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The Honorable Richard Hudson
U.S. House of Representatives
2112 Rayburn House Office Building
Washington, D.C., 20515

The Honorable Anna Eshoo
U.S. House of Representatives
272 Cannon House Office Building
Washington, D.C., 20515

Dear Representatives Hudson and Eshoo:

Over the last several years of the COVID-19 pandemic, hospitals and healthcare providers across the country have faced unprecedented challenges. With the pending reauthorization of the *Pandemic and All-Hazards Preparedness Act (*PAHPA), Congress has a unique opportunity to use recent experiences and lessons learned to better prepare for future pandemics. More broadly, Vizient believes that it is critical that public health, medical preparedness, and response capabilities are meaningfully improved to minimize potential harm and disruption from future emergencies.

Vizient is the nation's largest healthcare performance improvement company. Vizient provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers and more than 25% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Vizient is pleased to offer feedback to the Request for Information (RFI) in preparation for the upcoming PAHPA reauthorization. Our comments are divided into two sections. The first section lists suggestions directly related to programs being reauthorized in PAHPA, and the second section provides additional policy solutions for the House Energy and Commerce Committee's consideration that Vizient believes will better position the country to address future crises.

## Recommendations Related to Existing PAHPA Programs

### National Health Security Strategy (NHSS)

Drug and medical device shortages create numerous risks to patients, including causing possible delays in care. Shortages also place additional resource constraints and financial burdens on healthcare institutions that increase costs. Vizient's Drug Shortages and Labor Cost Report found that drug shortages cost $359 million in additional labor expenses per year and 8.6 million additional personnel hours per year. Thus, the need to address medical supply chain shortages during an emergency is even more critical given the impact to patient care and the strain on already overwhelmed staff.

Supply interruptions for both drugs and medical devices are caused by a range of factors—including quality failures, demand surges, capacity reductions, coordination challenges, and cessation of operations due to business reasons, among myriad other reasons. Yet, when

supply disruptions first emerge, there is often limited information shared with stakeholders. For example, even basic manufacturing and sourcing information is not routinely shared with purchasers or other stakeholders, making drug and device shortages significantly more challenging to anticipate and mitigate.

*Increased Supply Chain Transparency*

When critical medical supplies are sourced, manufactured, packaged, labeled, or sterilized in a single location, whether domestic or overseas, a disruption at any point in this sequence could upend the entirety of the supply chain for a variety of products and for an indeterminant amount of time. Transparency of key data elements critical to the supply chain, including raw materials, active pharmaceutical ingredients, manufacturing, sterilization, and packaging, is important for broader efforts to predict drug and device shortages and the development of alternative options. Vizient has long supported and highlighted the need for greater supply chain transparency as this will support informed decision-making regarding the sourcing of medical products, among other benefits.

Although the *Coronavirus Aid, Relief, and Economic Security (CARES) Act* provided the Food and Drug Administration (FDA) with new authorities to help identify, prevent, and mitigate drug and medical device shortages, information reported to the FDA is not necessarily made publicly available nor is it available to select supply chain stakeholders, such as group purchasing organizations (GPOs). To improve supply chain assurance, including information reported to the FDA, Vizient supports the following policies:

- Broader reporting regarding geographic locations for critical elements of medical products to better assess risk of supply disruptions for critical products;
- Notification of permanent discontinuances and significant interruptions in manufacturing, including in circumstances other than a public health emergency (PHE);
- Require manufacturers of products critical to public health to develop, maintain, and, as appropriate, implement a redundancy 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;
- Provide incentives to support the creation and sharing of risk management plans for drugs, including sharing information with a broader array of stakeholders such as GPOs and healthcare providers;
- Consider opportunities to increase access to reported information regarding the overall volume of listed drugs and biological products manufactured; and
- Consider opportunities to ease manufacturers' costs and administrative burdens associated with both mandatory and voluntary reporting.

Additionally, the circumstances under which information is reported to the FDA is limited. For example, drug manufacturers are not required to report anticipated shortages when there is an unexpected, sudden spike in demand for a product. Also, as provided in the *CARES Act* (Sec. 3121), reporting of information to the FDA to prevent or mitigate medical device shortages is limited (i.e., certain notifications required "during, or in advance of, a public health emergency declared by the Secretary under section 319 of the *Public Health Services Act*"). Vizient encourages broadening the circumstances in which drug and device manufacturers report shortage-related information to the FDA.

