PREMIER TRANSFORMING HEALTHCARE TOGETHER®

Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain

House Energy and Commerce Subcommittee on Health

February 3, 2021

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Health Subcommittee's hearing titled "*Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain,"* scheduled for February 3, 2021. We applaud the leadership of Chairs Pallone and Eshoo, Republican Leaders Rodgers and Guthrie and members of the Subcommittee for holding this hearing to ensure a more robust national response to the COVID-19 pandemic by expanding access to vaccines, tests, and critical medical supplies.

Premier's Reflections & Learnings From COVID-19 Response Efforts

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,100 U.S. hospitals and health systems and approximately 200,000 non-acute 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.

From the beginning of the COVID-19 pandemic, Premier has been at the forefront of response efforts working around the clock to identify and implement innovative solutions and best practices that ensure hospitals, health systems, and alternate site providers across the country had access to the necessary PPE, medical supplies and pharmaceuticals to treat COVID-19 patients.

Premier has spent significant time reflecting on the experience of the healthcare industry during COVID-19 response efforts to determine elements that worked well as well as areas for improvement for the future. Premier's reflections have found that:

Elements That Have Worked Well:

- Nimbleness and ingenuity of the private sector to anticipate and identify needs as well as respond quickly to fill gaps
- Formation of the Private Sector Supply Chain Coalition to provide a coordinated and collaborative response
- Sharing of supply chain data that accounted for both supply and demand from neutral, vendor agnostic, and value orientated entities
- Regulatory flexibilities and waivers from FDA, CMS, HRSA, and CDC that were delivered rapidly
- Timely and regular access to government leaders and openness to input

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Elements That Led to the Current Situation:

- In spite of efforts to counter the trend by some, a focus for the past 20+ years to move manufacturing offshore as a means to reduce costs to offset decreasing reimbursement
- Emerging economies more willing to take greater environmental regulatory risks
- Large populations of low-cost labor
- Incentives provided by other nations to move manufacturing to their markets
- Lack of centralized upstream visibility into supply chain to determine source of raw materials and finished goods. This resulted in a lack of understanding of vulnerabilities, foreign reliance on manufacturing, and impact as export bans and manufacturing shutdowns were announced.
- Unprecedented demand both globally and nationally that led to an imbalance in the supply vs demand (17X increase in surge demand for N95 masks)
- Export bans and manufacturing shutdowns globally
- Insufficient supplies in the Strategic National Stockpile (SNS) and cumbersome process for accessing supplies in the stockpile
- More reactive approach vs a proactive approach by the government at the outset. Product was not allocated to the "hot spots" because there was not clear identification of them until late.
- Fragmented approach to securing supply (private sector vs federal vs states) led to increase in prices as multiple entities competed for the same inventory and out-bid one another
- Lack of clear visibility of distributor fulfillment led to uncertainty on where products were delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products.
- Insufficient national strategy and plan for addressing global pandemics, including confusion regarding which federal agency was responsible
- Existence of patent restrictions that impeded access to ancillary products needed for care such as viral swabs
- Lack of resources to contain the spread of COVID-19 in nursing homes and proactively identify emerging cases.

Strengthening the Healthcare Supply Chain to Address Future Pandemics

To strengthen the supply chain to address future global pandemics, Premier has robust recommendations on how the existing private sector supply chain can be further enabled and augmented. Premier's guiding principles include:

- Augment the existing private sector supply chain to better respond to global pandemics through diversification and transparency. The private sector supply chain is highly functioning and should be further enabled, not disrupted.
- Develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the US supply chain to respond to surge demand for critical medical supplies and drugs
- Identify critical medical supplies and drugs needed to treat a global pandemic and associated comorbidities. This identification should occur via a public-private advisory council that includes representatives from manufacturers, GPOs, distributors, physicians, pharmacists, laboratorians, and others. This list must be dynamic and regularly updated as technology advances, best practices are identified, and the practice of medicine evolves.

