Overcoming Supply Chain Disruption and Building Resilience

Jessica Covington, PharmD, BCPS, CPHQ
and
Jerrod Wright, MPH

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What did you do?

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In September of 2024, the nation experienced an IV fluid shortage due to a devastating hurricane in North Carolina that temporary closed the plant that manufacturers 60% of the US IV solutions.

How Did Your Organization Respond?

- Stockpile fluids when able?
- Borrow from other hospitals?
- Restrict and conserve IV fluids?
- Import fluid products?

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CMS Conditions of Participation

General emergent-preparedness rule (42 CFR 482.15)

- Develop and implement emergency-preparedness **policies and procedures** that cover subsistence needs for staff and patients — including medical and pharmaceutical supplies.
- In the broader “all hazards” risk assessment and planning, the plan must account for “loss of all/portion of supplies.” This means potential supply chain disruptions (e.g. shortage, delayed delivery) must be considered.

SOM Appendix A

CMS Conditions of Participation

General emergent-preparedness rule (42 CFR 482.15)

- Ensure continuity of operations: that includes planning what services can be delivered in an emergency, given possible supply interruptions (which could affect availability of medications).
- Because the Emergency Preparedness Rule is a Condition of Participation (or Condition for Coverage) for many types of providers and suppliers under Medicare/Medicaid, compliance is mandatory for certification and reimbursement eligibility.

SOM Appendix A

CMS Conditions of Participation Summary

- Facilities must include medical & pharmaceutical supplies in emergency plans.
- Plans must consider supply-chain disruptions (including drug shortages).
- Requirements include ability to provide in emergency, continuity of operations, and risk-based assessment.
- CMS does *not* mandate **which** drugs must be stocked, how many, or for how long
- Facilities should develop backup supplier strategies and shortage contingencies.
- CMS exploring broader policies to address national drug shortages.

SOM Appendix A

Challenges in Supply Chain

- Shortages and disruptions
- Counterfeit and diverted products
- Misbranded and adulterated drugs
- Inventory waste and expired products
- Regulatory compliance complexity
- Importation of unapproved products
- Cold chain management

Introduction

Pharmaceutical Supply chain is a comprehensive system that includes all processes and stakeholders involved in distribution and management of pharmaceutical products