Vizient also encourages providing the FDA with additional authorities, including:

- Providing the FDA authority to allow temporary importation of certain unapproved devices, so long as clinically appropriate and regulatory controls are adopted;

- In certain circumstances (e.g., with appropriate scientific data), the FDA should be authorized to permit devices to be distributed past their labeled shelf life to prevent or respond to shortages; and
- The FDA should also be granted additional authorities to conduct greater oversight of supply chain disruptions, 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.

Finally, in further support of efforts to create a more resilient supply chain, Vizient supports the FDA's efforts to pursue a rating system to help incentivize drug manufacturers to achieve Quality Management Maturity (QMM) at their facilities. Among other benefits, Vizient believes that manufacturers achieving QMM helps support supply chain resiliency and may help prevent drug shortages. Vizient supports this effort in particular and urges Congress to adequately fund FDA's QMM-related efforts.

**Hospital Preparedness Program (HPP)**

The Hospital Preparedness Program (HPP) provides funding through cooperative agreements to states, territories, and major metropolitan areas to help recipients plan for and respond to large-scale emergencies and disasters. The HPP is the primary source of federal funding for healthcare system preparedness, and several programs fall under the HPP umbrella, including Health Care Coalitions (HCCs).

Currently, the HPP program is coordinated at the federal level through the Administration for Strategic Preparedness and Response's (ASPR's) National Healthcare Preparedness Programs and Office of Strategy, Policy, Planning, and Requirements. However, operational decisions for the funding recipients (e.g., HCCs) are made at a local level, independent of federal guidance or standards. We encourage ASPR to provide additional guidance for the HPP program, particularly in the areas of program standards, training, materials, and data information gathering and sharing—and to include GPOs as a stakeholder in those efforts. GPOs play a critical role during times of crisis, sharing information on supply shortages and emergency response best practices. For example, during the COVID-19 pandemic, Vizient provided information to myriad federal agencies, including the White House, as both the Trump and Biden administrations addressed critical supply shortages, vaccine distribution, workforce challenges, shipping delays, and other emerging and persistent issues. This partnership was crucial in coordinating information, strategy, policy, and planning related to the country's preparedness and response efforts. A similar level of private-public coordination should occur with the HPP.

Further, during the COVID-19 pandemic, healthcare providers were required to submit data to various state and federal agencies, without standardized formats, terminology, or reporting structures. ASPR should work with the CDC, CMS, FEMA, and FDA, in addition to stakeholders with supply chain expertise such as GPOs, to identify and implement data standards, including supply chain and clinical data standards. Once such standards are identified, federal agencies and other stakeholders should develop efforts to coordinate adoption of standards and use those standards to ease provider and HPP funding recipient burdens.

More generally, Vizient encourages Congress to learn from the COVID-19 PHE and related reporting requirements of a range of stakeholders, including HPP funding recipients. To the extent possible and only when necessary, additional reporting requirements on HPP funding recipients and providers (e.g., CMS requirements through Conditions of Participation) should be

automated, there should be a single point of data entry, and provider burden should be heavily weighed when determining which information should be reported. Also, we encourage Congress to direct ASPR to convene stakeholders (e.g., HPP funding recipients, providers, GPOs) to identify opportunities to share federally reported information more broadly (e.g., with HPP funding recipients, including the HCCs and Regional Disaster Health Response System (RDHRS) pilot demonstration sites). For example, localized and actionable status reports that include federally reported information, when provided to the HCCs and the RDHRS pilot demonstrations, could help inform an appropriate, community or regionally specific disaster or emergency response.

*Health Care Coalitions*

HCCs are comprised of individual healthcare and response organizations in a defined geographic area, such as acute care hospitals, emergency medical service (EMS) providers, emergency management agencies, and public health agencies to prepare and respond to emergencies and disasters. The primary role of an HCC is to ensure each member of the coalition has the necessary information, training, equipment, supplies, and healthcare personnel to respond to emergencies and other events. There are 326 HCCs in local communities throughout the U.S., representing more than 42,000 individual member entities.