- Create upstream visibility into the supply chain to understand sources of raw materials and manufacturing facilities. This information is critical to assess vulnerabilities and prioritize what critical medical supplies and drugs should be focused on initially to assure adequate diversification of the supply chain.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles.
- Leverage supply and demand data from GPOs, who serve as neutral, vendor-agnostic, and value-orientated entities to drive transparency in the supply chain and forecast demand needs.
- Develop a real-time national surveillance system that includes supply chain data so that there is a real-time means to identify a disease threat as early as possible as well as its implications on healthcare resources.
- Advance payment and delivery system reforms that hold providers accountable for the health of a population, budgets and transparent outcomes. This will incent improving the health of a population, which will both improve patients' comorbidities and attention to care management to sick patients. Acting within a budget helps reduce long-term financial pressure from rising healthcare costs.
- Leverage technology to implement comprehensive infection prevention and antimicrobial stewardship programs in nursing homes to provide meaningful assistance with infection control.

Incentivizing Domestic Manufacturing

To increase domestic manufacturing of critical medical supplies and drugs, there are five major barriers that policy proposals must address. These barriers include: 1) capacity; 2) environmental regulations; 3) labor costs; 4) availability of raw materials, and 5) historical policy decisions that advantaged offshoring. To incentivize domestic manufacturing, Premier recommends Congress consider the following policy proposals:

- Section 3101 of the CARES Act requires a report by the National Academies of Medicine (NAM) on the foreign reliance on manufacturing for critical healthcare supplies, the risk to national security, and recommendations for improving the resiliency of the supply chain. However, these recommendations are not expected to be available in the near future and, therefore, Congress should accelerate the development of this report to strengthen domestic manufacturing in the long-term.
- Offer 0% interest loans to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity. (for example – investing in automation to offset labor costs)
- Offer tax incentives to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity, similar to incentives provided during the 1980's and 1990's to incentivize manufacturing in Puerto Rico.
- Ensure there is at least:
    - One domestic supplier of the final form, ancillary products and raw materials for critical medical supplies and drugs.
    - Three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions.
- Incentivize the domestic farming/cultivation of raw materials needed for critical medical supplies and drugs
    - For example: cotton for PPE and swabs, pigs for Heparin, poppy for sedatives, etc.
- Incentivize healthcare providers to purchase domestic manufactured critical medical supplies and drugs through programs such as tax incentives, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs.

Augmenting the Strategic National Stockpile

To develop a truly cohesive and holistic national strategy for addressing future global pandemics and stabilizing the U.S. supply chain to respond to surge demand for essential medical supplies and drugs, Premier recommends the following actions to augment the SNS:

- The SNS should not only focus on the quantity on hand for critical supplies, but also focus on the time to inventory and ensuring the U.S. has contractual relationships established, including contingency and redundancy plans, to ramp up production expeditiously and efficiently upon identification of need.
- The SNS is the supply chain of last resort for health systems, alternate site providers, and first responders. Therefore, the SNS must be built by providers for providers. The SNS must also leverage analytics and insights to assist providers in the delivery of care during global pandemics that is in the best interest of patients and ensure access to the right supplies at the right time.
- The SNS should maintain a minimum of a 90-day supply of critical medical supplies and drugs based upon surge demand from hot spots such as New York, Washington, Detroit, etc.
- The current process for accessing the SNS is cumbersome and state specific. Working alongside private sector partners, the Administration should create a streamlined and efficient process for accessing drugs from the SNS.
- The SNS should work proactively with GPOs to forecast demand and increase capacity/supply to avoid shortages.
- The SNS should work with GPOs to rotate soon-to-expire stock out of the SNS and into health systems at a discounted rate. This rotation is supposed to occur, but GPOs can make this happen and will ensure the SNS is continuously stocked with in-date products and allow the SNS to recoup some of their expenses associated with purchase of these products.
- The SNS should be transparent regarding distribution of supplies and drugs from the SNS. The SNS should provide, at minimum, a detailed monthly report of what supplies were distributed to where and in what quantities.
    - During a public health emergency, reporting should occur weekly
- The SNS, as well as state and local stockpiles, should be encouraged to purchase off GPO contracts to help aggregate purchasing volume and keep prices competitive.
- The SNS should work to ensure that critical medical supplies and drugs are located as close to the delivery of care as possible. This includes exploring opportunities to leverage health system warehouses in major metropolitan areas or in rural areas.
- Create a customized stockpile for nursing homes with appropriate supplies, drugs and other needs.
- Include health systems or regional buying groups as potential stockpile operators. These organizations would be responsible for managing the stockpile for the providers in a region. This would allow an efficient means to rotate inventory and assure accountability for the stockpile.
- To ensure the SNS can deliver during future global pandemics, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide the SNS with a specified quantity of product. An annual test allows the SNS to ensure all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.