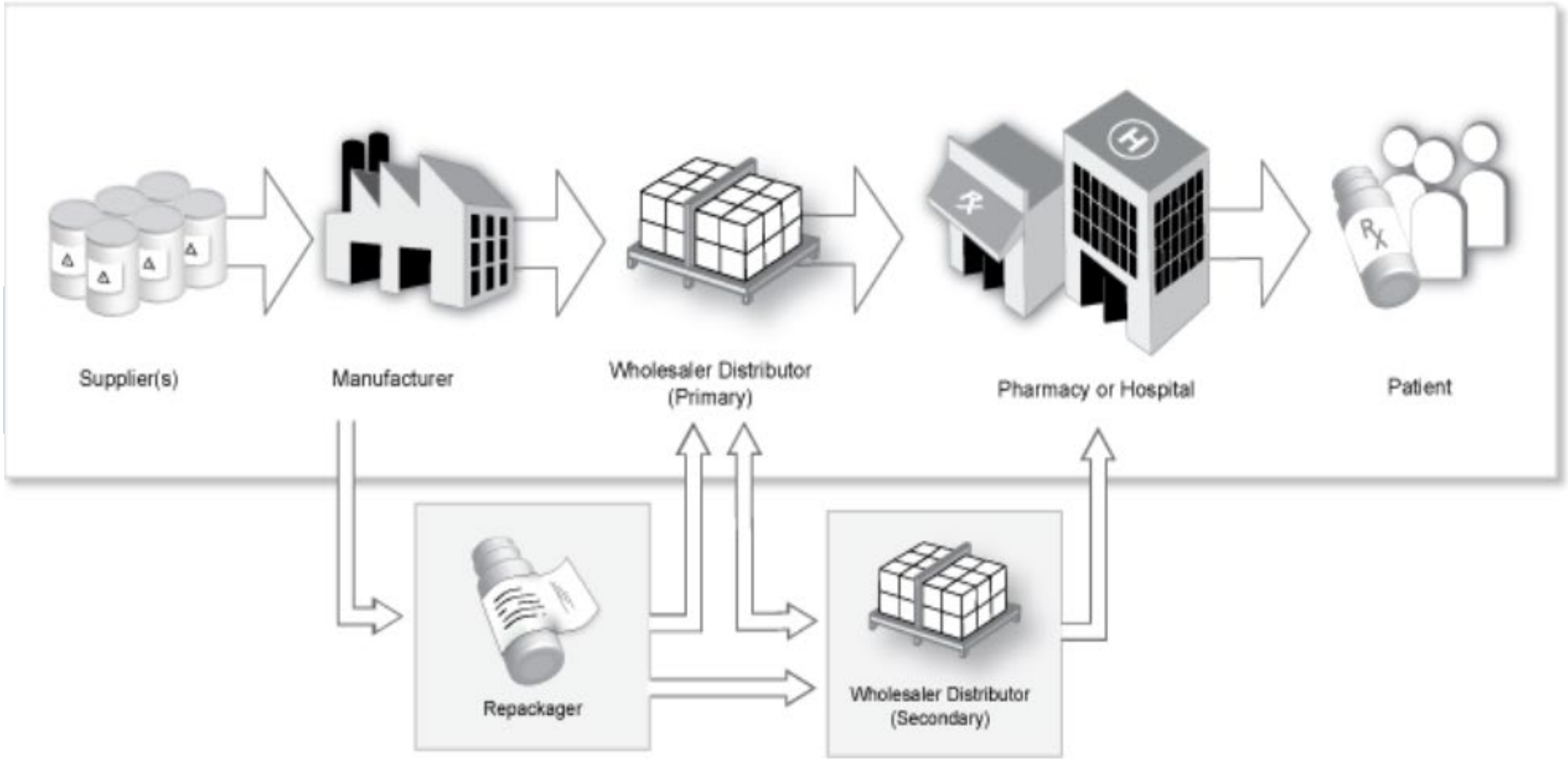
Key Supply Chain Process:

- Sourcing: raw materials and active pharmaceutical ingredients
- Manufacturing: drug production, packaging, and quality control
- Distribution: warehousing, allocation, and transportation
- Delivery to end user: hospitals, pharmacies, and patients

Key Stakeholders

- Suppliers
- Manufacturers
- Quality control teams
- Distributors
- Wholesalers
- Transportation
- Regulatory agencies
- Healthcare providers
- Pharmacies
- End-users