To the extent that it is feasible in a particular geographic location, Vizient recommends HCCs be encouraged to have a diverse body of public and private stakeholders (in addition to the healthcare providers and agencies listed above that are currently involved in the program) that are responsible for understanding supply shortages, staffing gaps, and patient load balancing in their regions. Importantly, GPOs should be considered as additional participants in these councils, given their substantial role in sourcing critical products for healthcare providers. In addition, HCCs should be encouraged to meet on a regular, ongoing basis to discuss preparedness needs, as there is currently not a standardized meeting cadence for the coalitions.

HPP funding for the HCCs is primarily funneled through state and territory governments, with the state or territory's government deciding the process for distribution and funding levels for each HCC in their state or territory. There are 62 HPP recipients, including recipients in all 50 states, 8 territories and freely associated states, Los Angeles County, Chicago, New York City, and Washington, D.C. Because each state or territory has a different process for awarding the HPP funding to HCCs, funding is not necessarily distributed in a standardized, equitable manner among HCCs across the country. Vizient recommends that states and territories solicit direct provider feedback and engagement on HCC fund distribution. We also suggest the federal government conduct a study on how the HPP funding is being distributed and update guidance on HPP funding allocations.

**Regional Health Care Emergency Preparedness and Response Systems (RHCEPRS) Program**

In addition to the HCCs operating at a local level, four Regional Disaster Health Response System (RDHRS) pilot demonstration sites, established by ASPR under RHCEPRS guidelines, coordinate regional hospital preparedness and response. These pilot demonstration sites develop multi-state partnerships, connecting local healthcare coalitions and trauma centers and integrating local medical response capabilities with emergency medical services, burn centers, pediatric hospitals, labs, and outpatient services to meet the healthcare demands created by disasters. Currently, the guidelines for the RDHRS pilot programs designate a list of entities that

must be included as partners in these demonstration projects. For example, the list includes hospitals, healthcare facilities, political subdivisions, and emergency medical service divisions. Additional entities are allowed (to be determined by the individual RDHRS pilot demonstration site) to facilitate regional emergency response, but the guidelines would be strengthened if examples of additional partners were provided. Vizient recommends that GPOs be added as an example of an additional partner to be considered as a participant in these regional pilot demonstrations because of their unique role in sourcing critical supplies, as well as advising healthcare providers on operations, supply chain assurance needs, and emergency preparedness actions.

**Strategic National Stockpile (SNS)**

*Updating the FDA Essential Medicines List*

In response to Executive Order 13944, the FDA created the Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs List (Essential Medicines List). This list is a critical tool in preparing the nation for future emergencies, such as pandemics; however, to date, the FDA has not published a methodology to update this list in the future. Updates to lists identifying essential medicines are critical in supporting patients and preventing harm should supply chain disruptions or other challenges occur. For example, Vizient's Essential Medications List is updated on a quarterly basis. Further, Vizient's Essential Medications List has evolved to include everyday essential medications (i.e., acute treatment drugs with no alternatives, chronic treatment drugs with no alternatives, high impact drugs, pediatric drugs, and antibiotic resistance drugs), antidotes, and life-saving cancer treatments, whereas the current FDA list is, generally, those most needed for patients in acute care medical facilities. The FDA's Essential Medicines List could be further improved upon to better reflect potential supply challenges and unique patient populations, such as pediatrics. Vizient recommends Congress pass legislation that would require the FDA to publish a process to routinely update the agency's Essential Medicines List. Future updates to the FDA's Essential Medicines List should be based on input from healthcare providers, manufacturers, GPOs, and other key stakeholders and subject matter experts.

*Inventory Gaps*

Per a recent GAO report, *Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks*, the budget for the SNS has been inadequate to close inventory gaps ("to purchase enough Medical Countermeasures (MCM) to meet all recommended quantities for the stockpile, the annual cost would be billions of dollars higher than the SNS's current budget allocation"). To address this inventory challenge, Vizient recommends ASPR be directed to convene with public and private stakeholders, including GPOs, to identify strategies to manage risks associated with gaps between recommendations and its SNS inventory. Vizient also recommends ASPR be authorized to explore contracts that require manufacturers to maintain minimum levels of stock for ready access when needed—as opposed to physical control over such products—to help bridge inventory needs.

Vizient also encourages collaboration between the SNS and the private sector, particularly as its inventory and supply chain are reviewed. GPOs, such as Vizient, can provide unique expertise and insights to help inform SNS decisions. Further, we suggest the SNS establish systems to support secured information sharing regarding supply chain inventory and related supply decisions, as this will help enable the private sector to complement the efforts of the SNS during an emergency.

