PREMIER TRANSFORMING HEALTHCARE TOGETHER®

October 19, 2023

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, D.C. 20510

Submitted electronically to: CDCModernization@help.senate.gov

Re: Request for Information on Modernizing the Centers for Disease Control and Prevention (CDC)

Dear Senator Cassidy:

Premier Inc. applauds your leadership and ongoing commitment to improve our nation's public health and preparedness infrastructure through the release of a request for information (RFI) on how to best improve, reform and modernize the Centers for Disease Control and Prevention (CDC). Premier further appreciates your thoughtful approach to seek stakeholder input in the development of policy proposals and the acknowledgement that collaboration across the public and private sectors is essential to ensuring the nation's readiness.

The existence of the CDC during the COVID-19 pandemic was instrumental in supporting the nation's rapid response, and as a nation, we would have been in a much worse situation had CDC's infrastructure not been available. However, the experience of the COVID-19 pandemic, and subsequently the Mpox public health emergency, demonstrated that there are opportunities to strengthen the CDC to be better responsive to public health needs during unprecedented times.

In our comments, Premier reflects on the lessons learned during COVID-19 and Mpox response efforts and provides recommendations to address the most critical public health challenges that demand increased attention. Specifically, Premier recommends strengthening our ability to respond to public health challenges by:

- Ensuring coordination among the various government agencies leading public health emergency response efforts;
- Leveraging technology to conduct syndromic surveillance to predict community outbreaks, prevent and control infections and automate tracking and reporting the spread of disease;
- Proactively facilitating collaboration between the public and private sectors;
- Broadening and better organizing lab networks; and
- Continuing to leverage private sector healthcare data to conduct robust research on the short-term and long-term impacts of infectious diseases on public health.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 300,000 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 stakeholders 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. LEADERSHIP STRUCTURE AND "MOVING FORWARD" REORGANIZATION

Clear Delineation of ASPR's Role

A Health and Human Services (HHS) review of the CDC's handling of the COVID-19 outbreak prompted then-CDC Director Walensky to acknowledge that the agency "did not reliably meet expectations" and to embark on an overhaul of the agency's operations and culture. While this is a positive step in the right direction, it is critical that Congress reflect on the entirety of the federal government's approach to the pandemic and solidify oversight and management structures to ensure a cohesive federal response for future public health emergencies.

In the case of the national response to COVID-19, the array of responding federal and state agencies had little insight into what their counterparts were doing, leading to overlaps, conflicts and duplication. In 2022, the Assistant Secretary for Preparedness and Response was elevated to an operating division within HHS and retitled the Administration for Strategic Preparedness and Response (ASPR). As part of this change, it was noted at the time that ASPR "leads the nation's medical and public health preparedness for, response to, and recovery from disasters and other public health emergencies." Seemingly, this indicated that ASPR would take point on future pandemic response and alleviate much of the confusion that existed during the early days of the COVID-19 pandemic regarding which federal agency was leading response efforts.

However, shortly after ASPR's elevation, a public health emergency for Mpox was declared. While many anticipated that ASPR would be named to lead response efforts given its newly elevated role and mission, it surprised many when officials from the Federal Emergency Management Agency (FEMA) and CDC were named as the primary and secondary leads for the Mpox response.

Furthermore, the Consolidated Appropriations Act of 2023 (CAA, 2023) established within the Executive Office of the President an Office of Pandemic Preparedness and Response Policy creating further confusion regarding the role of this new office versus ASPR, FEMA and the CDC.

Therefore, ***Premier recommends that Congress help clarify the roles and responsibilities of the CDC and other federal agencies during a pandemic response and articulate which agency, or agencies, should lead response efforts during a pandemic***.

CDC Authorization

Throughout the pandemic, a rate limiting step in federal agency response was contracting and hiring authority. While some agencies had more flexibility to increase resources to meet the task at hand, other agencies did not have the same authority or flexibility to increase their staff. To better respond to future pandemics, ***Premier urges Congress to ensure all federal agencies with a potential role in response to a future pandemic have similar contracting and hiring authority to expeditiously obtain the resources necessary to adequately carry out their duties.***

III. DATA AND SURVEILLANCE

Syndromic Surveillance to Predict Community Outbreaks

In the early days of the pandemic, Premier leveraged clinical decision support, powered by machine-learning, artificial intelligence and natural language processing, to effectively predict COVID-19 surges and regional flare ups well before patients started showing up at the hospital for treatment. Armed with positive results, Premier advocated for federal agencies to adopt a national system for syndromic surveillance to better track and predict outbreaks – and quicken response times.