Solutions to Environmental Issues Impacting Patient Care

Premier is committed to working with Congress, the FDA, EPA, and stakeholders to find a sustainable approach and path forward that addresses the concerns with sterilization techniques using ethylene oxide while carefully considering the unintended negative consequences that sterilization facility closures would have on patient care. Premier recommends a thoughtful approach to this delicate balance, so we do not hit a tipping point resulting in a greater crisis in medical supply shortages. Premier believes this requires the following steps:

- EPA should reassess requirements specific to the manufacturing of critical medical supplies and drugs and provide clear guidance on the requirements needed.
- The federal government should provide tax credits or incentives for manufacturers to upgrade facilities to meet EPA requirements to begin domestic manufacturing of critical medical supplies and drugs.
- EPA should provide clear guidance on the use of ethylene oxide (EtO) for sterilization of medical supplies. In 2019, several states took action against EtO facilities and closed them. During COVID, Illinois and Georgia permitted EtO facilities to reopen. This was critical to avoid additional shortages of PPE and other medical supplies due to a lack of sterilization capacity. Moving forward, it is critical that EPA define what is required for sterilization with EtO and provide an opportunity for EtO sterilizers to comply with the new requirements.

Maintaining Supply Chain Integrity

During the pandemic, unfortunately a lack of clear visibility of distributor fulfillment lead to uncertainty on where products where delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products thereby challenging the integrity of the medical supply chain.

To combat the gray market and ensure supply chain integrity, Premier offers the following recommendations:

- Establish a national, centralized clearinghouse to vet all gray market offers regarding vaccine availability. A clearinghouse approach would remove the risk and guess work from efforts by healthcare providers, states and other entities to secure a reliable supply of vaccine. The clearinghouse should:
    1. Hold all payments in escrow until testing is validated;
    2. Test lot samples through a certification process;
    3. Permit the sale of products that are validated; and
    4. Confiscate and take appropriate action against the gray market actor if the product is not validated.
- Require entities associated with the distribution of vaccine and ancillary supplies to implement checks and balances systems, similar to suspicious order monitoring requirements for controlled substances, to identify potential diversion of vaccine to the gray market.
- Promote the reporting of gray market offers to the FDA Office of Criminal Investigations and share reported incidents with the Federal Trade Commission (FTC).
- Implement civil monetary penalties (CMPs) for entities selling vaccine to the gray market.
- Establish best practices for security to minimize diversion from sites.

Expediting COVID-19 Vaccinations of the American People

Working with our provider members to understand the evolving on-the-ground realities, Premier has identified five systemic issues limiting the vaccine rollout that need immediate remediation. Premier urges Congress and the Administration to immediately take the following actions to overcome these obstacles and streamline and expedite the vaccination process throughout the country. We are pleased that the Biden Administration has already adopted some of these recommendations.

#1 Vaccine hesitancy

On the ground reports suggest that a consistent 30[1]-50[2] percent—and as high as 80 percent[3]—of healthcare workers eligible to receive the vaccine have not been vaccinated. This unanticipated high hesitancy rate has disrupted the CDC's prioritization pathway as providers grapple with finding willing persons to accept the vaccine in the short timeframe that it remains viable.

For healthcare providers, data transparency and an ability to review the data themselves and arrive at their own scientific and evidence-based conclusions is paramount to provider acceptance of new technologies. For the general public, broader education and communication efforts are necessary to explain the necessity of the vaccine and answer individualized questions. What we need is broad and consistent education involving:

- The FDA and vaccine manufacturers making all evidence supporting the safety and efficacy of COVID-19 vaccines publicly available as would normally occur for a new drug;
- A concerted, evidenced-based national public awareness campaign on COVID-19 vaccines that aggressively debunks myths while addressing vaccine safety, efficacy, their role in society, and their importance in our return to normal;
- Encouraging employers to leverage this campaign for their employees and engage in internal peer-to-peer educational opportunities with early adopters;
- Data transparency around vaccine safety and efficacy during phase IV clinical trials, ongoing surveillance for adverse events, and real-world evidence;
- Clear guidance and education on why the US approach to vaccinations may differ from those of other countries;
- Allowing the use of the Medication Therapy Management network for vaccine-related education; and
- Permitting unbranded direct-to-consumer advertising on vaccine availability, safety, and efficacy.

