may exacerbate existing product shortages. Distributors commonly place regular customers on allocation during shortages and decline orders from new customers during that time.

³ Health Industry Distributors Association (2018). Health Systems Rely on Distribution. Retrieved from: https://www.hida.org/distribution/resources/infographics/Health-Systems-Rely-On-Distribution.aspx



² AHealthcare Distribution Alliance (2021). 92nd Edition HDA Factbook: The Facts, Figures, and Trends in Healthcare. Retrieved from: https://www.hda.org/resources/92nd-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare

Supply Chain Vignette: Unconventional Delivery Methods

In preparation for Hurricanes Harvey and Irma in 2017, AmerisourceBergen staged healthcare supplies to support at-risk areas and used many unconventional methods to deliver them directly to patients and caregivers after the storms. For example, when many local couriers lost their vehicles due to flooding, AmerisourceBergen responded by sourcing rental trucks for them from other states to continue making their deliveries. The couriers communicated via two-way radios with AmerisourceBergen scout drivers to find the best routes to complete deliveries to hospitals, pharmacies, and clinics. AmerisourceBergen also used duck boats and helicopters to deliver supplies directly to clients.

— Healthcare Ready, <u>Heroes of the Supply Chain: Manufactures and Distributors</u>.

Third-party Logistics Providers (3PLs)

3PLs range from FedEx and other large postal service providers to smaller, regionally-or locally based companies. 3PLs frequently use unlabeled or unmarked trucks for deliveries. 3PLs play a critical role in "last mile" delivery.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Determine and communicate product shortages – When caching is not an option, or when stockpiles are depleted, distributors work with suppliers and customers to communicate availability of product(s) and viable alternatives/substitutions. Communicating to customers – Distributors often offer to provide inventory consultation to their customers, gauging their needs and allowing them to place advance orders to prepare for an event. Pre-positioning supplies – Increasing product inventory in warehouses and onsite at customer facilities (par levels), when possible, is an important pre-event activity distributors and facilities should work together to execute. These may be permanent increases (e.g., for mass casualty events) or temporary (e.g., in anticipation of a hurricane or blizzard). Distributors will often pre-position trucks with supplies along highways to get into the disaster zone promptly after an event (e.g., nearby exits or in rest stops to be able to make local deliveries once roads re-open). 	 Develop critical supply lists based on potential events. The Disaster Available Supplies in Hospitals (DASH) Tool can be helpful to generate initial lists. Work with HCCs and facilities to create distributor or facility-based caches or "push" lists to be delivered in case a disaster strikes and a request is received from the facility to activate their list. In some cases, distributors are included in healthcare facility disaster notifications and will automatically activate the distribution. Agree to acceptable alternatives and substitutions ahead of time. Understand communications and establish alternate forms of communication if primary ordering systems are down. Work with HCCs and providers to ensure understanding of specific delivery timeframes and vulnerabilities (e.g., if flooding closes a specific bridge, does this compromise delivery from a distributor, or does the distributor potentially need access to high clearance vehicles?)



Stage	Considerations	Mitigation and Response Strategies
	Anticipating common supply needs – Similar to manufacturers, distributors work to anticipate common supply needs and stock warehouses and customers accordingly. A spike in customer orders can be due to actual demand, anticipated demand, or multiple orders being placed with multiple vendors by the same entity in the hopes that one will get filled. Access and Re-entry – Facility access may be a challenge for third-party logistics providers transporting supplies in unmarked vehicles that may need to cross police lines. After a criminal event such as a terrorist attack, additional precautions would need to be taken to verify the origin of delivery vehicles.	 Work with all stakeholders to understand true demand during an event. Providers placing multiple excessive orders with multiple distributors only exacerbates shortages and places additional strain on the supply chain. Coordinate through Business Emergency Operations Centers (BEOCs), when applicable and available, and with jurisdictional Emergency Operations Centers (EOC) as required. Develop priorities specific to community incidents that will result in common supply needs (e.g., earthquakes, hurricanes, pandemic, Ebola/VHF cases, mass violence incident based on geography and patient population) Annual influenza season or COVID-19 surges can be used as models to understand usage/consumption. Collaborate with state and local authorities and private sector partners to develop a local program for pre-registration of supplier companies and personnel (include 3PLs, law enforcement, and other key stakeholders). Send delivery drivers letters of access on company letterhead or special "codes" or placards issued by law enforcement to expedite deliveries. Identify distributor as a key (known) vendor/partner. Develop coalition member agreements for storage and distribution of critical supplies as required. May include Disaster Response Centers where a large facility serves as the hub for storage and distribution to smaller facilities within a region. Coordinate with security providers to ensure suppliers are vetted and can access a facility after a criminal incident. Ensure distributors have a means of communicating with coalition and emergency management and understand how they receive assistance during a disaster that affects distributor operations.



Stage	Considerations	Mitigation and Response Strategies
Response	 Alternative ordering – During a response, customers often place larger orders than usual. In these instances, distributors will confirm an order that is out of the "norm" before processing. Feasibility of Surge Deliveries – Depending on the event, expedited deliveries may be requested, as well as more frequent deliveries. Considerations for these surge deliveries include those noted below in this section, as well as staff and product availability. Alternative transportation and routes – Identify navigable routes for delivery vehicles, and alternative delivery sites, as required. Securely transport deliveries – Distributors may work closely with law enforcement to receive assistance (routes, escorts). This is especially important during events when road access is compromised. 	 Create a streamlined communication process for efficient ordering, confirmation, and work to pre-populate orders, including an alternate communications plan. Ensure that the facility is not placing duplicate orders for the same items with multiple vendors (a common situation that leads to significant miscalculation of actual need by distributors and manufacturers). Provide customers with specific allocation limit amounts for operational planning at healthcare delivery sites. Work with manufacturers and parent (corporate) healthcare systems to anticipate needs and move additional materials to the distribution centers ahead of the event or requests. Be prepared to switch to alternative products when necessary and determine how deliveries will be prioritized if requests exceed inventory. Ensure providers understand how allocation and prioritization will work. Climate-control technologies (and awareness of temperature tolerance of materials in transport) in delivery vehicles should be sufficient for prolonged delays in transport. Source or create processes for obtaining specialty vehicles that may be needed (such as high-water vehicles, boats, and snowmobiles) as well as additional standard vehicles/drivers to meet increased delivery demands. Establish relationships and contacts with local emergency management – these may be helpful in restoring services and access to the distribution center, securing specialized vehicles, and allowing access to secure or restricted areas as well as obtaining current information on road status and hazards. Emergency management often does not have awareness of the distributors in their area and the key role they play in disaster response.



