Addressing Prescription Drug Shortages

Hospitals and health systems have continually faced substantial clinical and financial challenges due to prescription drug shortages. Vizient recommends the following policy solutions to help ensure the availability of needed prescription drugs:

	RECOMMENDATION	DETAILS
QUALITY	**Further develop Quality Management Maturity (QMM) rating system**	• Provide FDA with funding for efforts to pursue a rating system to help incentivize drug manufacturers to achieve Quality Management Maturity (QMM) at their facilities • Provide FDA with authority to require manufacturers to participate in the QMM rating system • Allow FDA to share manufacturers' QMM-related information with various entities in the supply chain, including Group Purchasing Organizations (GPOs) and hospitals, to help inform purchasing and contracting decisions
QUALITY	**Further develop the Quality Metrics (QM) Reporting Program**	Provide FDA with funding to further develop the QM Reporting Program and ensure such a program addresses the following: **Reporting Levels** • Require aggregated reporting at the facility and National Drug Code (NDC) level • Clarify how a manufacturing location would be identified (i.e., include facility's address) **Quality Metrics** • Clarify how to use and interpret different measures and the relative importance of each metric included in a QM Reporting Program • Require QM data, including information that is not necessarily included in a metric (e.g., location of source of APIs), to be shared with stakeholders, including GPOs • Create process to regularly (e.g., quarterly or bi-annually) update QM Reporting Program data • Require manufacturers to update stakeholders, including GPOs and FDA, when there are updates or changes in production that would be expected to impact QM outcomes **Communications** • Ensure manufacturing quality-related initiatives, such as the QM Reporting Program and QMM rating system, are communicated to stakeholders to minimize supply disruption (e.g., a "low quality" facility may still be able to sell products)
REIMBURSEMENT	**Implement payment policies that support a competitive drug marketplace and patient access to medications**	• Vizient encourages Congress and CMS to consider payment adjustments (i.e., N95-like policy and/or add-on payments) for generic essential medications frequently in shortage, like sterile injectables, where the manufacturer agrees to certain supply chain mitigation and resiliency requirements, including participation in the QMM rating system
COMPOUNDING	**Provide greater flexibility and transparency to facilitate compounding of medications during a shortage**	• FDA should consider including outsourcing facilities in QMM rating system efforts • FDA should provide a means for stakeholders to confirm information or for FDA to make information public about an outsourcing facility with FDA, such as whether issues in a 483 have been resolved • FDA should develop strategies to encourage manufacturers to seek approval for commonly compounded ready-to-use products • FDA should provide outsourcing facilities with more flexibility to meet provider demands (e.g., advance notice that a shortage will likely occur, such as if a plant closes)

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TRANSPARENCY	**Coordinate increased inventory**	• Vizient recommends relevant federal agencies (e.g., FDA, DHS, ASPR) and the private sector collaborate to develop a data-driven approach to ensure that additional inventory, to be used in the event of a shortage or other emergency, is readily available and that inventory requirements are not unnecessarily redundant
	Consider using multiple lists, such as Vizient's Essential Medications list, to direct drug shortage initiatives	• FDA should provide more information regarding the process and data sources used to develop the FDA's Essential Medicines list and share plans for future updates to the list • Congress and FDA should work to enhance FDA's Essential Medications list to better reflect products most likely to face potential supply challenges for providers during normal operations (e.g., products with persistent quality issues and products where the API and key ingredient sources are unclear) and for unique patient populations, such as pediatrics • FDA should work with stakeholders, including GPOs, on a long-term process to update the Essential Medicines list, including use of other lists, and identify how such lists will be used to prevent shortages
	Increase supply chain transparency	To help avoid shortages during normal operations and emergencies, improve information reported to the FDA and other agencies: • FDA and other agencies should review and make public a report on information currently collected from manufacturing facilities, including compounding facilities; this information should be categorized to clarify types of information that are publicly available, considered confidential or available upon request by the government • Broader reporting regarding geographic locations for critical elements (e.g., API) of medical products to better assess risk of supply disruptions • Notification of permanent discontinuances and significant interruptions in manufacturing, including in circumstances other than a public health emergency • Require manufacturers of products, starting with those critical to public health, to develop, maintain, and, as appropriate, implement a risk management plan that identifies and evaluates risks to the supply of the product, as applicable, for each establishment in which such product is manufactured • Broaden the circumstances to include demand spikes and other fluctuations, in which drug manufacturers report shortage-related information to the FDA • Grant additional authority to FDA to conduct greater oversight of supply chain disruptions and shortage prevention efforts, including requiring manufacturers to perform and provide risk assessments, implement redundancy risk management plans, and identify alternate suppliers and manufacturing sites in case of disruption • Share information, including aggregated information, when the agency has not received information from a manufacturer regarding a drug shortage that appears on FDA's or ASHP's shortage list, to help stakeholders evaluate manufacturers' efforts to provide notice of a shortage • Enhance FDA's Drug Shortage List functionality to share more information about the severity and causes of a shortage or anticipated shortage (e.g., scope of quality issues identified in an inspection) and manufacturers' plans, if any, to mitigate the shortage or anticipated shortage; this information will allow stakeholders to track and prepare for shortages more effectively Increase access to information and provide context regarding Form 483 and inspections: • Share non-redacted Form 483s with supply chain stakeholders, upon request • Establish a system to evaluate or grade risk of a given 483 to help stakeholders understand severity/seriousness of facility issues • Share additional detail regarding supply disruptions, including potential duration or severity, and mitigation efforts they are pursuing or have considered pursuing • Provide routine updates for on-site inspection scores and trends over time similar to what FDA published in their 2019 state of pharmaceutical quality report (see Figure 4 of the report). In subsequent annual reports, the chart showing site inspection scores for geographic regions, application types and manufacturing sectors does not appear to have been replicated. If such a chart is recreated, it would be helpful to provide additional context regarding on-site inspection scores (e.g., how should stakeholders view a score of 7.4 vs 8.4?)

