June 12, 2023

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

Re: Request for Information and Comments on the Development of an FDA Data and Technology Strategic Plan [Docket Number: FDA-2023-N-1052]

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) in response to the request for information and comment regarding the development of an *FDA Data and Technology Strategic Plan [Docket Number FDA-2023-N-1052].*

Premier applauds the FDA for embarking on an iterative approach to strategy development, starting with gathering stakeholder input via this comment opportunity, and then committing to share a draft of the strategic plan for further comments later this year. Premier looks forward to working with the FDA to build out this strategy and build upon the existing FDA Modernization Framework.

Premier believes this strategic plan can help drive a more integrated, streamlined environment for industry and better facilitation of data technology to treat diseases faster, create more effective practices and achieve better outcomes. An integrated approach to data and technology will help address critical issues such as drug and device shortages, patient privacy concerns and development of innovative health solutions. As outlined below, Premier has identified technologies and/or methodologies that can support solutions to these concerns and could be adopted into the strategic plan to advance FDA's overall mission. For example:

- Integration of Data Technology to Address Drug Shortages - Premier has worked extensively with our healthcare and federal partners to address drug shortages across the supply chain. Our experience with the public health emergency over the past few years has strengthened our data and analytical capabilities in this space. Premier believes it is critical to create robust, timely and transparent data to predict supply levels, product burn rates and sourcing challenges as well as the ability to pivot distribution response and share this vital information in a timely manner across the supply chain.

- Supply Chain Visibility - In addition to creating robust and timely data, Premier believes that there are gaps in transparency regarding potential medical device and product shortages. Automating manufacturer data collection and notifications will help address data reliability and quality issues, and thus improve trust in the data.

- Efforts to Improve Medical Device Cybersecurity - As the FDA develops its Data and Technology Strategic Plan, Premier believes it is important to highlight the need for final guidance related to cybersecurity of medical devices. The use of these devices is growing quickly, and it is vital to clarify security requirements for devices and comparative accountability for various entities.

- Use of Real-World Evidence to Inform Regulatory Decision Making - Premier recognizes that real-world data (RWD) and real-world evidence (RWE) are increasingly being utilized to inform regulatory submissions. Premier believes this data does provide actionable insights that improve research and accelerate the process of bringing new innovations to patients. However, Premier believes it will be important for the FDA to: 1) implement a transparent RWD and RWE screening process; 2) incorporate detailed guidance and protocols regarding selection of RWD sources; and 3) detail how RWD/RWE is applicable to specific areas of the strategic plan.

I. BACKGOUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters, and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products.

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. DATA AND TECHNOLOGY STRATEGIC PLAN RESPONSE

In response to FDA's request for comments regarding development of its Data and Technology Strategic plan, Premier has structured its comments into sections that highlight and address issue areas that are critical to modernizing and improving data and technology in healthcare. Leveraging our knowledge and expertise in data and technology solutions, Premier has laid out suggested solutions and methodologies in each area below. Premier believes there are numerous opportunities to modernize technology efforts and improve outcomes through a collaborative and transparent effort.

i. Integration of Data Technology to Address Drug Shortages

Premier has been a leader in addressing drug shortages for more than twenty years and is committed to eliminating drug shortages from both a policy perspective via legislative and regulatory action as well as pursuing market-based solutions. Premier's ProvideGx program identifies safe, high-quality supply sources for drugs that are or may be at risk of being added to the national drug shortage list. Guided by more than 1,600 hospitals across the nation, Premier's ProvideGx program creates long-term committed buying contracts that provide participating manufacturers with the surety needed to increase production. Premier's programs, including ProvideGx, currently provide hospitals access to more than 150 drugs that are or have been recently designated as shortage drugs.

Since 2020, Premier's drug shortage programs have:

- Successfully resolved 14 drug shortages, resulting in their official delisting from the FDA shortage list;
- Ensured uninterrupted supply of many shortage drugs despite demand spikes of more than 150 percent during the pandemic; and
- Continued to bring resiliency to the market by incenting the domestic manufacture of vital drugs through investments in VGYAAN and Exela Pharma Sciences, which combined are working to bring new, domestic sources of 20 different shortage drugs and counting.

