



General Strategies and Resources for Shortages by Role

Role	Strategy	Resources
Federal Government	• Mitigate and prevent medical supply shortages by investing in domestic manufacturing, building public-private partnerships, and analyzing supply chain vulnerabilities • Work with manufacturers on contingency plans • Expedite regulatory compliance processes • Identify similar international products that may be importable • Identify shortage and update status on Food and Drug Administration (FDA) and other federal websites as applicable • Determine options for reasonable regulatory relief (e.g., compounding, shipping) and additional safety and other monitoring • Consider extension of shelf-life as appropriate	– ASPR: Center for Industrial Base Management and Supply Chain – CDC: Conserving Supplies of Personal Protective Equipment in Healthcare Facilities during Shortages – FDA: Drug Shortages – FDA: Expiration Dating Extension – FDA: Medical Device Shortages List
Specialty/ Advocacy Societies	• Determine alternate formulations/preparations • Recommend best practices for substitution, conservation (including risk-stratified strategies based on degree of shortage, dose-sparing/splitting), adaptation, and reuse • Monitor safety of strategies and adjust recommendations • Advocate for reimbursement for alternate strategies by payors	– American College of Physicians: Bolstering the Medication Supply Chain and Ameliorating Medication Shortages: A Position Paper from the American College of Physicians – American Society of Health-System Pharmacists: ASHP Guidelines on Managing Drug Product Shortages

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Manufacturers ¹	• Anticipate shortages (e.g., based on seasonality) and increase stockpiles • Identify production lines that can be repurposed/retooled for shortage product or alternate • Identify alternate sources of raw materials/active pharmaceutical ingredients • Communicate shortage, degree, and duration information promptly • Increase length/number of production shifts • Consider changes in packaging depending on type of shortage • Consider compounding when appropriate (e.g., 503B, etc.)	
Distributors	• Communicate shortage information to purchasers • Determine potential changes to third party logistics shipping routes, resources, and requirements (e.g., transport mode, increased security) • Implement a fair allocation framework to ship percentages of orders • Determine if certain clients have specific justification for higher percentages of order fulfillment based on best practice guidelines • Work between manufacturer(s) and purchasers to balance resources and needs	– Health Industry Distributors Association: Role of Medical Products Distributors in Emergency Preparedness

¹ Includes manufacturers of similar/substitute products that will experience increased ordering pressure.

Role	Strategy	Resources
Health Care Coalition/Regional Response Structure (e.g., Regional Disaster Health Response System)	• Establish and maintain relationships with key distributors • Establish and maintain shortage information sharing including qualitative and quantitative monitoring • Convene clinical leaders to gather best practices and determine local adaptations • Distribute recommended strategies • Adjust strategies based on new recommendations or changes in supply/demand • Monitor for crisis (i.e., significant risk of life-changing/life-ending outcome) conditions related to shortage and have a contingency plan to share/redirect resources to mitigate these • Depending on governance, broker resource requests and fulfillment within the served area	
Healthcare System/Facility	• Use tools such as Disaster Available Supplies in Hospitals (DASH) to have adequate par levels on hand and adjust according to threat • Refrain from purchasing surplus product when a perceived shortage begins • Identify and maintain/initiate contracts with alternate suppliers • Consider compounding or changes to administration/dosing as appropriate (e.g., crushing tablets for pediatric suspensions) • Consider centralized control of stock (e.g., remove from floor stock, require consultation, monitor distribution)	– ASPR TRACIE: DASH Tool



Role	Strategy	Resources
	- Utilize an advisory committee to review and implement best practices for stewardship - Use incident command/scarce resource allocation processes to monitor and adjust use in proportion to degree of shortage and develop internal and external (i.e., patient/community) communications about the shortage and impacts - Integrate strategies into electronic medical record and other systems - Monitor use, quality, and safety data to determine impact of strategies and adjust both ordering and allocation accordingly - Coordinate with other facilities to share information and current practices (e.g., “tier” of restrictions) and potentially share supplies - Seek reimbursement for alternate treatment regimens	
Provider/Nurse	- Steward resources by following best practice guidance - Anticipate impact of shortages on patient care and adjust treatments and interventions accordingly - Identify gaps or issues with strategies and communicate to leaders at facility and within specialty societies as appropriate	
Patient	- Be aware of evolving shortages and how they may impact ongoing care or initiation of treatment - Work with provider on treatment plans and understand they may change over time based on resources available	