Stage	Considerations	Mitigation and Response Strategies
Recovery	 Resume normal operations and communicate the resumption of normal allocation/delivery/activities. Coordinate with manufacturers and providers as needed on product substitutions (which ideally should be identified and agreed to prior to an event) and transition back to primary product when available. 	 Coordinate with local authorities on primary delivery route restoration if event caused the need for alternative routes. Adjust delivery schedules as needed for facilities. Communicate transition plan and timing back to primary products and normal supply and delivery process.
	 Distributors coordinate on substitutions of the same medical product (e.g., substituting the same generic medicine from a different manufacturer.) They are not involved in decisions regarding substitutions when there is a medical and patient care consideration. 	

Coalitions and Distributors

The plans and activities of distributors and HCCs can – and often do – directly impact one another. Accordingly, robust information sharing, collaboration, and partnerships between distributors and HCCs contribute to a strong preparedness, response, and recovery posture for a region. Integrating distributors into ESF-8 and regular engagement through coalition meetings, trainings and exercises will highlight the importance of these relationships and also identify key contacts that can be called upon during a response. Distributors should have a clear understanding of the role the local coalition plays during a disaster and how the coalition and distributor interface with the formal emergency management response structure in the jurisdiction so that information and resource requests can be managed according to local policy (including how to connect with local and state emergency management). During shortages, HCCs can play a key role integrating clinical options (from the provider level) and vendor options (from the distributor level) to define appropriate and consistent strategies.



Providers

Providers are a large and diverse group of facilities and professionals licensed to supply healthcare services and expertise, to include disbursing and dispensing medicines and products to patients. Key activities they undertake within the supply chain include submitting orders to distributors and providing data and information on healthcare services and needs that help identify shortages and potential distribution challenges. The considerations and mitigation and response strategies differ among provider groups considerably. The following table captures high-level considerations generally consistent across provider types but is not intended to be exhaustive.

Supply Chain Vignette: Serving Affected Communities

In May 2022, the Healthcare and Public Health Sector Partnership held a public-private coordination call to provide an update and best practices regarding the shortage of iodinated contrast media. The call included briefers from the HHS Supply Chain Logistics Operation Cell on the status of the supply as well as briefers from the American College of Radiology and major US healthcare systems. Through the call, stakeholders were able to share alternative sources for contrast material and learn best practices for reducing use of the material in standard operations and triaging, if needed.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Identify hazards, vulnerabilities, and threats – Focus on events that could significantly disrupt supply delivery or compromise current supplies (e.g., by damage or consumption) and those that are most likely in specific regions. Define triggers or thresholds for activation of emergency plans – Emergency plans should include policies and procedures for requesting supplies and managing disruptions in supply chains as well as authorities for procuring alternate supplies and for implementing rationing strategies. Define how subject matter experts will be used to inform rationing – Experts from the affected domains should be engaged to make recommendations on a step-wise approach to rationing scarce supplies. When available, regional and national recommendations should be adapted to facility use. Identify alternative mechanisms for ordering, receiving, and tracking supplies. 	 Develop emergency response and business continuity plans informed by HVAs and risk assessment tools. Based on your community and facility risks, use the DASH Tool to anticipate commonly needed medications and supplies and consider caching or increasing par levels of those supplies at the facility. Planning may include non-medical supplies such as cots and food or water. Consider "push" lists of commonly needed medications and supplies to replenish or augment facility stock that the distributor can have available and establish policies on when to request these. Scenario-based exercises should allow providers to identify thresholds for instituting substitution and conservation procedures and document the process through which this occurs. Exercises should be used to document and determine how these strategies and situational information are communicated to key partners including the coalition.



Stage Con	nsiderations	Mitigation and Response Strategies
•	Identify multiple delivery locations – Depending on the situation, distributors may make deliveries to individual healthcare facilities/ alternate care facilities or a central warehouse where items will be later redistributed. Stockpile non-medical product(s) – Not all supplies providers may need during an emergency are stocked in large quantities by suppliers (e.g., hazmat suits). These should be present onsite in adequate quantities to address expected scenarios. Define triggers and thresholds for changes to standards of care – While implementing crisis standards of care is a last resort, discussing and planning for a system and procedures for operating under these conditions is important, and can have implications on supply orders (e.g., implementing re-use of N95 masks). Work with key stakeholders to establish Memoranda of Understanding (MOUs) or Memoranda of Agreement (MOA) – MOU/MOAs between HCCs, providers, and other supply chain stakeholders can assist in managing expectations of additional support available during an emergency.	 Implement pilot programs and training to rapidly integrate new products into electronic health records and educate providers on labeling and concentration changes. The facility steady-state drug shortage processes may have applicability for developing disaster shortage policies. Maintain communications with distributors to understand shortages and delivery issues. Establish alternate communications plan with major distributors in case primary means fail. Establish an alternate distributors list for critical supplies as well as understand the location, transport time, and potential interruptions in delivery between the distributors and provider. Identify alternate methods and routes for deliveries based on predicted hazards. Determine the coalition's role in for planning, information sharing, indexing, and managing resource requests/brokering with distributors and other facilities/systems during an incident. Develop and test protocols and redundant communication channels with coalitions and emergency management agencies for reporting supply status and needs during incidents. When crisis standards of care are necessary, ensure a coalition-level plan for communicating the criteria and strategies to all stakeholders and determining timelines and product needs and availability with distributors. Providers should become established customers ahead of a disaster (not during) and maintain contacts with industries that manufacture supplies (e.g., orthopedic hardware) as required.



Stage	Considerations	Mitigation and Response Strategies
		 Request and review MOUs from sister facilities or coalition members have in place with supply chain components. For example, major chains and Federal facilities may receive designated "preferred status" through an MOU with supply chain components. This status helps these facilities to be prioritized during emergencies. Provide information to at-risk patients about planning for disasters including delivery interruption, medication access, and
		storage requirements.
Response	• Forecasting needs – Ability to provide care hinges on having needed supplies on-site and a plan for replenishment. Anticipating supply needs, and capacity for receiving and storing them, are key activities for responses (e.g., DASH Tool). Sharing forecasts with supply chain partners can greatly enhance their ability to support providers during a crisis.	Use models, especially those based on past events (e.g., recent catastrophic hurricanes, severe flu seasons) to help determine likely supply needs and quantities and proactively try to obtain them prior to shortage (also understand the potential to return items to the distributor) Description health data for the surrounding area are informed.
	Supply chain support activities – Providers should alter their	» Population health data for the surrounding area can inform forecasting efforts.
	practices as appropriate (ideally without compromising quality of care) to decrease demand and increase the safety of substituted supplies. Examples include revising downtime procedures and refrigeration prioritization.	Work with the coalition to communicate and share strategies with other facilities, including developing guidance for adapting to crisis conditions when required.
	Coordinate with public sector responders – Public health and medical sector (ESF-8) typically receives information about supply needs from a facility, and mainly engage with distributors after healthcare facilities report an expected lag in availability of a needed product.	Ensure a mechanism at the facility level for development of clinical recommendations for substitution, conservation, adaptation, re-use, and re-allocation of supplies to ensure consistency. Implement step-wise rationing proportional to the degree of shortage to provide the most effective services possible.
	Partnerships across relevant supply chains – Relationships with all components of the healthcare supply chain (e.g., linen and blood) and other sector supply chains (e.g., fuel and food) may be leveraged for ad hoc solutions.	Contribute to supply chain efficiencies during crises by conserving and using substitute medical and non-medical supplies (e.g., pharmaceuticals, blood products, fuel, medical gases, refrigeration).