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Vizient Strategies for Drug Shortage Management

Participants in the Vizient Pharmacy Program have access to resources and expertise to help navigate drug shortages, including:

- **Drug Shortages Task Force**: Vizient team focused on development of solutions and resources to support members with drug shortages.
- **Novaplus® private label**: Offers 200+ drugs representing 900+ NDCs. Vizient members that use Novaplus see the highest fill rates in the industry.
- **Novaplus Enhanced Supply**: Sourcing strategy for essential medications to create up to 6 months of additional inventory based on historical purchases warehoused in the United States by the suppliers, covering more than 120+ drugs representing 480+ NDCs and 130 million units of additional inventory. Vizient members have accessed over 1.4 million units of additional inventory in the last 12 months.
- **Clinical member engagement**: Members collaborate with Vizient to develop strategies that minimize the impact of shortages on the workflow.
- **Drug shortages resources**: Member webpage provides I.V. Shortages Resource Guide, drug shortage alerts and nine drug-specific mitigation strategies.
- **Vizient Essential Medications list**: Vizient pharmacy experts continue to identify essential medications where, if not available, they would prove the greatest threat to a hospital's ability to provide immediate and high-quality patient care. Also included are accompanying mitigation strategies.
- **Partnership with the University of Utah**: Enables collaboration and provides daily alerts on the latest drug shortages.
- **Advanced analytics**: With real-time visibility into expense management across all care settings, organizations rely on Vizient analytics to help hospitals reduce pharmaceutical spend while improving outcomes. Algorithm identifies products at risk of going short, influences member engagement and drives sourcing strategies.
- **Sourcing resources**: Include our failure-to-supply program – which brought $38.3 million in value back to members in 2018; wholesale fill-rate monitoring and damages; wholesale agreement support; and effective contracting strategies (e.g., contracts with commitments and allowing price increases to give manufacturers flexibility if there are challenges).
- **Advocacy**: Vizient supports legislative and regulatory efforts to proactively address the systemic causes of the drug shortage crisis (e.g., by consulting with the FDA Drug Shortage Task Force and engaging in coalition efforts with the Campaign for Sustainable Rx Pricing "CSRxP"). Vizient also hosted a series of congressional briefings on hospital providers' drug shortage management and mitigation strategies, participated at multiple events hosted by FDA and other healthcare partners on drug supply chain resiliency, pharmaceutical quality, compounding quality and a competitive marketplace for biosimilars.

Additional Resources and White Papers

- Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals to identify and quantify the labor-related operational and financial impact of drug shortages on member health systems and hospitals
- Quantifying Drivers of Supply Chain Resilience in Pediatric Oncology Medications in partnership with Angels for Change and United States Pharmacopeia (USP) to evaluate supply chain risks to improve access to critical pediatric oncology drugs
- Pediatric Drug Shortage Trends and Best Practices for Mitigation Strategies together with the Children's Hospital Association (CHA) to identify the impact of drug shortages on pediatric hospitals
- Implications of the National BCG Drug Shortage in collaboration with the End Drug Shortages Alliance (EDSA) to present current BCG market trends and insights from the findings of the Vizient member survey

As the nation's largest member-driven healthcare performance improvement company, Vizient provides solutions and services that empower healthcare providers to deliver high-value care by aligning cost, quality and market performance. The Vizient® member-focused Pharmacy Solutions leverages supply chain and clinical insights, experienced pharmacy consultants and therapeutic class-specific expertise to help members manage spend, optimize savings and prepare for market shifts. To learn more, please contact the Vizient Public Policy and Government Relations team.

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