## Additional Policy Recommendations for All-Hazards and Emergency Preparedness

### Mitigating Drug Shortages

*Prioritizing Review of Generic Drugs to Prevent Shortages*

Currently, as provided in the FDA's *Manual of Policies and Procedures* (5240.3, Prioritization of the Review of Original ANDAs, and Supplements), the agency may prioritize review of generic drug applications under certain circumstances, including if the submission relates to a drug shortage or PHE. While such flexibility helps to address shortages during challenging circumstances, this policy could be improved if anticipated drug shortages could also lead to prioritization. A more proactive approach could help manufacturers increase supply in advance of a shortage, mitigating disruption to healthcare providers. Further, such approval in advance of a shortage may help ease provider concerns that arise in advance of an upcoming shortage. Vizient recommends Congress provide policy to support the FDA's ability to prioritize review of generic drug applications in advance of an anticipated shortage.

### Improving Emergency Care Delivery

In addition to the programs mentioned above that were established through previous PAHPA legislation, Vizient encourages Congress to consider other proposals that will ease healthcare provider burden and improve care delivery during an emergency. For example, during the COVID-19 PHE, providers were given additional flexibilities to provide care in non-traditional settings and via telehealth. While several of these flexibilities have been extended, others have not. Vizient encourages Congress to direct the Department of Health and Human Services (HHS) to work with stakeholders to identify which flexibilities that have not been made permanent should be made available during an emergency. Such information would help with emergency planning, as providers would have more predictability regarding the regulatory framework that would govern them during future emergencies.

Also, as demonstrated during the COVID-19 PHE, and as recognized by Congress in creating the Provider Relief Fund, providing care during an emergency involves significant additional resources and expenses that are not typically included in standard payer (including Medicare) arrangements. As a result, Vizient encourages Congress to consider establishing additional financial resources to healthcare providers that would be available during an emergency to help ensure that access to care is not threatened.

*Workforce Shortages and Provider Burnout*

As COVID-19 demonstrated, an already strained healthcare workforce faces immense, additional challenges during prolonged emergencies. It is critical that Congress look for any opportunity to strengthen our healthcare workforce—and PAHPA provides an opportunity to recognize and address the current workforce crisis that has resulted from three years of pandemic response. Specifically, Vizient recommends:

- Additional funding to support provider mental health and reduce provider burnout;
- Licensure flexibility during emergencies;
- Resources and funding to improve hospital security and safeguard against threats and violence towards healthcare workers;
- Expanding access to unused immigrant visas for essential medical professionals;

- Authorizing additional Graduate Medical Education (GME) slots—Vizient supports legislation that would add an additional 14,000 GME slots over seven years; and
- Support for expanded nurse faculty training programs.

*Extraordinary Circumstances Exception*

Vizient recommends allowing HHS to trigger an extraordinary circumstances exception (ECE) for CMS quality reporting whenever a federal emergency is declared under any authority. In the case of natural disaster-related emergencies, this would create a separate process for hospitals to use to report that they are operating under an ECE, with less paperwork and documentation needed. The ECE would remain in place through the duration of the emergency unless the Secretary of HHS, Administrator of FEMA, or other designated federal official determines that the need for the ECE has passed. This additional process for ECE waivers would not replace the current process, but rather supplement it in times of significant hardship for hospitals.

## Vizient's Top Three PAHPA Policy Recommendations

Per the Committee's request, and discussed in more detail above, Vizient recommends the following three categories as our top policy priorities:

1. Increased supply chain assurance
2. Hospital preparedness funding and coordination
3. Strategic National Stockpile improvements

## Conclusion

We thank you for your continued leadership and engagement with stakeholders to prepare for the reauthorization of PAHPA. Vizient is pleased to offer our recommendations, and we appreciate your ongoing commitment to improving the nation's emergency preparedness and response. We look forward to seeing any proposals that may stem from the RFI and hope to continue serving as a resource for your efforts.

Please do not hesitate to contact me at shoshana.krilow@vizientinc.com or 202-354-2607 if you have any questions about Vizient or if there is any way we can be of assistance as you move forward in reauthorizing PAHPA.

Sincerely,

Shoshana Krilow
Senior Vice President, Public Policy & Government Relations