Stage	Considerations	Mitigation and Response Strategies
	Mitigate or adjust to staff shortages – Staff absenteeism during events may occur, especially for downstream components (distributors, last mile, and healthcare facilities). This can be a challenge to maintaining healthcare operations during events, especially for healthcare facilities – including ancillary care.	 Maintain current ESF-8 contacts through trainings, exercises, and other methods. Activate mutual aid agreements within your healthcare coalition or with facilities not impacted by the hazard. Explore and look for options from parent or "sister" facilities for resources if usual methods are not an option or do not provide sufficient resources. Ensure disaster augmentation plans for pharmacy and supply personnel. Plan for workforce shortages including information for other providers to fill supply/warehouse/distribution roles and explore and engage with medical volunteer programs including the Medical Reserve Corps (MRC) and Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP). Ensure information sharing with patients regarding services provided, facility status, and any changes they should be aware of with pharmacy supplies and home delivery of medications and medical supplies (e.g., nutrition, oxygen).
Recovery	 Resume normal operations and communicate the resumption of normal allocation/delivery/activities with distributors and coalition partners. Communicate to patients and providers about resumption of normal activities/processes. Manage transition back to daily operations/usual products and practices. 	 Disseminate supply chain disruption situation reports to local, regional, and state health authorities as requested. Coordinate with distributors and others as needed on product substitutions and transitions back to primary product if event caused a shortage. Share information on sustained supply chain impacts. Work with distributors to resume normal operations, distribution volumes, and schedule.



Coalitions and Providers

As both key members and stakeholders of HCCs, providers drive coalition activities. HCCs play an important role in developing and disseminating information between their stakeholders (including emergency management) and with distributors, monitoring impact, and coordinating response activities during emergencies as per local ESF-8 plans. Providers look to HCCs for information sharing and standardization of activities, including those related to the supply chain such as substitution and conservation guidance. HCCs may also play a role in resource management and requests depending on the region. HCCs help prevent multiple providers from engaging multiple distributors about the same issues during emergencies and thereby can serve as a single point of contact between distributors and providers and can also engage emergency management if formal resource requests or community assets are needed. HCCs can use their After Action Reports (AARs) following exercises or events to highlight supply issues and encourage changes in policy and practice as part of corrective improvements.

- ASPR emPOWER
- ASPR TRACIE Disaster Available Supplies in Hospitals (DASH) Tool
- CDC Supply Chain Disaster Preparedness Manual
- Health Industry Distributors Association. <u>Lessons Learned</u>: Pandemics and Medical Supplies
- Health Industry Distributors Association. Role of Medical Products Distributors in Emergency Preparedness
- Healthcare Ready. How it Works: The Supply Chain
- Healthcare Ready. How it Works: The Supply Chain in Disasters and Disease Outbreaks
- Healthcare Ready. Partnering with the Pharmaceutical Supply Chain
- National Academies of Medicine / Institute of Medicine 2012. Crisis Standards of Care



Patients

Patients and their caregivers are the primary end-users in the supply chain and typically only engage with providers although certain materials (e.g., nutrition, home dialysis supplies) are sometimes directly delivered to patients by distributors. The diverse needs of patients – from acute care needs, to chronic conditions, to unique demands from different demographic groups like pediatric patients – contribute to the complexity of this aspect of the supply chain.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Understand insurer limitations on filling prescriptions – Generally, insurance plans prevent patients from obtaining a prescription refill before their current supply is depleted or close to it. During a declared disaster, a no refill order may be lifted. Identify and plan for critical healthcare equipment delivery and maintenance – An important preparedness activity for patients is to ensure access to their homes for deliveries of critical supplies such as durable medical equipment (DME) and oxygen, and also to ensure proper refrigeration (if needed) of temperature sensitive medical products. 	 "Refill too soon" overrides may be allowed through an emergency declaration or at the discretion of insurance plans during emergencies. These overrides can allow patients to receive a 30-day supply of prescription medicines in advance of a forecasted event. As this is not always the case, it is important for patients to be educated on this issue and know what options they have. Follow instructions on labels or patient instructions given by providers to help make sure medical supplies are properly administered and maintained by patients. Plan with distributors to ensure continued access during a disaster for home-delivered products and plan how the patient can communicate their new location to a distributor if the patient is forced to relocate during a disaster. Plan alternate source of refrigeration, if needed (e.g., portable cooler, locations that may have back-up power near the patient).
Response	 Disseminate information on open facilities and how to access them – Evacuated patients may not be familiar with or know of nearby open facilities. Knowledge of waivers and sources of information (e.g., insurance hotlines) – Coverage may change during an emergency due to waivers and other exemptions. 	 Plan with healthcare providers in advance of an event to identify back up facilities, particularly ones within the insurance network. Use locator services like Rx Open to identify open pharmacy facilities. Follow training and awareness campaigns and seek patient resources during emergencies. Consult with a medical provider in advance if possible if a medication shortage or difficulty accessing medication ensues. An alternate strategy or medication may be temporarily needed (e.g., going to a clinic to receive insulin versus storing it at home).



Stage	Considerations	Mitigation and Response Strategies
		Understand how health insurance benefits and restrictions may change during a disaster (e.g., in-network coverage changes)
Recovery	Transition care and services to a new or temporary facility.	 Develop continuity of care plans with care teams, including primary care providers, pharmacists, and insurance providers. Understand timeline for restoration of services / deliveries. Resume usual medications and schedules. Plan for deliveries and supply chain needs if temporary healthcare facilities are used or patients relocated.

Coalitions and Patients

Though HCCs do not connect directly with patients, they may help coordinate risk communication to the community and development of consistent information for patients that can be provided through an emergency management Joint Information System. Further, HCCs may have a role with coordinating medical support of shelter and relocation activities that can require provider and distributor solutions to problems of delivery and maintenance of products.