Accurate demand signals and early indicators of potential disruption are vital to greater visibility and enabling a stronger supply chain. At Premier, we leverage fill rate trends as one mechanism to help determine the health of the supply chain. For drugs, Premier considers a healthy fill rate to be above 90 percent, and anything that falls below 80 percent is an early indication that demand is outpacing supply and that shortages may be imminent.

Monitoring fill rates and other robust data using CognitiveRx® – a comprehensive drug shortage risk management and communication platform containing hundreds of millions of proprietary and open-source data points spanning more than 30 years – Premier provides early communication to both our members and government stakeholders on potential or impending shortages of any healthcare product.

Notably, and following the Premier team's engagement in early spring 2022 to share data and report the contrast media shortage, contrast media was added to the FDA's shortage list – paving the way for waived prior authorizations and improved patient access. In addition, for two years during the height of the pandemic, Premier voluntarily shared fill rate data with the FDA for 250 drugs used in the treatment of COVID-19 to help monitor for any potential supply chain challenges.

The answer to this problem is greater end-to-end visibility, enabling the FDA and other federal agencies to understand risk potential and work with private sector partners to make adjustments long before a crisis occurs. These needs can be addressed through the creation of robust, timely and transparent data to predict supply levels, product burn rates and sourcing challenges as well as the ability to pivot distribution response and share this vital information in a timely manner across the supply chain.

PINC AI™ technology and predictive analytics can help stakeholders predict demand surges and product shortages far in advance with over 90 percent accuracy. This enables them to see changes occurring in the market around them, and ahead of them, in ways never before possible. Honing capabilities through intelligence from signals in sourcing and fulfillment, today providers are leveraging actionable data to pinpoint market signals for early drug shortage detection and management – and plan and communicate medication strategies in advance with all caregivers.

For example, in the future, in lieu of waiting for manufacturers to report a supply disruption to the FDA, the FDA should be leveraging data to proactively identify potential shortages and proactively work to mitigate the shortages well before a reporting requirement is ever triggered. By leveraging data assets, the FDA can place itself in the driver's seat of proactively addressing shortages. Therefore, ***Premier urges the FDA to ensure that its strategic plan incorporates the compilation of public and private data sources to conduct predictive modeling and proactively monitor for shortage signals***. ***Furthermore, the FDA should work alongside public and private partners to leverage existing shortage algorithms and train them to be more predictive, rather than attempting to build new algorithms from scratch that will take significant resources and time to mature.***

ii. Supply Chain Visibility

COVID-19 exposed weaknesses in the U.S. supply chain and the country's overdependence on medical supplies, devices, and components imported from overseas. Shortages persist today and span a variety of categories, including supplies essential for patient care such as blood collection tubes, contrast media and more.

The FDA device shortages authority from the CARES Act required certain medical device manufacturers to provide information to the FDA on product availability, and on potential meaningful supply chain disruptions, during or in advance of a PHE. Premier continues to advocate for that statutory authority to be revised to require notifications from manufacturers any time there is the potential for a device shortage (similar to the FDA's broader authority for drugs) - and not just during or in anticipation of a PHE.

A vital component of end-to-end supply chain visibility is an on-call data infrastructure that the U.S. can summon at any time to manage a large-scale emergency. The nation needs data that comprehensively tracks critical product availability, from manufacturers, distribution, stockpiles, and hospital inventory. This makes possible accurate inventory management, dynamic allocation, and a data-driven approach to ramping up supply via mechanisms such as the Defense Production Act. Not only will a solid data infrastructure help providers and manufacturers anticipate product demand, but it will also allow the nation to better manage supplies during a crisis by providing advanced alerts of demand signaling and inventory levels, and enabling rapid movement of product to points of care.