Pharmacy Supply Chain Flow



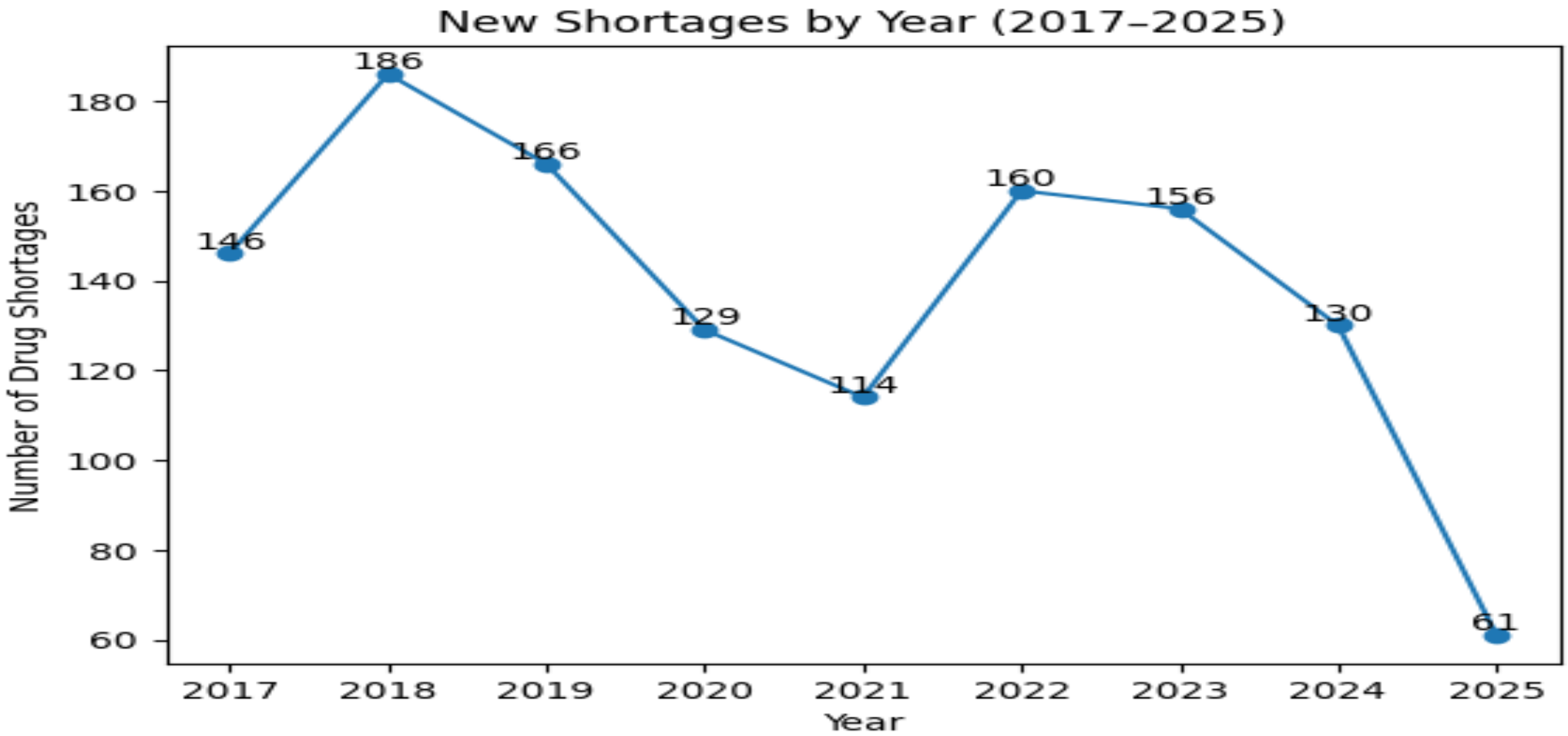
Graphic | A Drug Supply Chain Example | FDA

Drug Shortage Statistics

- Active Shortage: 214
- ~72% of all active shortages began in 2022 or later
- Shortages most commonly impact medications used by large patient populations, including:
  - Chronic disease management
  - Chronic pain treatment