- CDC: <u>Prepare Your Health</u>
- Healthcare Ready: <u>Healthcare Preparedness Tips for Natural Disasters and Outbreaks.</u>
- Ready.gov
- RxOpen.org



Healthcare Coalitions

Healthcare coalitions (HCCs) serve as a unifier of healthcare preparedness, response, and recovery activities across a community – working to link the disaster partners and plans to provide care and protect public health in their area. All HCCs should be able to act as an information-sharing hub for distributors and providers, including product and delivery information and strategy sharing. For HCCs with a broader role in emergency response, activities may include tracking barriers to product delivery, resource request management and brokering, and monitoring operational status and needs of healthcare facilities within the HCC. HCCs also play a key role creating liaison between public sector response agencies, including emergency management agencies and public health departments, and private healthcare entities that serve as points of service.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Reconcile and align private sector member business continuity plans and public sector member emergency response plans – With diverse members, HCCs can help set emergency response priorities and translate resources, needs, and concerns across and between members. With healthcare owned and operated by the private sector but public sector agencies charged with responding, mediation and understanding before an event is essential. Foster and forge relationships with supply chain components – HCCs play an important role in establishing key external relationships and fostering collaboration and partnerships during steady state. Determine emergency protocols and procedures – HCCs can play a lead role in developing and disseminating guidance within their membership on how to conserve, substitute, adapt, re-use, and re-allocate supplies. Establish information-sharing protocols and reporting flow – HCCs should determine how information about impacts to healthcare services and supply alternatives will be shared throughout the coalition. (e.g., through Situation Reports, coordinating conference calls, and event dashboards). Include supply chain representatives, especially distributors, in coalition meetings and activities. 	 Use the ASPR TRACIE <u>DASH Tool</u> as a way to connect and work with HCC members to establish baseline supply assumptions in the event of an emergency. Build relationships through routine coalition interactions (e.g., inviting distributors to coalition meetings, trainings, and exercises). Understand and document the major distributors in the area including key product lines, location(s), points of contact, and means of delivery. This may include distribution points owned and operated by major healthcare systems. Understand the process for resource requests – when do healthcare facilities rely on their distributors, alternate distributors, and/or other facilities (in their system or in the coalition) or emergency management? What is the process for resource requests to the coalition/emergency management? This could include requests that need to come from the SNS, for example. Understand the role of the coalition in drug and supply shortages when emergency management is not activated (e.g., during steady state operations). Review agreements, protocols and procedures of nearby or more mature HCCs to identify components that may work for your coalition.



Stage	Considerations	Mitigation and Response Strategies
		Codify essential elements of information (EEIs) relevant to supply chain in emergency operations plans as well as roles and responsibilities for compiling and disseminating information through Situation Reports and other mechanisms.
		Ensure that the coalition role in response is understood by both distributors and providers and that the mechanisms for obtaining emergency management assistance are understood.
		Conduct trainings to build capacity and identify key coordination points across coalition members.
		Include supply chain objectives in community-wide exercises to improve engagement and understanding of key issues and solutions.
Response	Coordinate response activities across members – Including through coordination calls, development, and dissemination of	Establish coordination conference calls or use other information platforms to share information.
	Situation Reports, dashboard updates (if applicable), liaising with ESF-8 and emergency management partners. • Collect and aggregate EEIs from members and provide this data to local, state, and federal partners.	Establish communications with major distributors and share hazard/impact information relevant to supply deliveries and
		security concerns as well as anticipated needs.
	Create and share common strategies for scarce resource management among members.	 Monitor and/or manage response requests, determine allocations and delivery and other operations according to the coalition role in the jurisdiction.
	Broker or allocate resource requests (depending on the defined coalition role).	Coordinate guidance for local implementation of crisis recommendations during protracted events (in conjunction with state-level efforts and local subject matter experts).
		Share identified EEIs with supply chain partners (e.g., distributors, 3PLs) to establish information-sharing expectations and requests.



Stage	Considerations	Mitigation and Response Strategies
Recovery	Communicate transition from response to recovery – This might be signaled through emergency operation centers (EOCs) standing down and information sharing cadences slowing.	Ensure consistency of delivery/care across region – moving from crisis to contingency and then conventional status for materials use.
	 Facilitate resumption of normal supply delivery and clinical use. 	Monitor situation and share information until conventional delivery and supply use is attained.
	 After-action reports and identify lessons learned – Coordinate with stakeholders to identify opportunities for improvement. 	Share lessons learned with local, regional, and state health authorities.
	 Incorporate lessons learned – Integrating lessons learned and best practices into future supply chain integrity assessments as needed for HPP capability requirements. 	
	Replenish and re-assess any regional stockpiles that were depleted or damaged by the emergency	

Coalition Engagement during the COVID-19 Pandemic

In 2021, ASPR TRACIE conducted a multi-phased project to gather and analyze information about the COVID-19 response to identify success stories and better understand the technical assistance (TA) needs of HCCs to prepare for future all-hazards emergencies. Using quantitative and qualitative methods, ASPR TRACIE explored which HCC functions worked, which did not, and which should be emphasized for future responses. Figure X illustrates an excerpt of project observations, focusing on strengths, areas of opportunity, and challenges. Access the infographic and full report for more information.



OVERALL PROJECT OBSERVATIONS

Strengths

- » Identified information sharing as their most important function during the pandemic.
- » Brokered the acquisition and distribution of needed supplies.
- » Filled a crucial role in supporting less resourced members.
- » Drove consistency of repose polices in their communities.
- Played an important coordination role and supported unified command.
- » Leveraged strong relationships built through years of joint planning.
- Found ways to add value to the overall response in the communities they serve.

Areas of Opportunity

- » Explore promising practices related to MOCCs and provide guidance on their application to future emergencies.
- » Align CSC planning with state frameworks and shift focus from scarce resource allocation to supporting provider decision-making.
- » Define urban versus rural expectations for response roles.
- » Avoid "planning for the last disaster."

Challenges

- » Sustaining member engagement once the crisis ends.
- » Addressing immediate and long-term staffing concerns – both the resilience and availability of staff.
- » Clarifying local, state, and federal executive branch expectations of HCC roles.
- » Providing flexibility in how HCCs can achieve federal program requirements.

- ASPR. 2017-2022 Health Care Preparedness and Response Capabilities
- ASPR TRACIE Disaster Available Supplies in Hospitals (DASH) Tool
- ASPR TRACIE Healthcare Coalition Planning Tools
- ASPR TRACIE Healthcare Coalition Recovery Plan Template
- ASPR TRACIE Healthcare Coalition Resources
- CDC. Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health (updated 2019)
- FEMA. Supply Chain Resilience Guide
- ASPR TRACIE Partnering with the Healthcare Supply Chain to Improve Disaster Response. <u>Appendix B: Scenarios to Consider.</u>





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HIDA is the trade association representing medical products distributors. Since 1902, HIDA has provided leadership in the healthcare distribution industry. Membership in HIDA provides a wide range of resources and relationships that help companies perform profitably within today's complex healthcare supply chain. Special acknowledgement to **Linda Rouse O'Neill**.

