

CFDMC Supply Chain Integrity Assessment Approved by CFDMC Board 12-17-24

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Record of Changes & Distribution

Changes	Distribution
Plan Created 5/21	Sent out for 30 day member review Approved by Board 6/15/21 Posted to website
Update 5/22 (based on COVID19 AAR)	Sent out for 30 day member review Approved by Board 6/21/22 Posted to website 6/30/22
Updated by Supply Chain Integrity Workgroup, based on new ASPR requirements and lessons learned from supply chain disruption events	Sent to members for comment Approved by Board 12-17-24 Shared with Members/posted to website 1/10/25

Resource Needs

The East Central Florida 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 Programs

Under normal 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.

In 2021 and 2022, Florida's healthcare coalitions worked together to develop surveys to assess supply chain integrity in each region. Inputs into this process included a review of literature regarding supply chain integrity and the coalition's HVA. The Healthcare Coalition Task Force shared the survey tool with all coalitions to ensure that results would provide both a regional and statewide view. CFDMC distributed the survey in both an electronic survey and a Word document. The survey was deployed in two phases. In the first phase, CFDMC sent the survey via email to the Coalition points of contact at every Region 5 hospital. Also in the first phase, CFDMC distributed the survey to the region's nursing homes through multiple methods, including emails to nursing home members, through the CFDMC Long-Term Care Board Member and through the four Florida Healthcare Association District Presidents in Region 5. In the second phase, the survey was sent electronically to all Coalition members.

Survey respondents reported that in recent events, vendors met their needs in a timely manner. The most significant supply chain challenges were:

- Pharmaceuticals
- Medical supplies
- Oxygen
- Blood products
- Fuel
- Food and water

Respondents also noted that there are at times supply chain gaps during blue skies due to manufacturers' shortfalls, and transportation of supplies following an event at times caused gaps. Respondents felt all the issues seen in those events would continue to pose challenges in future events.

Respondents reported a wide variety of communication equipment used, including land lines, cell phones, satellite phones, ham radios, walkie talkies, and other emergency alert/notification systems. Respondents reported on vendors/contracts in place. There appears to be diverse vendors across the region for transportation services, medical gas suppliers, fuel suppliers, biomedical equipment suppliers,

disposable supply distributors and PPE suppliers. Most respondents use one vendor for blood supplies, and most respondents use one of two vendors for waste management services.

Vulnerabilities

Central Florida is uniquely vulnerable to large scale disasters due to its population and critical infrastructure. The 2023 US Census data shows more than 4.7 million people reside in the nine counties representing East Central Florida (Central Florida Regional Domestic Security Task Force, Region 5). Winter residents dramatically increase this population. In addition, domestic and international tourists flock to Central Florida for golf, shopping, water sports, theme parks, conventions, and the speedway. Orlando is the number one most visited destination in the world. Orlando International Airport was the 10th busiest airport in the nation before the pandemic with approximately 50 million passengers each year and rebounded at twice the average rate of travelers since December 2020. Visitors also arrive in Central Florida via cruises at Port Canaveral, Florida's fastest growing port and the second busiest port in the world, with more than 5 million travelers annually. NASA and SpaceX have a rigorous launch schedule, with an average launch every five days at Brevard County's Cape Canaveral Space Force Station. Patrick Force Base is also located in Brevard County. The region has 161 miles of coastline from Volusia to Martin County. There are three large chemical manufacturing plants within the region, multiple international and commercial airports, both freight and passenger railroad service across the region, and a nuclear power plant in St. Lucie County. All these factors increase the potential for a large-scale event in Central Florida.

The Region 5 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). Supply chain can also be impacted by a sudden large surge in demand for products (e.g., PPE during the pandemic). When one element is compromised there can be cascading effects up and down the supply chain. Disruptions to these systems can be caused by various hazards, underlying vulnerabilities, and threats that can directly impact every level of the supply chain. 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. Common hazards include hurricanes, snowstorms, tornadoes, flooding, wildfires, and earthquakes. All phases and components of the chain may be affected after events regardless of 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 catastrophes 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.