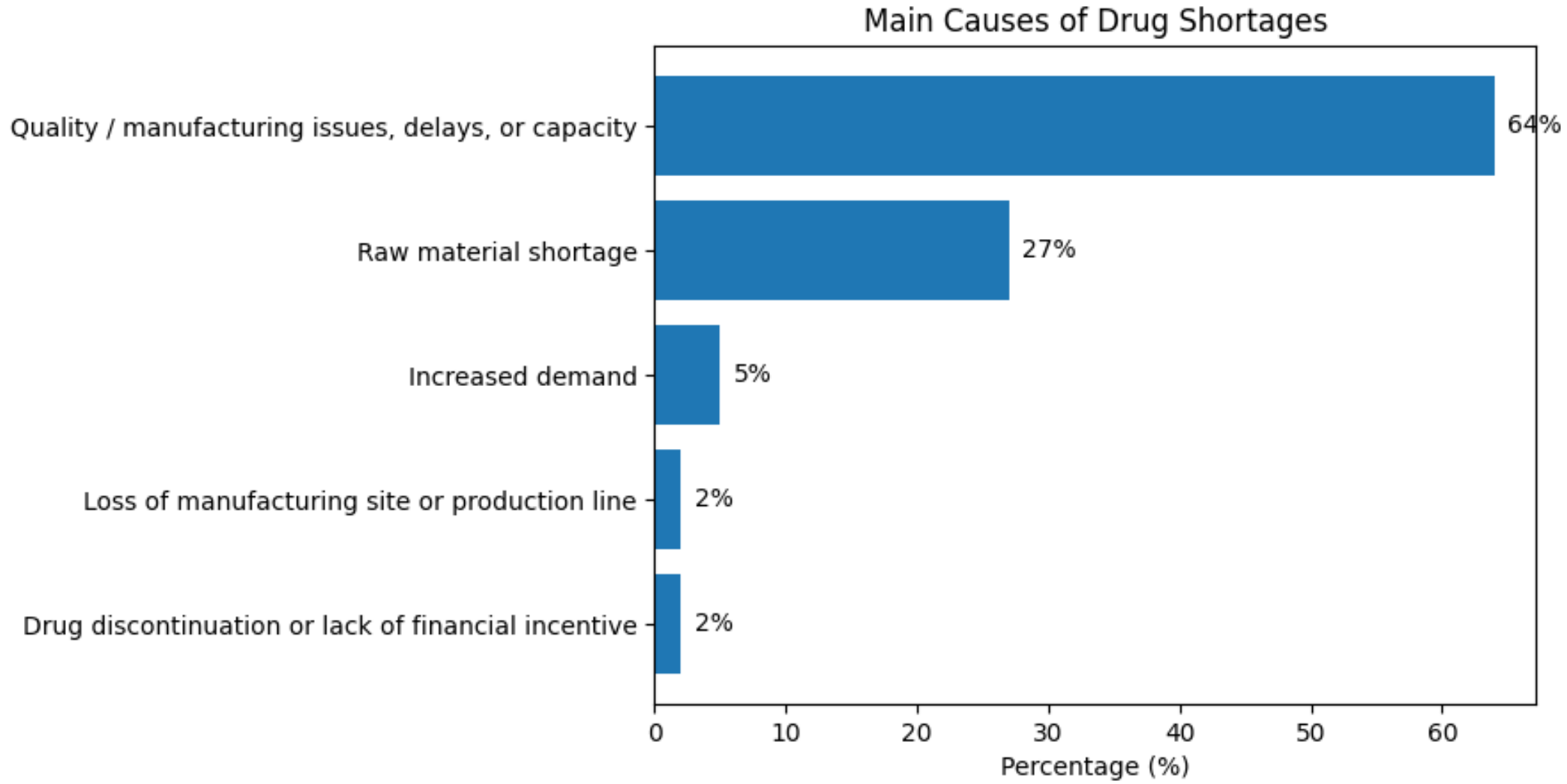
Data from ASHP

Drug Shortage Statistics



Data from ASHP

Drug Shortage Causes



Data from drugs.com

Medical Supply Chain

Medical Supply chain refers to how medical supplies, pharmaceuticals, and equipment is moved from manufacturers to healthcare providers.