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Appendix A: Supply Chain Integrity Self-Assessment - A Resource for Healthcare Coalitions

Introduction

Specific language from the 2019 ASPR Hospital Preparedness Program (HPP) Funding Opportunity Announcement (FOA) includes requirements for both recipients and healthcare coalitions (HCCs) to conduct a supply chain integrity assessment to evaluate equipment and supplies that will be in demand during emergencies and develop mitigation strategies to address potential shortfalls at the HCC level. The recipient must provide documentation that this assessment was conducted, along with corresponding mitigation strategies to ASPR. Specifically, the HCC "should examine its supply chain vulnerabilities by collaborating with manufacturers and distributors to determine access to critical supplies, amounts available in regional systems, and potential alternate delivery options in the case that access or infrastructure is compromised. The HCC should then collect and use this information to coordinate effectively within the region, in collaboration with the ESF-8 lead agency. The HCC should further collaborate with healthcare organization members and other stakeholders to develop joint understanding and strategies to address supply chain vulnerabilities."⁴

ASPR TRACIE was asked to develop a self-assessment checklist for HCCs to meet this capability requirement and assist them in examining the disaster readiness of their member organizations, with an emphasis on their individual supply chains. HCCs are not required to use this tool if they have an alternate means or method of meeting the HPP FOA requirements. There is not an expectation that individual supplies and their vulnerabilities are addressed. However, common supply and pharmacy needs (e.g., PPE, sterile supplies, commonly needed medications) can be found in the DASH Tool. These general strategies and conclusions should be documented along with local distributor capacity to meet facility needs. Documentation of any specific supply quantities or analysis is not required to fulfill the requirement. The goals that should be achieved and documented are:

- Promote engagement and relationships between supply chain and coalition partners.
- Understand the strengths and vulnerabilities of the supply chain in the coalition (and by extension, the recipient) area.
- Analyze, at the facility and coalition level, the general types of supplies that will be required in disasters likely to affect the area, the local distributors providing them, and strategies to assure those supplies are readily available for patients in need.
- Determine mitigation and potential response strategies for supply chain interruptions (e.g., caching materials, alternative delivery vehicles, pre-event delivery of supplies).

The following checklist is informed by the mitigation and response strategies noted within this document. The strategies are intended to provide a starting point. Each HCC will need to determine the priority risks for their communities and the key private sector healthcare supply chain partners to be engaged in collaboration. Facilitating these discussions in each HCC will likely lead to other mitigation strategies specific to their communities and population. Not all items in the assessment are applicable to all coalitions and some will be much more important than others depending upon geography, the number and type of distributors and healthcare facilities in the area, and local hazards. Finally, HCCs (and their members) must work with each jurisdiction's legislatively and legally defined ESF-8 structure to determine local expectations for



⁴ The 2017-2022 Healthcare Preparedness and Response Capabilities (Capability 3, Objective 3, Activity 1- Assess Supply Chain Integrity), Page 62.

medical supply request and fulfillment processes during disasters (e.g., in some cases, the medical sector is required to work with their vendors and other facilities until all possibilities are exhausted before involving emergency management).

Process

The checklist supports the previously listed goals and contains a variety of activities for the coalition to complete, divided into three sections:

- 1. Risk and Vulnerability Assessment
- 2. Coalition Supply Chain Partner Engagement
- 3. Coalition Planning

HCC leaders can use this tool as a basis for discussion between and among coalition members and regional supply chain partners. This assessment is designed to produce a general impression of the gaps to be addressed in order to bolster supply chain preparedness.

For each function, the activity should be assessed on a 0-5 scale⁵, based on the estimated level of effort required to attain adequate operational function:

- 5 No plan or asset currently exists
- 4 Inadequate plan or assets exist
- 3 Potentially adequate plans or assets exists, but have not been evaluated or tested, and/or are incomplete
- 2 Adequate plans or assets exist, but require minor modifications based on exercises, events, or other evaluation
- 1 No work remaining plans or assets have been tested in exercises and/or real-world events and currently require no further modification
- 0 Not applicable activity outside the scope of coalition responsibilities or capabilities.

This assessment may help coalitions determine priorities for supply chain contingency planning. Each activity identifies the primary supply chain components involved in executing or meeting the activity goal.

⁵ This scale is consistent with scales used in other ASPR TRACIE Resources such as HCC Influenza Pandemic Checklist and HCC Resource and Gap Analysis Tool.



1. Risk and Vulnerability Assessment

This set of activities is designed to help HCCs identify the sites and members within their coalition most vulnerable to supply chain disruptions. It also presents activities that can help increase awareness and understanding of supply chain operations and dependencies within the HCC as well as identify critical medication and supply gaps to address with distributors.

Activ	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
1.1	Identify or categorize impact and hazards using a hazard vulnerability assessment (HVA), jurisdictional risk assessment (JRA), and/or other tools.		Coalitions	
	 Consult the <u>Healthcare and Public Health Risk Identification</u> and <u>Site Criticality (RISC) Toolkit and other comparable</u> resources to determine healthcare facility criticality and vulnerability. 			
	 Document specific risks to the healthcare facilities / service providers that may result in their isolation / make access difficult. How long could these conditions last? (HCC members can provide this input for their respective facilities to the HCC for aggregation). 			
	 Document key community injury / illness scenarios that should be addressed in planning (e.g., penetrating trauma event with 25 casualties, 100 person chlorine exposure, or pandemic – also access Activity 1.6). 			
1.2	Share existing and developed risk assessment, vulnerability information, agreements, and contingency plans with neighboring coalitions, key stakeholders, and recipient.		Distributors; Providers; Coalitions; Recipient	
	 Consider reaching out to neighboring coalitions to jointly initiate discussions with regional and state supply chain partners 			



Activi	ties	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
1.3	Determine categories of critical medical product considerations for hospitals and other care sites, such as:		Distributors; Providers	
	 Likely surge demands and needs relative to par levels. (healthcare facilities should utilize the <u>DASH tool</u> to estimate appropriate supplies and quantities based on their hospital role in the community) 			
	 Other priority medical products (e.g., blood, sterile/ surgical, linen). 			
	 Available on-site supply, warehousing, or health system local/regional warehouses, facility or coalition-based caches of materials. 			
1.4	Identify distributors (including potential secondary distributors/ suppliers) in relevant domains by creating a matrix, list, or map of supply chain "footprints" within the coalition's jurisdiction. Can also include less commonly used local or regional vendors on the list. These may include:		Manufacturers; Distributors; Coalitions; Providers; Recipient	
	Blood banks			
	Medical gas suppliers			
	Fuel suppliers			
	Water suppliers			
	Emergency power suppliers			
	Telecommunications suppliers			
	 Transportation (e.g., buses, vans, tractor trailers – include high clearance, boat, and non-traditional transport where this may be needed) 			
	 Nutritional suppliers and food vendors 			
	Pharmaceutical wholesalers			



Activ	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
1.5	 Leasing entities for DME and biomedical equipment Vendors for disposable medical supplies Personal protective equipment (PPE) distributors and (potentially) manufacturers Hazardous waste removal services Linen services Discuss critical pharmaceutical supplies and their availability during emergencies in your region. Suggested sub-tasks to complete this activity are below: 		Providers; Coalitions	
	 Assess patient population needs and list critical medications (e.g., acute needs such as analgesia and sedation medications, or for chronic conditions such as diabetes, etc. that require medication – refer to the <u>Disaster Available Supplies in Hospitals (DASH) tool</u>). Assess public health impact of event on both general and vulnerable populations and pharmaceuticals that may be needed (e.g., bioterrorism, pandemic) including through SNS or private sources. Discuss potential demand increases with supply chain and options to meet the need for a variety of scenarios. 			
1.6	Discuss critical medical supplies and equipment and their availability during emergencies in your region to minimally include mass trauma, HAZMAT, pandemic, Ebola Virus Disease / Viral Hemorrhagic Fever and other special pathogens (based on region), and events that may isolate the facilities from distributors (e.g., hurricane, blizzard). Refer to the Disaster Available Supplies in Hospitals (DASH) tool.		Distributors; Providers; Coalitions	