There are many areas of concern regarding the healthcare supply chain, including:

- Supply issues (not providing normal supply levels, not providing any supplies, etc.)
- Manufacturing issues (not enough raw materials, staffing issues, plant closures)
- Surge on the market (numerous large orders from multiple organizations)
- Opaque supply (supply chain visibility, what we see and what we are being told)
- Increased disasters (hurricanes, flooding, earthquakes, wildfires, etc.)
- Cybersecurity threats (ransomware, increase digital=increase cyber threat risk)
- Shipping issues (unavailability, strikes, delays, route congestion, weather, new regulations)
- Foreign government issues (tariffs, bans, fees, data collection, seizure of orders)
- Quality assurance (how good are the items when they arrive)
- Product recalls (impacting manufacturing, distribution, sale, and use of items)
- Regulatory changes (stricter quality control, increased complexity, disruptions)
- Contract constraints (limitations on ordering practices)

Supply challenges noted by CFDMC members during the 2021-2022 surveys were:

- There are existing supply shortages prior to an emergency that impact the healthcare system during an emergency.
- Main supply challenges occurred after the event, with manufacturers. In particular, one hurricane event that significantly impacted Puerto Rico on its way to Florida brought the realization of how much production was going on in Puerto Rico and affected supplies moving forward.
- Long term care needs are for power (fuel), food, water, and medical supplies. They discovered that medication delivery is a challenge during a storm situation as the roads close early and do not open until after the storm. Most used pharmacies are not local and deliver medications multiple times a day. They are unable to fill narcotic medications early due to new laws which can cause a resident to go without medications until the end of the storm.
- Maintaining linen supplies
- Maintaining supplies at correct temperatures post-storm due to no power / water
- Transporting equipment needed
- Getting refrigerated trucks as part of an MOU
- Medical supplies, food and water
- Communication
- Back orders due to manufacturer short fall
- Supplier manufacturing resources being located in affected areas with no secondary source
- Blood product and oxygen supply sources

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 and 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.

The Coalition conducted a preliminary after action report for the COVID-19 pandemic in the summer of 2020. The most challenging issue identified was acquisition of personal protective equipment (PPE). The supply chain was not equipped to surge and provide a sufficient supply of PPE for hospitals or across the continuum of care including home health. Previously established systems and processes for requesting resources did not function as planned and it was reported that federal agencies exercised dominion over access to PPE supply chain. During this response it was recognized that many organizations need to determine how to prioritize services and the Coalition and other public response agencies need a system for determining how to prioritize multiple requests for the same resources. Unified command is needed and though some were able to successfully implement ICS, others noted a need for more ICS training and position descriptions. Some facilities had success with just-in-time training systems for PPE use and event updates while others struggled with having to train and re-train staff on PPE and other protective measures.

As the pandemic progressed, it became evident that long-term care facilities lacked expertise and infrastructure in infection prevention and control as evidenced by their inability to appropriately isolate residents and use of PPE.

Below are opportunities related to the supply chain identified in the COVID after action report:

- PPE was not available, the supply chain was unable to meet demand, and facilities had to come up with alternative procedures for the extended use and re-use of PPE. Centralized management of PPE acquisition and distribution at the state, county, and facility level is needed. FEMA usurping of the authority of locals on PPE orders further challenged the supply chain and acquisition of PPE. Also, vendors requiring advance payment also made it difficult to acquire PPE. Checks and balances are needed in the system for PPE acquisition, including allowing the Coalition to assist with access and coordination of PPE. Multiple agreements are needed for access to PPE and access to PPE needs to be ensured across the continuum of care including home health and long-term care.
- Supply chain shortages presented many challenges for all. The coalition needs to strive to
 identify strategies for mitigating supply shortages including how to better prepare for shortages
 in the future by exploring regional and out of state back up vendors and increasing stockpiles of
 various supplies. Planning ahead for how to best access and use state assets and not-for-profit
 organizations vs. private for-profit vendors may also help with cost containment.

Current Access and Infrastructure

The Region has a robust healthcare system, with a total of 85 hospitals and free-standing emergency departments, including a Level I trauma center and a Level 1 pediatric trauma center in the metro Orlando area, five Level 2 trauma centers across the region, and three children's hospitals.

Current access and infrastructure by partner are identified below:

Florida Hospital Association:

Following the issues that arose during the pandemic, the Florida Hospital Association began working with all Florida healthcare coalitions to identify supply chain components and develop mitigation strategies to limit shortfalls.

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 considerations and mitigation and response strategies below capture high-level themes common across the different types of manufacturers.

Manufacturing occurs "upstream" in the supply chain. Given the healthcare coalition's 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. CFDMC will keep current and informed on significant impacts to manufacturing capabilities, such as drug or PPE shortages. CFDMC will share information and strategies for addressing the shortage between providers in their HCCs as well as potentially coordinate information exchange between distributors and providers.