Building an effective data infrastructure should start with a focus on leveraging existing technology and automation capabilities to enable a more seamless reporting process. Automating manufacturer data collection and notifications will help address data reliability and quality issues, and thus improve trust in the data. Medical device data standards can also support interoperability and information exchange across the care continuum.

Therefore, ***Premier urges the FDA to ensure that its strategic plan incorporates the development of a near real-time supply chain data infrastructure to help determine the location and quantity of critical medical supplies and pharmaceuticals on U.S. soil.*** Currently. Congress is considering a bipartisan bill, H.R. 3577 – The Medical and Health Stockpile Accountability Act, that would create a similar data infrastructure.

iii. Efforts to Improve Medical Device Cybersecurity

Alongside technology innovations and the frequent electronic exchange of health information, cybersecurity for medical devices and equipment has become a top priority for healthcare providers. Life sustaining medical devices, such as ventilators and infusion pumps, are now connected wirelessly to a variety of systems, networks and other tools within a hospital – ultimately contributing to the Internet of Medical Things (IoMT) and presenting potential points of breach as well as incremental costs and operating risk to providers.

Patient care disruptions and safety issues related to medical device security vulnerabilities are a critical concern as the number of IoMT medical devices is expected to skyrocket from 10 billion to 50 billion over the next decade.[1] These cyberattacks not only threaten patient privacy and clinical safety and outcomes, but also a hospital's financial resources. According to a recent report, the average breach costs in

[1] Musumeci, Beth and Ramsey, Ralph and Brennan, Stephen and Fraser, Heather. "Medical Devices are Vital, but Vulnerable." IBM Institute for Business Value, https://www.ibm.com/thought-leadership/institute-business-value/report/medical-device-security

healthcare surpassed $10 million in 2022, with the industry maintaining its top rank for costliest industry breaches for the 12th consecutive year.[2] Alongside direct costs related to a breach, providers may see added costs in hardware, software, firmware and labor.

It is vital that manufacturers incorporate and sustain industry-identified cybersecurity best practices and data management controls over the reasonable economic life of IoMT devices and equipment. Hospitals today are taking critical security steps to safeguard clinical technologies, information systems and their network environment(s) while enhancing data protection capabilities – but cooperative and accountable action with manufacturers is necessary to further reduce cyber vulnerabilities and the unsustainable costs they drive.

Cybersecurity risk management for medical devices is a shared responsibility among manufacturers and healthcare providers to address patient safety risks and ensure proper device performance. Historically, however, several factors have introduced and sustained ambiguities in this accountability, including misaligned expectations on cybersecurity controls and management throughout a device's lifecycle, which is often ill-defined by the manufacturer. A lack of clear manufacturer-defined guidance on security requirements for devices, both new and old, is particularly problematic for providers when considering the comparative accountability for risk associated with non-compliance.

Beginning to reconcile these issues starts with strong partnerships between manufacturers and health systems to ensure cybersecurity objectives and expectations are clearly outlined and agreed upon within the larger context of a sustainable economic environment. As a regulator, the FDA has a leadership role in creating expectations that manufacturers will proactively minimize risk by building cybersecurity into products by design, providing security tools to health systems, and updating and patching devices as new intelligence and threats emerge.

Under current regulations, manufacturers of newer devices must disclose vulnerabilities as they are discovered, but older legacy devices remain a critical vulnerability. Given their useful lifespans, many legacy devices were not built with cybersecurity in mind and may use outdated or insecure software, hardware and protocols – making them difficult to patch and leaving them vulnerable to attack.

While cybersecurity incidents are a continual threat to the U.S. healthcare industry, healthcare providers, medical device manufacturers, lawmakers and regulators have made considerable progress in defending networks, securing data and protecting patients. With greater collaboration, predictability and consistency in cybersecurity management, together we can make even greater strides toward patient safety and a more secure and sustainable healthcare system.

