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Statement for the Record

Submitted by

The Premier healthcare alliance

An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

Senate Committee on Health, Education, Labor and Pensions

March 3, 2020

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Health, Education, Labor and Pensions (HELP) Committee hearing titled "An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus." We applaud the leadership of Chairman Alexander, Ranking Member Murray and members of the Committee for examining how the federal government can better equip the nation for responding to the coronavirus.

Premier Inc. is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 175,000 non-acute providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier works around the clock with the nation's hospitals and other healthcare providers, suppliers, distributors and federal and state agencies to ensure products get into the right hands so every patient gets the care they need. Given Premier's unique position in the supply chain as an extension of America's healthcare providers, we understand firsthand the impact to patient care when hospitals and health systems do not have access to the drugs and medical supplies needed to treat patients. The coronavirus outbreak underscores what Premier has been advocating for the better part of a decade – that the U.S. must be more forward-looking and strategic about our supply chain. When the system works, no one thinks about it, but in an outbreak, vulnerabilities are on display.

Premier has been a longstanding advocate for supply chain diversity and resiliency, taking lessons learned from disasters and past outbreaks such as Ebola and H1N1. Creating permanent solutions to ensure a reliable supply of drugs has been the mission of Premier since day one. We need, however, policy changes for us to continue to succeed in our work. It is critical that Congress act now to proactively address known supply chain vulnerabilities.

Congressional Action is Needed to Address Supply Chain Vulnerabilities

In the face of emerging public health crises, such as what we saw with H1N1 and Ebola, and potentially now with coronavirus, Congressional action is imperative to prevent gaps in vital medical supplies. To truly address supply chain vulnerabilities, additional transparency is needed to understand the risk of supply interruption. Creating incentives for domestic manufacturing is also urgently needed to ensure a steady supply of vital drugs and medical supplies, such as N95 masks, are available for patient care. These are common-sense, market-based, holistic, and sustainable solutions that Congress can enact.

Preventing Drug Shortages

Premier supports the ***Mitigating Emergency Drug Shortages (MEDS) Act (S. 2723)*** introduced by Senators Susan Collins (R-ME) and Tina Smith (D-MN). Supported by over 75 provider organizations and health systems, the MEDS Act builds upon the prior work of Congress to provide additional authority to

the Food and Drug Administration (FDA) to help mitigate drug shortages and develop market-based incentives to help ensure a stable supply of medications critical for patient care.

A major concern with the COVID-19 outbreak in China is the overreliance on overseas production as well as in some cases a single nation for a significant portion of the United States' drug supply. The MEDS Act helps address this overreliance by requiring the Secretary of Health and Human Services (HHS) to develop a report to Congress with recommendations to incentivize the domestic manufacturing of finished dose formulations and active pharmaceutical ingredients (API). The MEDS Act also examines the risk to national security.

A lesson learned from Hurricane Maria is the lack of transparency regarding where critical drugs are manufactured, the source of API, and redundancy plans. The MEDS Act addresses this blind spot by requiring manufacturers to report to the FDA the exact location of manufacturing for these critical drugs, the exact source of all raw materials, and redundancy and contingency plans to ensure a stable supply. In the case of coronavirus, this type of information would be critical to understand exactly what is being manufactured in China, exactly what proportion of API and raw materials are manufactured in China, and what a manufacturers' contingency plans are should manufacturing in China no longer be feasible. This is all critical information to understand the true risk to the supply chain and potential drug shortages due to pandemics such as coronavirus.

Another major unknown currently is the downstream impact of any potential API shortages as a large portion of the world's API is manufactured in China. Currently, API manufacturers do not have to report supply disruptions to the FDA. The MEDS Act would expand FDASIA Title X reporting requirements to API manufacturers and require reporting of potential supply disruptions to the FDA, creating an early warning system that would allow the FDA upstream visibility to appropriately assess risk and rapidly work to identify alternative sources of supply.

Ensuring access to medical devices and supplies

Premier has also been working around the clock to ensure a consistent supply of medical supplies for U.S. healthcare workers, including personal protective equipment (PPE). We have been actively engaged with the FDA and the Centers for Disease Control and Prevention (CDC) to track developments and offer guidance, providing real-time data on ordering patterns, current consumption rates and future demand forecasts in order to inform our government's understanding of the current state and potential future vulnerabilities.

Premier recently ***conducted a survey[i] of our health system members*** and found:

- A three-fold increase over historic N95 mask purchasing and extensive backordering of necessary supplies, with most facilities only receiving about 44 percent of the masks they order.
- Because of limited imports from abroad, 36 percent of U.S. hospitals and health systems are preparing for broad-scale shortages and 54 percent have initiated conservation protocols to stretch supplies on hand. Meanwhile, 8 percent of respondents said at least one of their necessary personal protective supplies had dwindled to the point where they may have to consider cancelling certain elective surgeries.
- However, domestic manufacturers have also surged their production, and once full capabilities are reached, there should be an adequate mask supply, provided there are no further supply chain disruptions or a widespread outbreak in the United States.

Premier has provided these survey results to the FDA and CDC to help them better understand the current situation and prepare our nation's response to coronavirus. One crucial step Congress can take now is to arm the FDA with similar authority to act for medical device and other supply disruptions and shortages as they do in the drug space. As FDA articulated in the agency's FY 2020 budget request,

there is no statutory requirement for medical device manufacturers to notify FDA when they become aware of a circumstance that could lead to a device shortage. Creating such a requirement, as currently exists for drug manufacturers, would ensure that FDA has timely and accurate information about likely or confirmed national shortages of essential devices to enable FDA to take steps to promote the continued availability of devices of public health importance. Specifically, FDA requested authority to:

- Require firms to notify FDA of an anticipated significant interruption in the supply of an essential device;
- Require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and
- Authorize the temporary importation of devices whose risks presented when patients and healthcare providers lack access to critically important medical devices outweigh compliance with U.S. regulatory standards.

In addition to these FDA requests, Premier also recommends Congress require device manufacturers to report to the FDA the source of all raw materials, the exact location of manufacturing, the exact location of packaging, and the exact location of sterilization to provide a transparent and accurate picture of supply chain vulnerabilities.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate HELP Committee's hearing on the U.S. response to the coronavirus. As an established leader in the healthcare supply chain, Premier is available as a resource and looks forward to working with Congress as it considers policy options to continue to address this very important issue. If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.

[i] Premier's survey was conducted from Feb. 18- Feb. 26, 2020, and sent to a representative portion of the Premier membership. Approximately 300 hospitals provided responses. Additional information on backorders and ordering patterns was also collected from national med-surg distribution companies, as well as Premier's own purchasing data.