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.	• Design business continuity and disaster recovery plans around hazards, vulnerabilities, and threats identified in hazard vulnerability analysis (HVAs) and risk assessments.
	•Raw materials disruptions – A variety of events, including natural hazards, can disrupt manufacturer access to quality raw materials.	• Ensure redundant production capacity or alternate vendors. The Coalition will obtain and share vendor lists.
	• 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.	• 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).

	 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 COVID-19 pandemic of 2020, demand for PPE, including N95 masks, increased drastically. 	 Comply with U.S. Food and Drug Administration (FDA) requirements for product shortage notification. Verified information on shortages is publicly available on the <u>FDA website</u>. 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.
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. It is concerning that PPE and staff shortages still plague the industry. In fact, "while shortages of staff and PPE decreased slightly from the previous monthly period, around 1 in 9 nursing homes still reported not having a week's supply of PPE. More than 1 in 4 nursing homes reported a shortage of nurses or aides." 	 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.	Coordinate with distributors to resume normal delivery.

• Assess the impact of the event to staff, products, etc.	• Coordinate, as appropriate, with partners on product availability if event caused a shortage.
 Communicate resumption of normal allocation/delivery/activities. 	

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. 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. There are also several regional companies that may be significant partners, especially in smaller, more rural communities.

CFDMC has identified the below suppliers for our market.

Medica	al Gas Supplier Contracts/Agreements
•	Nexair (formerly Praxair) - they have a disaster plan.
•	Airgas
•	Matheson
•	National contracted vendor with Kindred Healthcare
•	Matheson TriGas
•	Medlogix
Fuel Su	upplier Contracts/Agreements
•	Cunningham Oil
•	Cunningham Oil Sugarland Supply
•	Cunningham Oil Sugarland Supply Greens Energy
•	Cunningham Oil Sugarland Supply Greens Energy National contracted vendor with Kindred Healthcare
•	Cunningham Oil Sugarland Supply Greens Energy National contracted vendor with Kindred Healthcare Lynch Oil

- FL City Gas
- Glover oil
- Jet Age Fuel

Biomedical Equipment (e.g., monitors, ventilators) Contracts/Agreements

- Aramark / Trimedex Siemens (imaging equipment) General Electric (imaging, patient monitoring, etc.) Sonodepot (ultrasound equipment) RF Technologies (infant security systems) Braun/Baxter (Prismaflexes) Medtronics (defibrillators)
- Crothall
- Spacelab's Monitors all monitors and telemetry. Ventilators are Covidien. Alaris pumps out large Volume Infusion pumps. Anesthesia carts are GE. PCA pumps are Hospira (Sapphire)
- Carefusion, Phillips
- Our internal Bio Medical Equipment's team maintains our equipment. If they aren't able to maintain the piece of equipment, they work with the manufacturer to fit or replace it.
- Mindray, Intermed-national contracted vendor with Kindred Healthcare
- Baxter Braun
- Phillips
- Cardinal
- Medlogix

Disposable Supply Distributors or Manufactures Contracts/Agreements

- Medicine Supply Works
- Medline
- Cardinal Health
- JanPak
- National contracted vendor with Kindred Healthcare
- Daniels

PPE Distributors or Manufactures Contracts/Agreements

- HotZone USA
- Cardinal Health
- Medline
- National contracted vendor with Kindred Healthcare
- Grainger

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. 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, 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.)