Key Functions of the Medical Supply Chain:

- Procurement
- Inventory Management
- Distribution
- Waste Management
- Supplier Relationship Management

Importance of Medical Supply Chain Management

- Patient Care
- Cost Efficiency
- Operational Efficiency
- Support Disaster Preparedness

KHA Director of Hospital Preparedness Role

- Subject Matter Expert to Regional Healthcare Coalitions
- Monitor Supply Chain issues and aid member hospitals
- Regional planning to ensure adequate emergency response
- Represent hospitals and/or the Kentucky Hospital Association on advisory boards, committees, and/or task forces related to disaster preparedness
- Provide assistance to individual member hospitals with issues or programs related to terrorism, Natural disasters, Emergency Preparedness and Response activities
- Purchase Supplies and Equipment for Regional Healthcare Coalitions including hospitals

KHA Response: Supply Chain Disruption

- Attended live shortage updates from Government Agency and Non-Government Organizations:
  - Health and Human Services (HHS)
  - Food & Drug Administration (FDA)
  - Administration for Strategic Preparedness and Response (ASPER)
- Send out pertinent information to the hospitals and specific departments affected
  - Mitigation resources
  - Field calls for member hospitals
  - Contacted manufactures on behalf of hospitals
  - Advocated on behold of member hospitals
  - Fielded clinical questions on shortages
  - Conservation strategies

Emergency Support Functions (ESFs)

- KYEM (Kentucky Emergency Management Agency) Coordinates the ESFs
- State Emergency Operations Center (SEOC) is where the state leads for the ESFs are located for Disaster response
- ESF-1 Transportation, ESF-9 Search and Rescue, ESF-4 Firefighting
- ESF-8 Health and Medical which includes EMS (Responsible for request of medical supplies/equipment by hospitals, EMS transport issues and Fatality Management)

Emergency Support Function-8 Health and Medical

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Request for Emergency Support Function (ESF-8) Supplies

- **Local first** - Call your Preparedness and Response Coordinator (PRC) and request county and regional items and keep your county Emergency Manager in the loop on any request so he knows
- If the PRC does not have the requested items in the region he or she may reach out to other regions to see if they have them and pull those resources over to the affected areas
- If the items are not available in any region, then the EM is contacted, and he will send the ESF-8 request on behalf of the requesting hospital through WEBEOC. That request goes to the State Emergency Operations Center (SEOC) to be filled.

HPP RRC Contact Map

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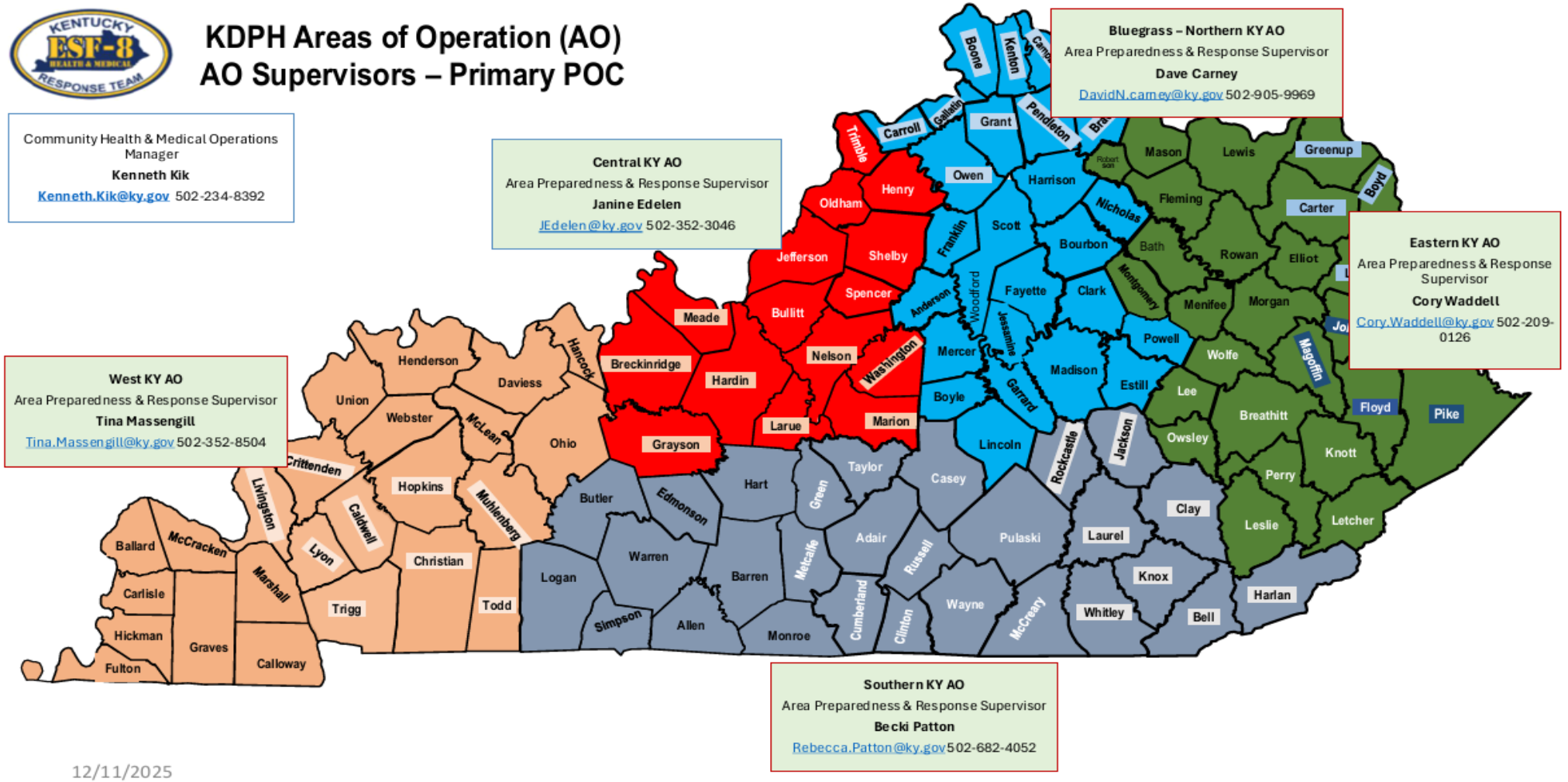