Symptoms are the earliest and most reliable indicator of the emergence of infectious diseases that threaten our nation's public health. Identifying suspected cases early is the best signal of the need to take action. However, a recent Government Accountability Office (GAO) report notes how a lack of federal action to modernize the public health data infrastructure seriously undercut efforts to combat the COVID-19 virus. This is a situation that was unfortunately replayed with the Mpox public health emergency.

America needs an automated, near real-time means to collect symptoms and confirmed case information consistently and comprehensively so that it can be shared between and among multiple public and private stakeholders, including federal, state, local, Territorial and tribal public health authorities as well as on-the-ground providers. Such a system can pull in information on symptoms, comorbidities and other vital information, allowing for targeted tracing and interventions to proactively prevent outbreaks. Earlier recognition of new hot spots speeds quarantining of potentially infected persons, reduces the spread of the virus and saves the nation money on contact tracing and testing. This reality is possible today and Congress should push federal agencies to explain how a system that was required under the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006 is still not operational today. In lieu of trying to remedy an antiquated 20+ year system, Congress should push CDC to start fresh by adopting 21st century technology.

Automated Tracking and Reporting the Spread of Disease

During the COVID-19 pandemic, virtually all reporting was done using paper-based forms that were then faxed back to the state and local public health departments for recording and follow up. Reporting was limited to hospitals providing treatment for the most severe cases and labs that encountered a positive COVID-19 test. This meant public health agencies received no information from milder cases diagnosed in a physician office, or from patients self-diagnosed via at-home tests.

By the time of the Mpox outbreak some improvements in reporting were made. Any labs performing a Mpox test were required to report all results directly to public health departments and were strongly encouraged to submit this data electronically, as opposed to via paper forms.

However, electronic reporting is still not a requirement and public health case investigation forms used to track the source of transmission are still paper based and very lengthy (e.g., more than six pages long for Mpox). ***The federal government should require and prioritize efforts for automated, streamlined nationwide public health data collection, exchange and sharing using data and interoperability standards.***

Infection Surveillance, Control and Prevention in Long-term Care Facilities

COVID-19 brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of facilities. While data about infections in nursing homes is limited, the CDC notes that, even prior to the pandemic, a staggering 1 to 3 million serious infections occur annually in these facilities and as many as 380,000 people die of infections in nursing homes every year.

Infection prevention oversight and training at nursing homes is a challenge in and of itself with limited staffing and several layers or reporting requirements. This challenge is compounded by limited Electronic Health Record (EHR) functionality at the sites. Without a comprehensive infection prevention surveillance workflow, the surveillance, tracking, documenting and reporting of epidemiologically significant organisms and infection is difficult for everyday risks, such as multi-drug resistant organisms, but also when an outbreak like COVID-19 occurs.

Clinical analytics technologies are currently widely leveraged in hospitals and acute setting to detect patient care issues through surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs. These systems utilize data from EHRs and have significantly helped clinicians and pharmacists in acute settings identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Those health systems already utilizing clinical surveillance technology were well positioned to respond to COVID-19 before the pandemic hit.

Unfortunately, clinical analytics technologies are currently not widely used in nursing homes and other long-term and post-acute (LTPAC) settings. These settings should have the same access to tools that will help them combat infection spread during any future disease outbreaks and during their day-to-day operations, but unfortunately funding remains a significant barrier as programs authorized and funded under the Health Information Technology for Economic Clinical Health (HITECH) Act excluded LTPAC providers. These entities are already challenged with meeting their more visible needs, such as testing and securing adequate PPE levels at their sites, but a more comprehensive approach is needed to ensure data collection is efficient, non-duplicative and being analyzed in ways that are helpful for facilities. Furthermore, it is critical that lessons learned from meaningful use are applied forward as we develop cohesive solutions to address the lack of EHRs and clinical surveillance technology in nursing homes and create appropriate incentives for adoption.

Premier encourages Congress to consider policies that incentivize nursing homes and other LTPAC providers to implement EHRs and electronic clinical surveillance technology to provide meaningful assistance with infection control.

IV. PUBLIC-PRIVATE COLLABORATION

From the early days of COVID-19 and through today, the public and private sectors have come together in unprecedented ways to tackle “once in a century,” pandemic-driven challenges:

- Developing and distributing life-saving vaccines and treatments in record time;
- Driving research and the practice of medicine forward; and
- Creating the Private Sector Supply Chain Coalition and the Administration’s Healthcare and Public Health (HPH) Sector Joint Supply Chain Resilience Working Group comprised of group purchasing organizations, distributors, manufacturers and others that share invaluable information on the current state of the supply chain and strategies to increase available supplies.