Stage	Considerations	Mitigation and Response Strategies
Pre-event	Determine and communicate product	 Develop critical supply lists based on
	shortages – When caching is not an option,	potential events. Work with HCCs and
	or when stockpiles are depleted, distributors	facilities to create distributor or facility-
	work with suppliers and customers to	based caches or "push" lists to be delivered
	communicate availability of product(s) and	in case a disaster strikes and a request is
	viable alternatives/substitutions.	received from the facility to activate their
		list. In some cases, distributors are included
	•Communicating to customers –	in healthcare facility disaster notifications
	Distributors often offer to provide inventory	and will automatically activate the
	consultation to their customers, gauging	distribution.
	their needs and allowing them to place	
	advance orders to prepare for an event.	 Agree to alternatives and substitutions
		ahead of time. Understand communications
	• Pre-positioning supplies – Increasing	and establish alternate forms of
	product inventory in warehouses and onsite	communication if primary ordering systems
	at customer facilities (par levels), when	are down.
	possible, is an important pre-event activity	
	distributors and facilities should work	• Work with HCCs and providers to ensure
	together to execute. These may be	understanding of specific delivery
	permanent increases (e.g., for mass casualty	timeframes and vulnerabilities (e.g., if
	events) or temporary (e.g., in anticipation of	flooding closes a specific bridge, does this
	a hurricane or blizzard). Distributors will	compromise delivery from a distributor, or
	often pre-position trucks with supplies along	does the distributor potentially need access
	highways to get into the disaster zone	to high clearance vehicles?
	promptly after an event (e.g., nearby exits or	
	in rest stops to be able to make local	Work with all stakeholders to understand
	deliveries once roads re-open).	true demand during an event. Providers
		placing multiple excessive orders with
	 Anticipating common supply needs – 	multiple distributors only exacerbates
	Similar to manufacturers, distributors work	shortages and places additional strain on the
	to anticipate common supply needs and	supply chain.
	stock warehouses and customers	
	accordingly. A spike in customer orders can	Coordinate through Business Emergency
	be due to actual demand, anticipated	Operations Centers (BEOCs), when
	demand, or multiple orders being placed	applicable and available.
	with multiple vendors by the same entity in	
	the hopes that one will get filled.	• Develop priorities specific to community
		incidents that will result in common supply
	 Access and Re-entry – Facility access may 	needs (e.g., earthquakes, hurricanes,
	be a challenge for third-party logistics	pandemic, Ebola/VHF cases, mass violence
	providers transporting supplies in unmarked	incident based on geography and patient
	vehicles that may need to cross police lines.	population).
	After a criminal event such as a terrorist	
	attack, additional precautions would need to	•Annual influenza season is often used as a
	be taken to verify the origin of delivery	model to understand usage/consumption.
	vehicles.	

		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
		• 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
Response	• Alternative ordering – During a response	•Create a streamlined communication
Response	customers often place larger orders than	process for efficient ordering confirmation
	usual in these instances distributors will	and work to pre-populate orders including
	confirm an order that is out of the "norm"	an alternate communications plan. Ensure
	before processing	that the facility is not placing duplicate
	berore processing.	orders for the same items with multiple
	• Eassibility of Surga Dalivarias	vondors (a common situation that loads to
	• reasibility of Surge Deliveries –	significant missalsulation of actual need by
	deliveries may be requested as well as more	distributors and manufacturars)
	frequent deliveries. Considerations for these	distributors and manufacturers).
	inequent deliveries. Considerations for these	· Drevide evetere ere with erecific ellegetion
	surge deliveries include those noted below	• Provide customers with specific anotation
	In this section, as well as staff and product	limit amounts for operational planning at
	availability.	nealthcare delivery sites.
	• Alternative transportation and resider	•Mork with manufacturers and recent
	Alternative transportation and routes –	• vvork with manufacturers and parent
	identify navigable routes for delivery	(corporate) nearthcare systems to anticipate
	venicies, and alternative delivery sites, as	needs and move additional materials to the
	required.	distribution centers ahead of the event or
		requests.

	Securely transport deliveries –	 Be prepared to switch to alternative
	Distributors may work closely with law	products when necessary and determine
	enforcement to receive assistance (routes,	how deliveries will be prioritized if requests
	escorts). This is especially important during	exceed inventory. Ensure providers
	events when road access is compromised.	understand how allocation and prioritization
		will work.
		•Climate-control technologies 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 and boats) as well as
		additional standard vehicles/drivers to meet
		increased delivery demands.
		•Establish relationships and contacts with
		local emergency management – these may
		he 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 bazards
		Emorgancy management often doos not
		Emergency management often does not
		area and the key role they play in disaster
		response
Pacovary	• Pesume normal operations and	Coordinate with local authorities on
Recovery	communicate the resumption of normal	nrimary delivery route restoration if event
	allocation / delivery / activities	caused the need for alternative routes
	anocation y delivery y activities.	caused the need for alternative routes.
	 Coordinate with manufacturers and 	 Adjust delivery schedules as needed for
	providers as needed on product	facilities.
	substitutions (which ideally should be	
	identified and agreed to prior to an event)	 Communicate transition plan and timing
	and transition back to primary product when	back to primary products and normal supply
	available.	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	
	natient care consideration	
	patient care consideration.	