12/11/2025

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State Warehouse in Frankfort 108,000 sqft

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Warehouse items available to request during emergencies

- Tyvek/TyChem Coveralls
- Booties
- Sanitizing Wipes
- Bed sheets
- Thermometers
- Biohazard bags
- Pulse Oximeters
- N95
- Surgical mask
- Gowns

Warehouse items available to request during emergencies

- Face Shields
- Ventilators-Zoll (Activate Medical Surge Plan, Cancel elective surgeries where they are used, and cannot get through normal supply chain)
- CAPR (Controlled air purifying respirator)
- Beds (non-electrical all manual to expand hospital during a surge event)
- No Pharmaceuticals
- No IV Fluids

Morgue Trailer

Mobile Pharmacy and Federal Medical Station (FMS) Supplies

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West Regional Warehouse Princeton

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Southern Regional Warehouse in Somerset

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Southern Warehouse Equipment

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East Regional Warehouse in Garrett

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Best Practice for Pharmacists

- Ensure availability, quality, and safety of drugs/medical supplies
- Inventory management
- Prevent medication errors
- Education
- Administer and distribute medication
- Identify drug interactions
- Coordinate and communicate with stakeholders
- Therapeutic substitution
- Drug security and environmental control

Best Practices for Supply Chain Leads

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- Diversify suppliers
- Increase supply-chain visibility
- Prioritize critical supplies
- Strendgthen supplier relationships
- Build strategic inventory buffers
- Develop contingency plans
- Improve internal coordination
- Communication and transparency
- Monitor regulatory and market changes
- Invest in resilience

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Best Practices for Quality Leaders

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- Crisis management
- Leadership and advocacy
- Documentation
- Communication
- Interprofessional collaboration
- Resource management
- Community assessment
- Capacity Building and training
- Continuity of care
- Preparedness

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Common Best Practices for Quality, Supply Chain, and Pharmacist Leaders

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- Integrate data systems across partners
- Foster supplier collaboration
- Implement continuous monitoring
- Maintain a patient-centered approach
- Use analytics to guide decision-making
- Communication
- Transparency

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Quality Tools to Use

- Root Cause Analysis(RCA)
- Fishbone diagrams
- 5 whys
- Failure Mode and Effects Analysis (FMEA)

Quality Tools to Use

Root Cause Analysis(RCA)

- **Purpose**
  - Identify the underlying cause of a supply chain disruption
- **When to Use**
  - After a disruption has occurred
  - For a recurring issue
- **Key Questions**
  - What happened?
  - Why did it happen?
  - What systems failures allowed it?