Premier encourages the FDA to expeditiously finalize guidance documents related to cybersecurity of medical devices to quell any confusion regarding their applicability and enforceability, as well as ensure sufficient staffing and expertise to help enforce this guidance. Cybersecurity guidance should be incorporated into the strategic plan.

iv. Enhancing the Use of Real-World Evidence to Inform Regulatory Decision Making

Real-world data (RWD) and real-world evidence (RWE) are increasingly being utilized to inform regulatory submissions and provide actionable insights that improve research and accelerate the process of bringing new innovations to patients. For example, Premier is currently engaged in a study relating to asthma exacerbation management and plans on leveraging validated RWD for both intervention and control arms

[2] "Cost of a Data Brach Annual Report." IBM Security, https://www.ibm.com/reports/data-breach 2022

to assess the patient outcomes of interest, which will significantly reduce the data collection time and reflect patients' real-world experience.

While this development is exciting, it comes with various complexities, including how to access the quality of RWD and RWE, how to validate the sources of data, and how to ensure appropriate methods are used in analyzing the data. It would be extremely helpful for the FDA to implement a transparent RWD and RWE screening process and incorporate detailed guidance and protocols regarding selection of appropriate real-world data sources and specific areas and phases of application of RWE/RWD into the strategic plan. Specifically, the following areas require clarity:

- Utilize Existing Commercialized Databases - It is important to use accurate, standardized, and timely data when RWE is used in FDA applications. Many commercially available databases, including the PINC AI™ Healthcare Database, have been widely used by academic and industrial researchers for decades, which provide a rich source of information. As a regulator, FDA can establish a process to access these databases on the market and provide insights on the advantages and limits of each database and make the information available to the public. It would significantly reduce the amount of preparation work from the applicants to establish the validity of data sources.

- Clarifying and Expanding the Use of RWD/RWE - While clinical trials are considered the gold standard, RWD provides a view on a broader and more diverse patient population. The cost and time to access RWD is minimal compared to clinical trials. When a clinical trial is not possible, such as in rare disease cases or surgical procedures, RWD provides an alternative to clinical trials. In other cases, RWD can be used to supplement clinical trials to give a better understanding on patient populations in the real world. When combined with clinical trial research, it can help researchers uncover early risk of disease, allow health systems to take a more proactive treatment approach and use the data to drive provider behavior change to be more in alignment with the latest evidence and guidelines.

  It is important for FDA to provide guidance on the disease or therapeutic areas where RWD/RWE may be particularly helpful and can be used in lieu of clinical trials. Additionally, among the applications involving clinical trials, it will be beneficial for FDA to provide recommendations on how to incorporate RWE as part of the application package. Examples may include the use of RWE in pragmatic clinical trials, the application of RWE in safety reporting, and the adoption of RWE in Phase IV studies.

- Utilize The Existing RWD/RWE Capacities for Device-Related Evaluation - There is currently a wide gap of knowledge regarding medical device effectiveness and safety in comparison to medications due to the differences in regulatory requirements. However, Premier believes it is just as important to assess the effectiveness and safety of medical devices to improve patient outcomes and save lives. One major challenge that the research community studying medical device-related outcomes is facing is the lack of accurate data in identifying different medical devices used in patient care. Establishing a robust device coding system that can be incorporated into the electronic medical record (EMR) system will enable researchers to assess the outcomes related to each specific device more accurately.

Premier supports FDA's recognition of the importance of gathering RWE to gain insights into safety, efficacy, patient outcomes and cost-effectiveness of drugs and biologicals and encourages the FDA to incorporate the use of RWE into future pathways. Premier also encourages the FDA to implement a RWD data source screening and certification program to help identify high quality RWD datasets

that can be used to support regulatory decision-making. Lastly, Premier advocates for the establishment of a robust medical device coding system to enhance medical device research.

III. Conclusion

In closing, Premier appreciates the opportunity to submit comments on the development of the *FDA Data and Technology Strategic Plan.* Premier looks forward to continuing to work with the FDA to support and advance the future course of FDA's data and technology capabilities.

If you have any questions regarding our comments or need more information, please feel free to contact me at Soumi_Saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.