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.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	 Identify hazards, vulnerabilities, and 	• Develop emergency response and business
	threats – Focus on events that could	continuity plans informed by HVAs and risk
	significantly disrupt supply delivery or	assessment tools.
	compromise current supplies (e.g., by	
	damage or consumption) and those that are most likely in specific regions.	•Based on HVA and other tools, anticipate commonly needed medications and supplies and consider caching or increasing par levels
	 Define triggers or thresholds for activation 	of those supplies at the facility (space and
	of emergency plans – Emergency plans should include policies and procedures for requesting supplies and managing	shelf-life permitting). This may include non- medical supplies such as cots and food or water.
	disruptions in supply chains.	
	 Identify alternative mechanisms for 	• Consider "push" lists of commonly needed medications and supplies to replenish or
	ordering, receiving, and tracking supplies.	augment facility stock that the distributor
		can have available and establish policies on
	• Identify multiple delivery locations –	when to request these.
	make deliveries to individual healthcare	•Sconario based exercises should allow
	facilities/alternate care facilities or a central	providers to identify thresholds for
	warehouse where items will be later	instituting substitution and conservation
	redistributed.	procedures and document the process
		through which this occurs. Exercises should
	•Stockpile non-medical product(s) – Not all	be used to document and determine how
	supplies providers may need during an	these strategies and situational information
	emergency are stocked in large quantities by	are communicated to key partners including
	suppliers (e.g., hazmat suits). These should	the Coalition.
	be present on-site in adequate quantities to	
	address expected scenarios.	•Implement pilot programs and training to integrate new products into electronic
	•Define triggers and thresholds for changes	health records and educate providers on
	to standards of care – While implementing	labeling changes.
	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	•The facility steady-state drug shortage
	implications on supply orders (e.g.,	processes may have applicability for
	implementing re-use of N95 masks).	developing disaster shortage policies.
	 Work with key stakeholders to establish 	•Maintain communications with distributors
	Memoranda of Understanding (MOUs) or	to understand shortages and delivery issues.
	Memoranda of Agreement (MOA) –	Establish alternate communications plan
	MOU/MOAs between HCCs, providers, and	with major distributors in case primary
	other supply chain stakeholders can assist in	means fail.
	managing expectations of additional support	
	available during an emergency.	Establish an alternate distributors list for
	0 0 0 0	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 planning,
		information sharing, indexing, and managing
		resource requests/brokering with
		distributors during an incident.
Response	• Forecasting needs – Ability to provide care	•Use models, especially those based on past
	hinges on having needed supplies on-site	events (e.g., recent catastrophic hurricanes,
	and a plan for replenishment. Anticipating	severe flu seasons) to help determine likely
	supply needs, and capacity for receiving and	supply needs and quantities and proactively
	storing them, are key activities for	try to obtain them prior to shortage (also
	responses.	understand the potential to return items to
		the distributor).
	•Supply chain support activities – Providers	,
	should alter their practices as appropriate	• Population health data for the surrounding
	(ideally without compromising quality of	area can inform forecasting efforts.
	care) to decrease demand and increase the	6
	safety of substituted supplies. Examples	 Work with the Coalition to communicate
	include revising downtime procedures and	and share strategies with other facilities,
	refrigeration prioritization.	including developing guidance for adapting
	0	to crisis conditions when required.
	•Coordinate with public sector responders	
	– Public health and medical sector (ESF-8)	•Ensure a mechanism at the facility level for
	typically receives information about supply	development of clinical recommendations
	needs from a facility, and mainly engage	for substitution, conservation, adaptation,
	with distributors after healthcare facilities	re-use, and re-allocation of supplies to
	report an expected lag in availability of a	ensure consistency.
	needed product.	
		•Contribute to supply chain efficiencies
	•Partnerships across relevant supply chains	during crises by conserving and using
	- Relationships with all components of the	substitute medical and non-medical supplies

