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December 4, 2020

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Public Health Focused Essential Medicines, MCM and Their Critical Inputs List to Address Section 3(c) of EO 13944 (FDA-2020-N-2123-0001)

Dear Commissioner Hahn:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) recently published Essential Medicines list.[1] Vizient applauds the FDA for its hard work and rapid development cycle in creating this Essential Medicines list since the President's Executive Order in August.[2] Like the FDA, we recognize the need to work proactively to identify medicines that are most needed for patients in U.S. acute care medical facilities. Vizient also appreciates FDA's efforts to identify medical countermeasures and critical inputs. We offer the following responses for FDA's consideration as it continues to identify Essential Medicines, Medical Countermeasures and their critical inputs to help protect against outbreaks of emerging infectious diseases, as well as chemical, biological, radiological and nuclear threats.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual group purchasing volume, to improve patient outcomes and lower costs. Both prior to and during the pandemic, Vizient has focused a significant amount of its sourcing, clinical, and analytics expertise on improving the resiliency of the supply chain to sustain access to high quality, essential medications. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

[1] https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs
[2] https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/

Comments

Do you have any feedback on the criteria developed by the FDA for inclusion of essential medicines, medical countermeasures, or their critical inputs on the list required by Executive Order 13944?
Vizient is deeply appreciative of FDA's effort to clarify criteria for inclusion on its Essential Medicines list through the document, "Criteria For Identifying Human Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order (EO) 13944". In the document, FDA identifies general criteria for inclusion on the list but does not detail the process by which those decisions about the criteria are made and how the criteria are applied. Like FDA, Vizient also maintains an Essential Medications List, first published in January 2020, with an established process to add or remove items as warranted. While Vizient's list focuses on essential medications in the context of a hospital/health system setting, we take a multifaceted approach to reviewing and updating the drugs included, which could be helpful for FDA to consider. Vizient's pharmacy team initially generated our essential medications list through a comprehensive review of the World Health Organization's (WHO) Essential Medicines list, the Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) algorithms, and medications included in Vizient member health systems' critical drug lists. To help stakeholders better understand and potentially contribute to FDA's efforts, Vizient encourages the agency to provide more information regarding which sources of information are used to update the list and that the agency gains feedback from stakeholders, particularly those with a clinical perspective.

Regarding medical countermeasures, as seen with the COVID-19 pandemic, certain medications and devices will be used more routinely together. Currently, the list is not designed in a way to inform stakeholders which products are interdependent of one another, and under which circumstances they are most likely to be utilized. Vizient believes this additional information would help stakeholders better understand and plan for future emergencies more effectively. Further, to the extent this information is adopted by other government entities' stockpiles, Vizient also recommends making that information available.

Vizient applauds FDA for including critical inputs as a portion of the list. As noted by FDA, critical inputs for essential medicines and medical countermeasures include active pharmaceutical ingredients (APIs), certain starting materials and other materials that satisfy the definition of "Critical Inputs" provided in the Executive Order. To the extent practicable, Vizient recommends FDA work with manufacturers and API suppliers to provide more information about the source of products (including the location of manufacturing) and to include that information on the FDA's list. Such information is critical in identifying potential vulnerabilities in the supply chain given the sources of API can be relatively limited. Therefore, a threat to API sources can also threaten access to medications. Currently, this information is not easily ascertained. While Vizient has made efforts to learn more about the origin of source materials, FDA's reach and role could help enhance and streamline these efforts.

Are there any additional essential medicines, medical countermeasures, or critical inputs you believe should be included on the list or ones you think should be removed and why?
Vizient compared FDA's Essential Medicines list with our list[3] and identified significant overlap.

[3] https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/essential_meds.pdf

For example, Vizient found 115 common medicines between Vizient's list (226 total line items) and FDA's list (242 total line items). However, not all medicines on Vizient's list were included by FDA. Vizient believes this variation is because Vizient's list addresses direct needs of the pediatric community (e.g., injectable indomethacin, injectable aprostadil) as well as long term, chronic essential needs (e.g., oncology – vincristine, vinblastine, asparaginase). With Vizient's list being developed from a different point of view than FDA's list, we welcome the opportunity to share additional insight regarding these vulnerable patient populations and the perspectives of the hospital and health system community. As such, Vizient encourages FDA to consider Vizient's most recent list for future consideration by FDA for future revisions. Vizient welcomes the opportunity to meet with FDA to further discuss these items and to identify a process to help inform FDA's work as Vizient's essential medicines list is updated quarterly.

Do you have any feedback on how frequently, and by what type of process, the list should be evaluated to determine the need for any additions or removals?
Vizient is sensitive to the needs of health care providers and the importance of them being aware of potential access issues immediately, and when possible, before they occur. However, we also recognize the tremendous amount of work that needs to be done to update these lists and the need for a regular cadence to help inform stakeholders. Currently, Vizient updates our list on a quarterly basis by reviewing changes to critical clinical practice guidelines and through receipt of direct member feedback regarding products that should be added or deleted.

While Vizient and our members utilize our list for various purposes, those needs have helped inform our decision to update it quarterly. Given the range of stakeholders who may utilize FDA's list, Vizient believes it is important FDA work with different stakeholders to identify how the list may be used to help protect Americans. Once this information is learned, stakeholders could better identify the approaches to updating the list based on different uses.

Lastly, as noted above, Vizient encourages FDA to gain stakeholder feedback regarding how it updates the list and how the agency will use the list going forward. Vizient uses the list to prioritize its strategic sourcing initiatives. Therefore, it would be helpful to understand how FDA will use this tool to direct its drug shortages initiatives, among other potential uses. Also, Vizient encourages FDA provide more clear information regarding the types of data the agency considers when it updates the list and for the agency to consider potentially convening an advisory committee to help inform the agency's decisions. Vizient would welcome the opportunity to support FDA in these efforts.

The unprecedented impact of the COVID-19 pandemic will resonate for years. FDA has taken bold steps to help support hospitals across the country during this crisis, including its efforts to develop an essential medicines list. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Sincerely,

Shoshana Krilow
Vice President, Public Policy & Government Relations