Continued information-sharing and collaboration will help ensure a path to a more agile and robust response to public health emergencies jointly by the federal government and industry.

As a prime example, the Strategic National Stockpile (SNS) should establish a public-private advisory council that includes representatives from the private sector such as manufacturers, group purchasing organizations, distributors, physicians, pharmacists, nurses, laboratorians, non-acute providers, patients, professional associations, and others as well as representatives from the public sector such as federal agencies (HHS, FEMA, ASPR, CDC, CMS, FDA, SAMHSA, the Veterans Health Administration, Indian Health Services, etc.), prisons, first responders, state and local representatives, and others. The advisory council should leverage a multi-committee structure to ensure the appropriate expertise is represented for

specific product categories such as pharmacy, lab, nursing homes, pediatrics, etc. The advisory council will be critical to ensuring the SNS is soliciting feedback from a broad range of entities to augment its operations through a data-driven approach, remain unbiased and vendor agnostic, support a collaborative decision-making process, identify innovative products, and continuously refine the vision of the SNS. Essentially, the advisory council structure helps ensure the SNS is built by providers for providers.

To accomplish this, statutory changes are required to amend the composition of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the group responsible for dictating the contents of the SNS. The PHEMCE is currently led by ASPR and includes three primary HHS internal agency partners: the CDC, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA). The PHEMCE currently does not include private sector feedback. This was also highlighted in a recent National Academies of Medicine report, Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise, that provides recommendations from an expert committee for a re-envisioned PHEMCE. Therefore, ***Premier recommends that Congress amend the composition of PHEMCE to include private sector representation and create a true public-private advisory council.***

V. EPIDEMIOLOGY AND LABORATORY CAPACITY GRANT PROGRAM

Early COVID-19 testing was plagued by a lack of testing locations, a shortage of specimen collection swabs, inadequate lab capacity to process tests and sporadic genomic sequencing to monitor for variants. With Mpox, efforts to speed access to testing were swifter as the CDC effectively onboarded commercial labs to expand testing for Mpox within one month. While an improvement, that one month delay did have consequences creating testing bottlenecks.

As we learned during COVID-19, delays of even a day can have dire effects on limiting transmission. ***The government should broaden and better organize the lab network to include hospitals, academic medical centers, and regional testing laboratories that have the ability and capacity to perform these tests in their communities.*** Broadening the lab network will help ensure that regionally based testing can produce more timely results, empowering immediate and effective public health action. It is also critical for the nation to develop a genomic sequencing strategy for Monkeypox to stay ahead of potential variants.

VI. EVIDENCE GENERATION

One area where Premier believes the CDC excelled throughout the COVID-19 pandemic is evidence generation by leveraging private sector data sets to publish a multitude of studies evaluating the short-term and longer-term impacts of the disease on public health. Specifically, the CDC leveraged Premier's PINC AI™ Healthcare Database (PHD) which captured more than 5 million confirmed COVID-19 patients who were treated in inpatient and outpatient settings across 956 U.S. health systems and more than 3.5 million patients who received a COVID-19 vaccine in these hospitals and health systems. With a lag time of approximately 60-90 days and detailed clinical data on hospital visits that include treatments, comorbidities, diagnoses, procedures, microbiology, general labs, vital signs and imaging, the PHD is one of the most comprehensive and timely databases driving research.

As of July 2022, the CDC had published 27 COVID-19 related research studies using PHD data in CDC's *Morbidity and Mortality Weekly Report* and peer-reviewed journals. Some of these studies include:

- **Is COVID-19 linked to a higher risk of myocarditis?** Viral infections are a common cause of myocarditis, an inflammation of the heart muscle that can result in hospitalization, heart failure and sudden death. During the pandemic, the CDC sought to understand if COVID-19 was associated with a higher risk of myocarditis. Using PHD data, the study found:

- The occurrence of myocarditis inpatient encounters in 2020 was 42 percent higher than pre-pandemic (in 2019).
- The risk for myocarditis among patients with COVID-19 was nearly 16 times higher than patients without COVID-19 during the pandemic.
- The association between COVID-19 and myocarditis was more pronounced among children (younger than 16 years old) and older adults (50 years old and older).

While myocarditis was uncommon overall, a diagnosis of COVID-19 significantly increased a patients' risk of myocarditis.

- **What were the trends around antibiotic use during the pandemic?** Antimicrobial resistance is a major concern, killing at least 1.27 million people worldwide with more than 2.8 million antimicrobial-resistant infections occurring in the U.S. each year. In a recent retrospective study using PHD data, the CDC sought to understand antibiotic use trends during the pandemic.