[
	healthcare supply chain (e.g., linen and	(e.g., pharmaceuticals, blood products, fuel,
	blood) and other sector supply chains (e.g.,	medical gases, refrigeration).
	fuel and food) may be leveraged for ad hoc	
	solutions.	 Maintain current ESF-8 contacts through
		trainings, exercises, and other methods.
	 Mitigate or adjust to staff shortages – 	
	Staff absenteeism during events may occur,	 Activate mutual aid agreements within the
	especially for downstream components	healthcare Coalition or with facilities not
	(distributors and healthcare facilities). This	impacted by the hazard.
	can be a challenge to maintaining healthcare	
	operations during events, especially for	•Explore and look for options from parent or
	healthcare facilities	"sister" facilities for resources if usual
	 including ancillary care. 	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	Disseminate supply chain disruption
-	communicate the resumption of normal	situation reports to local, regional, and state
	allocation/delivery/ activities with	health authorities as requested.
	distributors and coalition partners.	
		• Coordinate with distributors and others as
	•Communicate to patients and providers	needed on product substitutions and
	about resumption of normal	transitions back to primary product if event
	activities/processes.	caused a shortage.
	, F	
	 Manage transition back to daily 	 Share information on sustained supply
	operations/usual products and practices.	chain impacts.
		 Work with distributors to resume normal
		operations, distribution volumes, and
		schedule.

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 	• "Refill too soon" overrides may be allowed
	prescriptions – Generally, insurance plans	through an emergency declaration or at the
	prevent patients from obtaining a	discretion of insurance plans during
	prescription refill before their current supply	emergencies. These overrides can allow
	is depleted or close to it. During a declared	patients to receive a 30-day supply of
	disaster, a no refill order may be lifted.	prescription medicines in advance of a
		forecasted event. As this is not always the
	 Identify and plan for critical healthcare 	case, it is important for patients to be
	equipment delivery and maintenance – An	educated on this issue and know what
	important preparedness activity for patients	options they have.
	is to ensure access to their homes for	
	deliveries of critical supplies such as durable	 Follow instructions on labels or patient
	medical equipment (DME) and oxygen, and	instructions given by providers to help make
	also to ensure proper refrigeration (if	sure medical supplies are properly
	needed) of temperature sensitive medical	administered and maintained by patients.
	products.	
		•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
Description	. Discouring to information on an or facilities	may have back-up power near the patient).
Response	•Disseminate information on open facilities	•Plan with healthcare providers in advance
	and now to access them – Evacuated	of an event to identify back up facilities,
	partients may not be familiar with or know of	particularly ones within the insurance
	hearby open facilities.	
	•Knowledge of waivers and sources of	•Lise locator services like By Open to
	information (e.g., insurance hotlines) –	identify open pharmacy facilities
	Coverage may change during an emergency	
	due to waivers and other exemptions	• 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).
		•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:

CFDMC mission is to develop and promote healthcare emergency preparedness and response capabilities in the East Central Florida Domestic Security Task Force Region 5 (RDSTF Region 5), including the following nine counties: Brevard, Indian River, Lake, Martin, Orange, Osceola, Seminole, St. Lucie, and Volusia Counties.

The CFDMC will facilitate healthcare and other partners in working together collaboratively to build, strengthen and sustain a healthcare preparedness and response system within East Central Florida and to assist Emergency Management and ESF-8 (Health and Medical) with preparedness, response, recovery and mitigation activities related to healthcare disaster operations.

Stage	Considerations	Mitigation and Response Strategies
Pre-event	•Reconcile and align private sector member	•CFDMC will facilitate relationships through
	business continuity plans and public sector	routine coalition interactions (e.g., inviting
	member emergency response plans – With	distributors to coalition meetings, trainings,
	diverse members, HCCs can help set	and exercises).
	emergency response priorities and translate	
	resources, needs, and concerns across and	 Understand and document the major
	between members. With healthcare owned	distributors in the area including key
	and operated by the private sector but	product lines, location(s), points of contact,
	public sector agencies charged with	and means of delivery. This may include

	responding, mediation and understanding before an event is essential.	distribution points owned and operated by major healthcare systems.
	•Foster and forge relationships with supply chain components – HCCs play an important role in establishing key external relationships and fostering collaboration and	•CFDMC fits in as ESF-8 lead for the region. CFMDC attempts to identify regional resources to fill local needs
	 partnerships during steady state. Determine emergency protocols and procedures – HCCs can play a lead role in 	•Understand the role of the CFDMC in drug and supply shortages when emergency management is not activated (e.g., during steady state operations).
	developing and disseminating guidance within their membership on how to conserve, substitute, adapt, re-use, and re- allocate supplies.	•CFDMC's Trauma Advisory Board reviews protocols and procedures for recommendation.
	•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	•CFDMC has codified 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.
	dashboards). • Include supply chain representatives, specifically distributors and potential manufacturers, in coalition meetings and activities.	•CFDMC is working to 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.
		•CFDMC conducts trainings and exercises to build capacity and identify key coordination points across coalition members.
		•CFDMC will 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 Situation Reports, dashboard updates (if	• CFDMC will establish coordination conference calls or use other information platforms to share information.
	 applicable), liaising with ESF-8 and emergency management partners. Collect and aggregate EEIs from members 	• The Coalition routinely communicates with major distributors and shares hazard/impact information relevant to supply deliveries and security concerns as well as anticipated
	and provide this data to local, state, and federal partners.	needs.

