Prescription Drug Shortages

Hospitals and health systems have continually faced substantial clinical and financial challenges due to prescription drug shortages. One way Vizient helps prevent and mitigate shortages is by advocating for legislative and regulatory changes and collaborating with other industry and governmental stakeholders.

Factors that Contribute to Drug Shortages

According to the American Society of Health-System Pharmacists, drug shortages can occur due to one or a combination of factors such as:

- Manufacturing delays, quality problems and capacity constraints
- Shortages of active pharmaceutical ingredients or raw materials
- Manufacturer business decisions that are based on the availability of generic drugs, market size, and regulatory compliance, among other factors

Cost of Drug Shortages on Hospitals and Health Systems

According to Vizient's most recent Drug Shortages and Labor Costs survey, drug shortages cost hospitals **$359 million** per year in labor and require **8.6 million hours** of additional labor annually.

Other hidden costs include:

- Spend on additional staffing
- Loss of revenue from delayed or canceled procedures
- Staff overtime
- Updating technology

Vizient Advocacy

Drug shortages continue to challenge the health care ecosystem. Vizient has taken a leading role in advocating for and seeking policy solutions that provide marketplace stability to ensure consistent availability of needed prescription drugs.

Legislative Action

- Endorsed the Drug Shortages Shelf Life Extension Act that would require FDA to update guidance so that an extended expiration date can be included on a drug's label to help prevent or mitigate shortages.
- Endorsed the Mitigating Emergency Drug Shortages (MEDS) Act that would enable the FDA to help ensure a stable supply of medications critical for patient care. As a result of our advocacy, provisions of the MEDS Act that permit FDA's expedited review of abbreviated new drug applications (ANDAs) for generic drugs and expand manufacturer reporting requirements for active pharmaceutical ingredients (APIs) became law with passage of the CARES Act in 2020.
- Successfully advocated for expedited review and approval of ANDAs for products where there were three or fewer manufacturers, which was passed as part of the FDA Reauthorization Act of 2017.
- Supported market-based solutions to promote competition, including endorsing the Bolstering Innovative Options to Save Immediately on Medicines (BIOSIM) Act in 2021, which would incentivize utilization of biosimilar medications and encourage more biosimilars to the enter the marketplace.
- Built support for the Affordable Prescriptions for Patients Act, the Fair Access for Safe and Timely (FAST) Generics Act, and the Biologic Patent Transparency Act to help address "patent thickets" and other tactics used by drug manufacturers to delay market competition from generic and biosimilar drugs.
- Endorsed and advocated for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which was signed into law in 2019, and encourages greater generic competition by providing tools to address delay tactics used by brand manufacturers to block entry of generic drugs.

Regulatory Activity

Significant policymaking and drug shortage mitigation efforts occur within the Executive Branch agencies. Vizient's recent regulatory activity includes:

Supply Chain	• Provided feedback on the Drug Enforcement Administration's (DEA) proposed annual production quotas (APQs) for schedule I and II controlled substances to help ensure drug shortages are considered by the agency when setting APQs. We applauded DEA for incorporating insights from various stakeholders in its adjustment of the 2020 APQs for certain schedule II controlled substances in response to the COVID-19 public health emergency (PHE). • Shared insights with the White House Coronavirus Task Force, which included recommendations to maintain patient access to chloroquine and hydroxychloroquine for established indications and other strategies to avoid supply chain disruptions secondary to the pandemic. We also were the first to sound the alarm on the looming shortage of ventilator-use drugs as a result of the COVID-19 pandemic. • Submitted concerns on the FDA's proposed rule on the importation of prescription drugs to highlight the need to maintain current drug shortage mitigation strategies and supply chain management. • Shared proposals for FDA to consider as it applies provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to compound medications to help fill treatment gaps and maintain access to medications. • Offered proposals to reform the Unapproved Drug Initiative (UDI), which unintentionally lead to significant price spikes and supply chain disruption as products became sole source.
Competition and Transparency	• Offered additional considerations to FDA on the reauthorization of the Prescription Drug User Fee Act (PDUFA), including recommendations to increase transparency in the supply chain. • Submitted comments on the FY 2020, FY 2021, and FY 2022 Inpatient Prospective Payment proposed rules that advocated for payment policies that support a competitive drug marketplace and patient access to medications. • Shared feedback to FDA on Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") and suggested opportunities for improvement (e.g., incorporating information about manufacturing quality and the location where all pharmaceuticals components are made). • Provided comments to the USPTO on developing and implementing frameworks that support competitive marketplaces for pharmaceutical products. • Commented on FDA's Essential Medicines list and shared insights with the Department of Commerce on policies to strengthen the U.S. public health industrial base that highlighted the importance of increasing transparency of the manufacturing supply chain.

Other Key Efforts

Vizient continues to collaborate with government and private sector stakeholders by sharing expertise and critical information to help mitigate and prevent drug shortages, such as fill rate data**,** our essential medicines list and other analysis from our Pharmacy Market Outlook. In addition to our legislative, regulatory and coalition efforts with the Campaign for Sustainable Rx Pricing (CSRxP), Vizient hosted a series of congressional briefings on hospital providers' drug shortage management and mitigation strategies, participated at multiple events hosted by FDA and other health care partners on drug supply chain resiliency, pharmaceutical quality, compounding quality, and a competitive marketplace for biosimilars, and partnered with Angels for Change and United States Pharmacopeia (USP) to evaluate supply chain risks to improve access to critical pediatric oncology drugs.

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