Activi	ties	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
	 Suggested sub-tasks to complete this activity include: Assess patient population needs and identify any critical inpatient, outpatient, and durable medical equipment issues (e.g., acute needs such as airway, oxygen, ventilators, beds; chronic condition needs). Assess impact of public health event on populations with access and functional needs, and additional / alternate medical supplies that may be needed. Assess competing demands of public health efforts (e.g., mass vaccination) on local distributors and third-party logistics providers. 			
1.7	 Identify specialty supply considerations (e.g., decontamination, personal protective equipment, orthopedic hardware, pediatric, populations with access and functional needs). Should align with the events identified after conducting the risk assessment in Activity 1.1 (e.g., weather related, pandemic influenza, cyber, wildfires, utility outages, burn events). Communicate what events are a priority and the corresponding list of likely impacted pharmaceutical and medical product supplies / compromised suppliers as well as their associated mitigation/response strategies with supply chain partners. 		Distributors; Providers; Coalitions	

- ASPR. <u>RISC Toolkit</u>
- ASPR TRACIE Disaster Available Supplies in Hospitals (DASH) Tool
- ASPR TRACIE Topic Collection: Hazard Vulnerability/Risk Assessment



- ASPR TRACIE Topic Collection: Incident Management
- CDC. Supply Chain Disaster Preparedness Manual
- Kaiser Permanente. <u>Hazard Vulnerability Assessment Tool</u>
- Northern Utah Healthcare Coalition. Resource Management and Sharing Template

2. Supply Chain Partner Engagement

This set of activities is designed to assist coalitions in assessing the current state of supply chain relationships (including ensuring valid contact information) and vulnerabilities (including understanding normal versus emergency response contacts and operating procedures) in concert with distributors (and manufacturers as appropriate).

Activ	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
2.1	Gather and record contact information for account managers and emergency response points of contact (POCs) along the supply chain for those distributors and vendors identified in Activity 1.4 , including information for a back-up contact, the location of the facility, potential vulnerabilities for delivery, and potential assistance needed. Private-public coordinators at emergency management agencies should also be listed. This can be done by the facility and coalition, depending on the coalition's role. • Update contact information prior to the known hazard (e.g., forecasted hurricane), hazard season, or at least annually. • Is the POC for planning/administration the same one as for emergencies or 24-hour contact? • Relationships are important, consider creating an educational document on the goals of the partnership and role of each stakeholder.		Distributors; Manufacturers; Providers; Coalitions	
2.2	Collect and share ESF-8 contact information at the state and local level (including state emergency management agency) with coalition members and relevant distributors.		Coalitions	



Activ	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
2.3	Coalitions should discuss and update supply plans and policies in consultation with healthcare facilities and emergency management to ensure current understanding of resources and potential issues/needs, at least annually (e.g., coalitions may work with facilities to provide an update to the coalition annually about any changes to vendors, on-site supplies, or other factors that might affect their vulnerability).		Coalition	
2.4	 Provide training or guidance to distributors on submitting requests to ESF-8 at the jurisdictional (local and state level) and the potential resources that may be needed/available to them. Define when a facility should work on their own to acquire needed items versus when they are to work with coalition/ESF-8 so as to not duplicate efforts or compete for resources. Discuss triggers for when the coalition would become the conduit for requests and/or allocation decisions – this may also help ensure there are not disproportionate assets in the community due to parent healthcare systems having different levels of access to materials. 		Coalition	
2.5	Provide training or guidance on the responsibilities of the coalition in brokering and deconflicting resource requests between distributors and healthcare. (Note: some of these situations may not involve an EOC activation – for example shortages of lumbar puncture kits during the 2012 fungal contamination of injectable steroid incident.) These policies should be defined and agreed to prior to an incident.		Coalition	



Activ	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
2.6	 Engage supply chain partners in coalition exercise. Options to consider for exercises include virtual exercises, tabletop exercise, and full-scale exercise participation (e.g., movement of products/simulated products, testing access to disaster areas for deliveries, test alternate delivery methods, or tests of "pulls" of disaster list materials. Conduct an after-action review and identify opportunities to improve and test in future exercises. 		Distributors; Coalitions; Providers	
2.7	 Invite manufacturers, wholesalers/distributors in the region to coalition meetings, as appropriate. Consider scenario-based discussions between distributors and providers to help providers understand how the distributors (and the coalition) will manage a situation in which there are inadequate resources to meet the requests (e.g., how will allocation be handled if implemented, likely duration if a local event). 		Manufacturers; Distributors; Providers; Coalitions	
2.8	 Ensure a process for sharing emergency information that may impact logistics and delivery operations with distributors. Identify "triggers" in these public communications such as road closures and curfews that will affect delivery. Consider standard communication channels to notify supply chain partners and providers in community about specific impacts and the need to shift to alternative delivery schedules. Communicate to relevant state and local authorities that alternative schedules and routes are being implemented. Engage emergency management to request assistance with delivery when available resources are insufficient. Delivery should be based on acuity of need. 		Distributors; Providers	



Activi	ties	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
2.9	Plan with facilities and law enforcement to ensure relevant supply chain partners (including third-party logistic providers) are identified as key (known) vendors (partners) and ideally have credentials to access facilities that may be within a law enforcement perimeter during a disaster.		Distributors; Providers; Recipient	
	 Some states include supply chain in the governor's emergency declaration as critical entities. 			
	 Consider engaging relevant state and local law enforcement on various requirements. (e.g., certificates, badging). 			
	 Communicate plan to supply chain partners and HCC members. 			
2.10	Establish a process to share distributor/logistics provider capabilities for delivery should road transport be limited (e.g., use of rotor-wing or boat delivery).		Distributors; Providers; Coalitions	
	 If applicable to HCC location and topography, determine if and where high-water vehicles or boats are available to supply chain partners and how those assets are coordinated. 			
	 If applicable to geography of HCC, determine options to deliver limited supplies via helicopter if roads are not accessible (e.g., due to earthquake or flooding). 			
	 If applicable, determine availability of alternate vehicles if roads are compromised by snow or ice (e.g., snowmobile, four-wheel drive, all-terrain vehicle). 			
2.11	Understand distributor storage and warehousing capacity in the region and adjacent regions to better gauge regional capacity and timelines for deliveries.		Providers; Distributors; Coalitions; Recipient	
	 This may help the facilities and coalition determine priorities for stocking and potentially regional caches in Section 3. 			