	• Create and share common strategies for	•CFDMC will monitor and/or manage
	scarce resource management among	response requests, as seen in the state
	members.	WebEOC, determine allocations and delivery
		and other operations according to the
	•Broker or allocate resource requests	Coalition role in the jurisdiction.
	(depending on the defined Coalition role).	,
		•CEDMC will coordinate guidance for local
		implementation of crisis recommendations
		during protracted events (in conjunction
		with state-level efforts and local subject
		matter experts)
		•CFDMC will share identified EEIs with
		supply chain partners (e.g., distributors,
		3PLs) to establish information-sharing
		expectations and requests.
Recovery	•Communicate transition from response to	•CFDMC works with its partners to ensure
	recovery – This might be signaled through	consistency of delivery/care across region –
	emergency operation centers	moving from crisis to contingency and then
	(EOCs) standing down and information	conventional status for materials use.
	sharing cadences slowing.	
		•CFDMC produces daily situation reports for
	 Facilitate resumption of normal supply 	member agency during events so all
	delivery and clinical use.	partners have working knowledge of
		situational awareness and unmet needs.
	•After-action reports and identify lessons	
	learned – Coordinate with stakeholders to	 CFDMC shares lessons learned and
	identify opportunities for improvement.	improvement opportunities with local,
		regional, and state health authorities.
	 Incorporate lessons learned – Integrate 	
	lessons learned and best practices into	
	future supply chain integrity assessments as	
	needed for HPP capability requirements.	

Impact on Communities

Supply chain shortages/disruptions present many challenges to our healthcare system, including:

- Patient care with immediate life and death ramifications
- Impact on operations
- Altered care to patients
- Hindered quality outcomes for patients
- Inundation of communications of concern
- Rumors and fear

- Staff time spent on communications and redundant efforts
- Increased cost to the organization (cost of doing business)
- Cost to patients

Recent supply chain disruption/shortage events have highlighted the impact on specific communities, including:

- Disruptions in Availability of BD BACTECTM Blood Culture Bottles in July 2024: CDC alerted healthcare providers, laboratories, healthcare facility administrators, and state, tribal, local and territorial health departments of a critical shortage of Bectom Dickinson (BD) BACTECTM blood culture medical bottles. The shortage was caused by a supplier issue and the disruption in supply of this device impacted patient diagnosis, follow up patient management, and antimicrobial stewardship efforts. The Food and Drug Administration recommended that laboratories and health care providers consider conservation strategies to prioritize the use of blood culture media bottles, preserving the supply for patients at highest risk.
- **OneBlood Cyber Attack:** On July 29, 2024, OneBlood became the target of a ransomware cyber attack, which resulted in the organization having to move to a manual labeling process and which caused severe shortages of blood products and platelets throughout Florida. This impacted patient care, specifically for trauma patients, OB/GYN patients and patients receiving cancer treatment and delayed life-saving procedures.
- **Baxter IV Solution Disruption:** The closure of Baxter International's North Cove facility in North Carolina due to Hurricane Helene significantly disrupted the supply of intravenous (IV) and peritoneal dialysis solutions across the U.S. This facility is responsible for producing most of the IV fluids used in the U.S. and is the largest manufacturer of peritoneal dialysis solutions and this ongoing shortage has directly impacted patient care across the healthcare system.

Mitigation Strategies

Mitigation strategies by partner type are listed under Current Access and Infrastructure above.

In addition, each supply chain disruption/shortage event may have unique mitigation strategies. For example:

For the BD BACTEM blood culture media bottle event: the FDA recommended laboratories and health care providers who order blood cultures develop strategies to prioritize the use of blood culture media bottles, based on clinical need, to maintain quality and safety of patient care. In developing strategies to preserve the supply for patients at highest risk, these providers were asked to consider the following:

- Performing blood culture collections when medically necessary, following clinical guidelines, such as those provided below.
- Prioritizing use for patients with clinical signs and symptoms of a bloodstream infection.
- Performing routine disinfection of skin protocols prior to collection to minimize the risk of contamination of the blood culture.
- Ensuring proper blood volume collection to avoid a need to recollect additional samples.