Quality Tools to Use

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Fishbone diagram (Cause and Effect Diagram)

- **Purpose**
  - Visually organize potential causes of a supply chain problem
- **When to Use**
  - During RCA brainstorming
- **Common categories**
  - People
  - Process
  - Material
  - Management
  - Equipment
  - Environment

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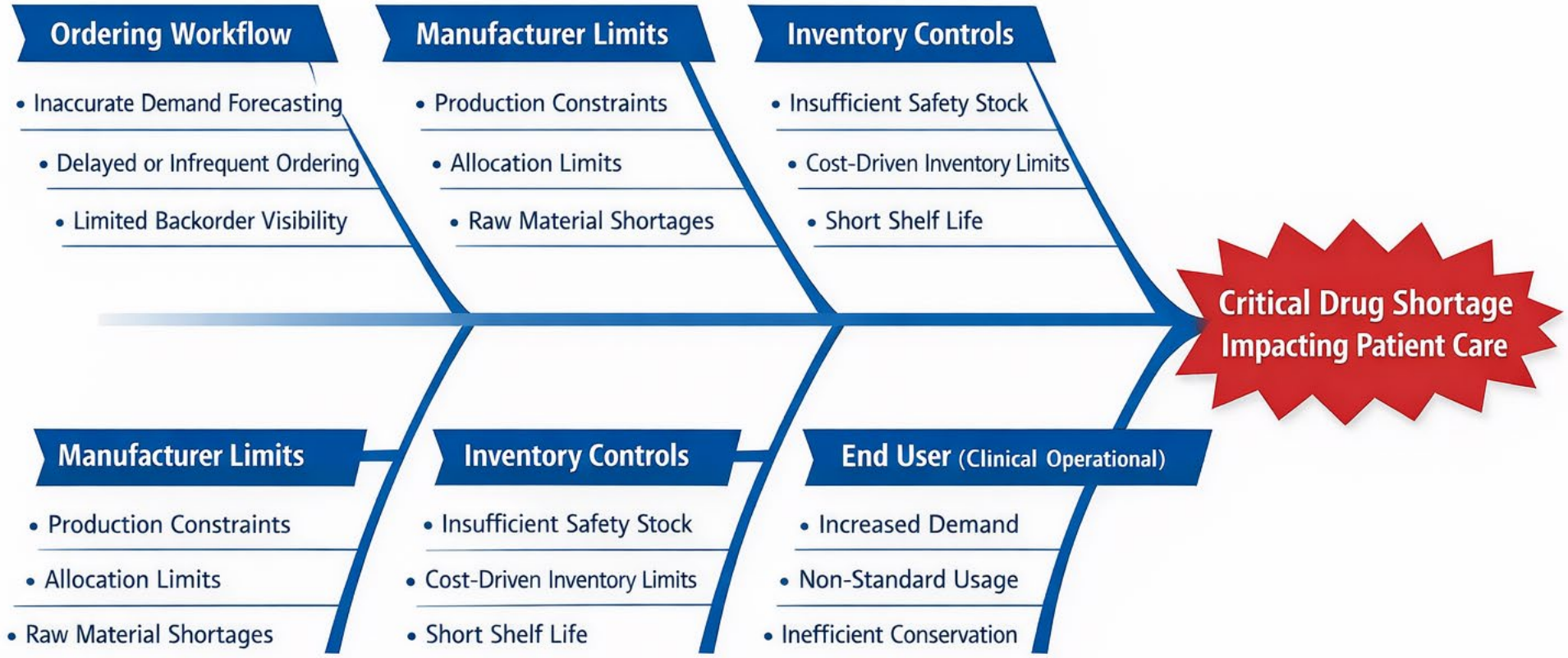
Quality Tools to Use