- ASPR. Coalition Emergency Management Program
- ASPR. The Healthcare Coalition in Emergency Response and Recovery
- ASPR TRACIE Disaster Available Supplies in Hospitals (DASH) Tool
- ASPR TRACIE Healthcare Coalition Resource and Gap Analysis Tool
- ASPR TRACIE Topic Collection: Coalition Models and Functions
- ASPR TRACIE Topic Collection: Coalition Administrative Issues
- ASPR TRACIE Topic Collection: Information Sharing
- FEMA. Supply Chain Resilience Guide
- Health Industry Distributors Association (HIDA)
- Healthcare Distribution Alliance (HDA)
- Healthcare Ready. Access Denied: Delivery of Critical Healthcare Products and Personnel to Disaster Sites
- HIDA. <u>Healthcare Distribution Overview.</u>
- U.S. Department of Homeland Security. Crisis Event Response and Recovery Access (CERRA) Framework



3. Planning

This set of activities is designed to assist coalitions in assessing available contingency guidance and plans, gaps in needed guidance, and standardizing guidance across members to harmonize response operations. This section also addresses formalizing relationships through joint plans, policies, procedures, memoranda of understanding (MOUs), and contracts.

Activities		Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
3.1	Determine alternate delivery processes should an event limit road transport Consider developing and sharing key planning questions that coalition members can share with distributors on this topic as well as potential solutions (e.g., alternate delivery methods or routes for specific at-risk healthcare facilities).		Distributors; Providers	
3.2	Consider changes to frequency of deliveries and resupply. • Facilities that are resupplied by distributors less frequently or have the ability to store more inventory have different needs than facilities dependent on more frequent deliveries.		Distributors; Providers	
3.3	 Advise coalition members to have contingency plans, should regular ordering processes be unavailable. Examples include paper-based ordering plans, protocols for submitting orders via phone, etc. Discuss how to utilize coalition members' corporate support structures where applicable. 		Distributors; Providers; Coalitions	
3.4	Establish coalition-wide process for developing and implementing guidance for Crisis Standards of Care (in collaboration with state efforts and in consultation with supply chain partners) to include triggers and plan(s) for conservation, substitution, adaptation, reuse, prioritization and reallocation of scarce supplies and consultation with clinical experts.		Providers; Coalitions	



Activi	ities	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
3.5	 Determine if an increase in par levels or caching of certain medications and supplies is warranted at the provider, state, and/or coalition levels. Regional caches should prioritize critical supplies with long shelf lives to minimize rotation. Distributor-managed caches may be an option. Policy on the request, allocation, distribution, use, and replacement must be in place for any regional assets. 		Providers; Coalition	
3.6	Transportation of medical material: If movement of coalition cache materials is required, HCCs and recipients should determine how transportation of medical materials will occur, put necessary agreements in place and gain pre-approvals as necessary. • HPP grant funds can (with prior approval) be used to lease vehicles for movement of materials, supplies and equipment by HCC members.		Coalitions; Recipient	
	 HPP grant funds can (with prior approval) be used for HCCs to make transportation agreements with commercial carriers for movement of HCC materials, supplies and equipment. Establish a written process for initiating transportation agreements (e.g., contracts, memoranda of understanding, formal written agreements, and/or other letters of agreement). 			
	Transportation agreements should include, at a minimum, the following elements:			
	Type of vendor			
	 Number and type of vehicles, including vehicle load capacity and configuration 			
	Number and type of drivers, including certification of drivers			
	Number and type of support personnel			



Activi	ties	Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
	Vendor's response timeVendor's ability to maintain cold chain, if necessary			
3.7	Facilities may wish to work with distributors to establish a "push list" of critical medications or supplies likely to need replenishing early in a disaster or in anticipation of a specific incident, and a process to request these supplies. • Common elements may be standardized across multiple facilities within a coalition for simplicity.		Distributors; Providers; Coalition	
3.8	Work with distributors to ensure understanding of restocking/ return/rotating options.		Distributors; Providers; Coalition	
3.9	Understand the distributors' redundancies and potential needs during a disaster as well as any resilience issues they are trying to address or have addressed through business continuity planning (e.g., whether they are located in a flood plain, with limited access to their facilities, and whether they have a contingency/continuity plan that is regularly reviewed and tested).		Manufacturers; Distributors; Providers; Coalitions	
3.10	Request members share established distributor memoranda of understanding (MOU) related to emergency operations to better understand status of agreements in the region. • This identifies instances where multiple coalition members and possibly distributors have identified the same resource solution and that vendor capacity would potentially not be sufficient to fully meet the needs of all.		Distributors; Providers; Coalitions	



Activities		Coalition Assessment (0-5)	Relevant Supply Chain Component	Coalition Work to Date & Remaining Work Needed
3.11	Consider and plan for the diverse needs of patients related to the supply chain– from acute care needs to chronic conditions, to unique demands from different demographics like pediatrics.		Providers; Coalitions; Patients	
	Examples include:			
	 Limitations on filling prescriptions by insurers 			
	 Identify and plan for critical healthcare equipment delivery and maintenance including oxygen 			
	Information on and access to open facilities (e.g., Rx Open)			
	 Knowledge of waivers and sources of information (e.g., insurance hotlines) 			
	 Transitioning care and services to a new or temporary facility 			
	 Partnerships with regional or national organizations to collect and disseminate patient-level guidance, which can be used and amplified by the HCCs 			
3.12	Determine alternate delivery processes should an event limit road transport.		Distributors; Providers	
	 Consider developing and sharing key planning questions that coalition members can share with distributors on this topic as well as potential solutions (e.g., alternate delivery methods or routes for specific at-risk healthcare facilities). 			

- ASPR. 2017-2022 Health Care Preparedness and Response Capabilities
- ASPR HPP 2019 Funding Opportunity Announcement
- ASPR TRACIE Considerations for Oxygen Therapy in Disasters



- ASPR TRACIE Disaster Available Supplies in Hospitals (DASH) Tool
- ASPR TRACIE Healthcare Coalition Preparedness Plan
- ASPR TRACIE Healthcare Coalition Response Plan
- ASPR TRACIE Topic Collection: Coalition Response Operations (Including Mutual Aid)
- ASPR TRACIE Topic Collection: Continuity of Operations (COOP) / Failure Plan
- ASPR TRACIE Topic Collection: Information Sharing
- CDC. Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health (updated 2019)
- FEMA. Business Continuity Plan
- FEMA. <u>Developing and Maintaining Emergency Operations Plans</u>
- Rx Open



Appendix B: Scenarios to Consider (for facility and coalition supply planning)

Determine how many casualties is reasonable to plan for given the facility (and its role in the community – e.g., is it a pediatric center or trauma center), surrounding community hazards, and other healthcare resources available in the area:

- 1. Mass casualty incident penetrating trauma/blast
 - Primary supply challenges airway supplies, surgical supplies, blood products, medications (analgesia, sedation, intubation)
- 2. Mass casualty incident pediatric
 - Primary supply challenges age-appropriate intravenous supplies, airway supplies, medications may vary from adults
- 3. Mass burn incident
 - Primary supply challenges analgesia, intravenous fluids, dressings, possibly airway supplies
- 4. HAZMAT chlorine
 - Primary supply challenges provider PPE, redress/gowns, possibly airway equipment
- **5.** HAZMAT organophosphate
 - Primary supply challenges provider PPE, antidotes atropine/pralidoxime, airway equipment, pharmaceuticals (e.g. benzodiazepines)
- **6.** Pandemic
 - Primary supply challenges provider PPE, critical care supplies and medications, antivirals, antibiotics, sedation/analgesia, airway supplies, general patient
 care supplies
- 7. Ebola Virus disease/VHF suspect case
 - Primary supply challenges specialty provider PPE, waste containment



Appendix C: Key Federal Programs and Agencies

Although the healthcare supply chain is largely owned and operated by the private sector, several federal offices and agencies have a role in supporting the continuity of supply chain operations during emergencies and events that could impact healthcare operations and have established partnerships with key components of the supply chain in order to accomplish this. Below is provided as a brief overview (not-exhaustive) of some of the key federal partners involved in healthcare supply chain issues.

- The US Department of Health and Human Services (HHS), Administration for Strategic Preparedness and Response (ASPR), Division of Strategic National Stockpile (SNS) partners with industry, particularly distributors, to ensure timely delivery of select medicines and medical products in the event of a large-scale public health emergency. The SNS works to quickly distribute and deliver assets in the stockpile by leveraging commercial supply chain operations in place through contracts and memoranda of understanding (MOUs). The SNS also works with manufacturers and distributors to understand additional capacity in the system and how that might be used during a disaster as well as anticipate and help mitigate barriers to rapid delivery that benefit all participants in the supply chain. For examples of SNS response activities, click here.
- ASPR's Industrial Base Management & Supply Chain (IBMSC) Program Office was established to coordinate strategic industrial base expansion and innovation efforts
 across ASPR, federal partners, academia, and the private sector to bring novel solutions and practices for response and recovery operations to life. IBMSC focuses
 on expanding, securing, and building resiliency across the entire public health and medical industrial base, as well as addressing shortages of life-saving medical
 countermeasures, inclusive of pharmaceuticals, personal protective equipment, durable medical equipment and other ancillary devices and equipment to diagnose,
 manage, and treat patients. To view the ASPR Industrial Base Expansion Portfolio, click here.
- ASPR's Supply Chain Control Tower (SCCT) Program aims to enable end-to-end visibility for supply chain monitoring and readiness for informed decision making in preparedness and response environments.
- ASPR's Supply Chain Logistics Operation Cell (SC-LOC) monitors, analyzes, and mitigates vulnerabilities in the supply chains associated with public health and
 medical resources and serves as the focal point for supply chain and operational strategies. SC-LOC establishes a common operating picture for key public health and
 medical resource categories that impact the supply chain and works with federal partners, HHS-stakeholders, private sector manufacturers and distributors to analyze
 supply chain risks.
- ASPR's Division of Critical Infrastructure Protection (CIP) engages national-level public and private sector partners to identify supply chain threats, and to collaborate on solutions. CIP facilitates the Healthcare and Public Health Sector on behalf of HHS as the lead agency responsible for the protection of our nation's health critical infrastructure. This includes convening forums to advance the sector's understanding of emergency-response supply chain concerns and how to proactively mitigate these issues. CIP works with an advisory group of federal and private sector representatives to advance bidirectional communication and problem-solving in steady state and response situations. CIP also works to identify potential and current threats to the supply chain in order to gather relevant information and determine approaches to reduce or eliminate the disaster's impact.
 - » ASPR CIP also leads a public-private partnership, the <u>Healthcare and Public Health (HPH) Sector Critical Infrastructure Security and Resilience Partnership</u>. This partnership supports information sharing and coordination during emergency events and is comprised of the Government Coordinating Council (GCC) and Sector Coordinating Council (SCC.) The GCC represents government interests and perspectives and includes ASPR, U.S. Department of Homeland Security, and the U.S. Food and Drug Administration in its membership. The SCC represents private sector interests and perspectives and includes supply chain trade associations and companies in its membership.



- The Healthcare and Public Health (HPH) Sector Critical Infrastructure Security and Resilience Partnership operates the Joint Supply Chain Resilience Working Group which experts from the private sector and across the government to share information and best practices, identify threats, and mitigate risks to make U.S. supply chains stronger.
- <u>ASPR's H-CORE</u> brings together government experts to partner with public health and industry stakeholders to fast-track solutions to health security threats. H-CORE leads the coordination of the acquisition and distribution of COVID-19 vaccine and therapeutic treatments.
- ASPR's Hospital Preparedness Program set forth the 2017-2022 Health Care Preparedness and Response Capabilities which outlines high-level objectives that the nation's health care delivery system, including HCC's and healthcare organizations, should undertake to prepare for, respond to, and recover from emergencies. Within the continuity of health service delivery capability objectives, healthcare organizations (with support from their local HCC's) are encouraged to identify essential functions for health care delivery, to include supply chain management and assess its supply chain vulnerabilities.
- Sector-based <u>Information Sharing and Analysis Centers (ISACs)</u> collaborate and share information within and across the DHS-designated 16 critical infrastructure sectors. ISACs are trusted entities established by critical infrastructure owners and operators to foster information sharing and best practices about physical and cyber threats and mitigation. They provide incident response coordination and share information during emergency events. The Healthcare and Public Health Sector designated two organizations as the Sector's ISACs: Healthcare Ready and the Health ISAC, or H-ISAC.
- The Centers for Disease Control and Prevention (CDC) outlines the Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health (2018) which outlines the capability for (and associated functions) for medical material management and distribution. CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement program is administered by the Division of State and Local Readiness and provides eligible recipients guidance and funding to help build and operationalize public health response capability and consideration strategies. CDC also develops guidance and policies related to protective personal equipment (PPE) and outlines basic principles to help healthcare supply chain managers prepare for disasters by highlighting the advantages and ways to achieve a whole community, coordinated effort.
- ASPR's Public Health Emergency (PHE) created a <u>National Strategy for a Resilient Public Health Supply Chain</u> in July 2021 in response to the COVID-19 pandemic.
 This strategy has three goals: build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability; transform the U.S. Government's ability to monitor and manage the public health supply chain through stockpiles, visibility, and engagement; establish standards, systems, and governance to manage the supply chain and ensure fair, equitable, and effective allocation of scarce resources.
- The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. The Cares Act gave the FDA authority to "help mitigate and prevent device shortages during or in advance of a (public health emergency)" (FDA, n.d.). The Act requires certain medical device manufacturers to provide information to the FDA on product availability and potential meaningful supply chain disruptions, during or in advance of a public health emergency.