  Observing data from 716 hospitals that reported at least 100 antibiotic days of therapy per 1000 patient days from March to October 2020, the study found that 77 percent of inpatients hospitalized with COVID-19 received antibiotics and 81 percent of them were started on admission — even when data showed limited reported evidence for bacterial coinfections among COVID-19 patients.

  Antibiotic stewardship programs are an essential component in antimicrobial resistance efforts and health systems can leverage their infrastructure to address challenges that COVID-19 presented. Even during a pandemic, antibiotics should be used responsibly and sparingly to help avoid unintended long-term consequences associated with overuse.

- **Were patients with Type 1 diabetes at a higher risk for serious complications?** In one CDC study, researchers investigated whether patients hospitalized with COVID-19 and Type 1 diabetes mellitus (T1DM) were at a higher risk for severe outcomes.
  - Utilizing PHD data, researchers found that COVID-19 patients with T1DM had a 21 percent higher risk of intensive care unit (ICU) admission and invasive mechanical ventilation (IMV) use compared to COVID-19 patients without T1DM.
  - Although the risk of ICU/IMV was 9 percent higher among patients with T1DM than those with T2DM, the difference attenuated after accounting for diabetic ketoacidosis. Patients with T1DM had a 5 percent higher risk of mortality than patients without diabetes.

- **Did body mass index (BMI) play a role in severe COVID-19 outcomes?** Obesity affects 42.4 percent of U.S. adults and is a recognized risk factor for severe COVID-19, impaired lung function and other chronic diseases. One CDC study using data from the PHD assessed the association between BMI and severe COVID-19 outcomes. The findings included:
  - Among patients with a COVID-19 diagnosis and in emergency department or inpatient care, 28.3 percent were overweight, and 50.8 percent had obesity.
  - Obesity was a risk factor for hospitalization and death, and risks increased with increase in BMI categories.

- **Did COVID-19 adversely affect pregnancy outcomes during the pandemic?** In a cross-sectional study of U.S. delivery hospitalizations, the CDC leveraged PHD data to assess differences in select maternal and pregnancy outcomes between April through December in 2019 and 2020.

  In-hospital maternal death increased from 2019 to 2020**,** while maternal ICU admission and preterm births decreased**.** However, there was no significant difference in maternal death after excluding deliveries with a COVID-19 diagnosis. The proportion of cesarean deliveries with pre-labor rupture of membranes (PROM), prolonged labor, and attempted forceps or vacuum slightly increased, as did high-risk cesarean deliveries in 2020 compared to 2019. Researchers saw an increase in

gestational diabetes from 8.4 percent in 2019 to 9.8 percent in 2020. Overall delivery length of stay (LOS) was shorter in 2020 compared to 2019.

- **What were the trends associated with severe COVID-19 illness?** Clinical severity of COVID-19 ranged widely from asymptomatic infection to multiorgan failure and varied over time as new variants emerged. One PHD data-informed CDC study analyzed the severity of acute illness trends over time among hospitalized patients with COVID-19 in the U.S.

  Findings demonstrated that clinical severity of hospitalized COVID-19 patients fluctuated over time, but no evidence was found for consistent worsening of COVID-19 severity between April 2020 and April 2021.

  Severity in COVID-19 illness tended to be lower among women, younger adults and those with fewer comorbidities compared to their counterparts**.** In addition, severity across racial and ethnic groups tended to be similar.

- **How substantial was the cost for COVID-19 inpatient care during the pandemic?** A recent CDC study, using PHD data from more than 800 hospitals covering all payers in the U.S., assessed the average per-patient cost of inpatient care for hospitalized adult COVID-19 patients, overall, and by severity, age, sex, underlying medical conditions and acute complications.
  - The study found that overall cost among 654,673 patients hospitalized with COVID-19 was $16.2 billion between March 2020 and July 2021.
  - Estimated per-patient hospitalization cost was $24,826.
  - Among surviving patients, estimated per-patient cost was $13,090 without ICU admission or IMV, $21,222 with ICU admission alone, and $59,742 with IMV.
  - The estimated cost among patients who died was $27,017 per-patient and costs ticked higher for patients with underlying medical conditions and acute complications.

Given the importance of ongoing evidence generation for new infectious diseases, variants, patterns of infection, vaccine and booster efficacy, impacts on health outcomes, antimicrobial resistance, costs, and healthcare resource utilization (HRU), ***Premier urges Congress to continue CDC's ability to conduct robust research utilizing private sector healthcare data sets***.

VII. CONCLUSION

In closing, Premier applauds your commitment to improve the nation's public health response capabilities for emergencies. Premier looks forward to working with Congress to further refine the capabilities and authorities of the CDC and develop a cohesive and holistic national strategy for addressing global pandemics.

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.