Fishbone Diagram: Drug Shortage



Quality Tools to Use

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The 5 Whys

- **Purpose**
  - Drill down to the true root cause by repeatedly asking "Why?"
- **When to Use**
  - Quick analysis
- **How it Works**
  - Ask "Why?" until a process failure is identified

Quality Tools to Use

Failure Mode and Effects Analysis (FMEA)

- **Purpose**
  - Proactively identify and prioritize supply chain risks before failures occur.
- **When to Use**
  - High-Risk or critical supply items
  - New or changing processes
- **How it Works**
  - Identify potential failures
  - Assess severity, likelihood, detectability
  - Priotrticae actions based on risk level

Quality Processes

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- **Optimize Inventory Management**
  - Use par-level optimization and dynamic inventory models
  - Segment inventory (critical vs routine medications)
  - Implement cross-site redistribution protocols in health systems
  - Use first-expire-first out process to reduce waste
- **Improve Communication transparency**
  - Weekly or biweekly drug shortages team huddle
  - Real-time shortage dashboards
  - Standardize alerts to pharmacists, clinician, and quality leads
  - Clear guidance on therapeutic alternatives and prioritization

Quality Processes

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Strengthen suppliers and partner relationship

- Evaluate supplier performance (lead times, fill rates)
- Conducting supplier reviews (annual or more frequent)
- Collaborating on contingency plans
- Sharing forecast data with manufactures/distributors

Measure performance and use data for improvement

- Useful Key Performance Indicator (KPIS)
  - Number of active shortages and availability
  - Average time to resolution
  - Critical drug days-on-hand
  - Number of shortages with contingency plans in place
  - Stockout tracking, frequency, and duration
  - Supplier fill rate
  - Avoided patient-care disruptions and use of therapeutic alternatives implemented
  - Drug shortage risk score

Quality Processes

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- **Implement patient-centered approach**
  - Standardize therapeutic interchange protocols
  - Evidence-based frameworks
  - Consistent education for clinician about shortage impacts
  - Ensuring quality and safety when importing or substituting products

- **Establish a drug and medical shortage monitoring system**
  - Implement automated inventory threshold and alerts
  - Use predictive analytics to identify patterns of impending shortages
  - Track shortage signals from the FDA shortage database, ASHP, and wholesalers

Technology and Innovation

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Emerging tools:

- AI & Predictive Analytics: Anticipate demand and shortages
- Blockchain: Enhance traceability, transparency, and trust
- IoT Sensors: Real-time temperature and handling monitoring
- Automation: Improve warehouse and dispensing efficiency

Building Resilience

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- **Awareness**
  - Communication
  - Analytics
  - Transparency
- **Mitigation**
  - Hardening
  - Diversification

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Building Resilience

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Preparedness

- Inventory stockpiling
- Capacity buffering
- Contingency planning
- Readiness

Response

- Supply increase
- Demand Reduction
- Prevention

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Sustainability and Ethics

- Recalls
- Reducing pharmaceutical and medical waste
- Reverse logistics and recycling
- Transparency

Future Outlook

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- AI-driven optimization
- Invest in employees
- Enhanced transparency and patient trust
- Digitalize supply chain
- Regional sourcing hubs

Conclusion

- Everyone has a role to play
- Preparedness and pivoting
- Resilient, transparent, and use of technology enables supply chain to protect patient safety, ensures quality, and advances healthcare outcomes

Conclusion

- **KHA Supply Chain Committee**
  - Virtual quarterly meetings
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References & Resources

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