- Utilizing safe blood collection and transfer devices to minimize the risk of damage to blood culture media bottles.
- Referring to the following guidelines for best practices for blood collection and potential considerations for prioritization for use of blood culture media bottles:
 - <u>Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases:</u> 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)External Link Disclaimer
 - World Health Organization (WHO) guidelines on drawing blood: best practices in phlebotomyExternal Link Disclaimer
 - CDC resources:
 - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals
 - Blood Culture Contamination: An Overview for Infection Control and Antibiotic
 Stewardship Programs Working with the Clinical Laboratory

For the OneBlood Event: Florida Hospital Association (FHA) took a leadership role in assessing the impact on hospitals and trauma centers across the state and held daily conference calls for the duration of the event. Mitigation strategies included the NAABB task force rapid response in identifying additional sources, and FDA approval to extend shelf life for products. FHA is working on a statewide after action report. CFDMC and the Region 5 Trauma Advisory Board wrote to the Florida Department of Health and FHA to make the following recommendations:

- This event highlighted the need for redundancy in the healthcare supply chain. We recommend that an assessment be conducted to ensure that critical healthcare supplies, such as blood, oxygen, pharmaceuticals, etc., are not reliant on a single or small number of providers.
- It is vital that trauma centers and hospitals have access to more than one blood supplier. Currently, there are contract issues that impede hospitals' ability to do this.
- There is a need for transparency in the process for allocation of resources during shortages. Where possible, it is recommended that key stakeholders have input into that process, and that all stakeholders be kept informed of how decisions are made.

For the Baxter IV Solution Event: Florida Hospital Association (FHA) took a leadership role in assessing the impact on facilities, through surveys and held conference calls during the initial phase of the event to share information. FHA also created a web page for sharing resources and weekly updates at: <u>IV</u> <u>Solutions Summary 08NOV2024.pdf</u>.

Regional Mitigation Strategies:

CFDMC facilitates information sharing among participating CFDMC members and with jurisdictional authorities to promote common situational awareness. CFDMC facilitates resource support by expediting the mutual aid process or other resource sharing arrangements among CFDMC members and supporting the request and receipt of assistance from local, State and Federal authorities. If a Coalition member organization needs assistance during a disaster response (staff, equipment, supplies, or other

resources), the member organization submits a request to the County Emergency Operations Center (EOC). It is the county's responsibility to try to fulfill the individual's request. If the County EOC is unable to fulfill the request, the County submits requests to the State EOC through WebEOC. Once a request has been received by the State EOC from a county, it is initially processed by the County Liaison Desk under the direction of the Operations Support Branch, who verifies the information. From there, it is assigned to the proper branch for tasking to the appropriate ESF. If the ESF can meet the provisions of the request, resource information is forwarded to the county EOC. If the ESF cannot provide the requested resources, it is then forwarded to the Logistics Section, who will work with either private vendors or through the Emergency Management Assistance Compact (EMAC) to secure the resources. If the resources are identified from private sources, the vendor information is given to the county emergency operations center. CFDMC monitors all ESF8 mission requests from Region 5 to see if we can fulfill the request.

CFDMC has reinstated a Supply Chain Integrity Workgroup to continue to identify resource needs, vulnerabilities, and identify and share mitigation strategies, including ensuring redundancy in suppliers for critical healthcare supplies, and inquiring regarding continuity of operations plans for these vendors and exploring/sharing best practices. For example, Orlando Health shared a recent mitigation strategy with the workgroup: Orlando Health has established a Supply Chain Command Center, including equipment and technology, a supply chain command center team with identified roles and responsibilities, trigger points to activate the supply chain command center, and supply chain command center trainings and exercises.

At the December CFDMC Conference, a panel comprised of representatives from Florida Hospital Association, Florida Committee on Trauma and Orlando Health shared lessons learned from recent supply chain disruption/shortage events.

CFDMC facilitates an annual regional drill to check mutual aid agreements and vendors/suppliers. In this year's "A Glass of Mutual Aid" drill, the Coalition encouraged healthcare organizations participating to ensure redundancy in their supply chain and discussing continuity of operations plans with critical suppliers.