In addition to broad and consistent education to overcome vaccine hesitancy, incentives throughout the entire healthcare ecosystem should be leveraged to encourage vaccination via a multi-faceted approach where multiple parties are incentivized to achieve the common goal of vaccinating the American public as expeditiously as possible. These incentives should include:

- Temporarily waiving the Stark and anti-kickback requirements to allow providers to offer patients incentives to receive the COVID-19 vaccine;

[1] https://nypost.com/2021/01/05/around-30-of-ny-medical-workers-refusing-covid-19-vaccine-official/
[2] https://www.desertsun.com/story/news/health/2021/01/05/half-riverside-county-hospital-workers-refusing-covid-19-vaccine/4118966001/
[3] https://www.modernhealthcare.com/providers/vaccine-rollout-hits-snag-health-workers-balk-shots?utm_source=modern-healthcare-covid-19-coverage&utm_medium=email&utm_campaign=20210110&utm_content=article4-headline

- Urging Medicare Advantage (MA) plans to leverage the Rewards and Incentive Programs to encourage MA enrollees to receive the COVID-19 vaccine; and
- Providing bonus payments to providers and payers and temporary tax incentives for employers for vaccinating a specified percentage of their patient and employee population by the end of fiscal year 2021.

#2 Clinical staffing limitations

According to a November survey of Premier members, 53 percent said lack of clinical staff was the top challenge to their COVID-19 response efforts – and that was before the current caseload surge and the added staff needed to administer vaccines that has only exacerbated staffing shortages.

States and the Biden Administration should take the following steps to identify new cohorts of vaccinators to prevent bottlenecks at vaccination sites:

- Recruiting retired pharmacists and pharmacy technicians, as well as student pharmacists who have successfully completed coursework related to the administration of vaccines;
- Leveraging the National Guard to assist with logistical vaccination support, including to support hospitals, retail settings, and community physicians to achieve mass vaccination;
- Temporarily waiving state reciprocity requirements for vaccinators if they are licensed vaccinators in good standing in another state; and
- Appealing to employers to support licensed healthcare workers who are in non-healthcare roles to return to the frontlines.

#3 Distribution challenges

The current Operation Warp Speed decentralized, opaque distribution process is creating uncertainty for providers around shipments, leading to throughput limits and/or wastage. At the same time, there are proliferating concerns about an emerging counterfeit market for vaccines and the integrity of the distribution channel.

The key to overcoming distribution challenges is building a true end-to-end supply chain that is transparent and resilient. To do this, we need:

- A centralized national real-time tracking and tracing system to provide visibility into the complete vaccine supply chain to replace the current process of states independently reporting this information, a process that is archaic, delayed, and prone to error;
- A data-driven dynamic allocation process to match vaccine allocation with the number of eligible patients in the state based upon the prioritization pathway; and
- Concrete steps to prevent the gray market and ensure supply chain integrity by:
    - Establishing a national, centralized clearinghouse to vet all gray market offers regarding vaccine availability;
    - Requiring entities associated with the distribution of vaccine and ancillary supplies to implement checks and balances systems;
    - Promoting the reporting of gray market offers to the FDA Office of Criminal Investigations;
    - Implementing civil monetary penalties for entities selling vaccine to the gray market; and
    - Establishing best practices for vaccine security to minimize diversion from vaccination sites.

#4 Supply shortages

Shortages of needles and exam gloves are obstacles limiting the speed of vaccination. Premier members report an inability to order the additional needles needed to administer the maximum number of doses per vial, as well as a 40 percent increase in exam glove demand, which has caused spot shortages.

The key to overcoming supply shortages is to leverage a data-driven approach to drive transparency in the supply chain and forecast demand needs, which can be accomplished by:

- Adding to the ancillary kits accompanying vaccines the additional needles and syringes needed, as well as nitrile exam gloves;
- The Strategic National Stockpile (SNS) releasing any existing supply of needles to Operation Warp Speed to support vaccination efforts and leveraging the Defense Production Act to expeditiously refill the SNS inventory;
- Leveraging public-private partnerships to monitor the rollout, collaboratively discuss challenges, and work proactively to resolve any supply chain challenges that may arise; and
- Ensuring the FDA device shortage list is more specific around the exact product and manufacturer that is impacted.

#5 Communication gaps

Operation Warp Speed is a large-scale effort but with insufficient coordination. As a result, vaccination sites report widespread confusion, with providers unsure of which state or federal agency is making decisions or where to turn to solve problems.

The key to overcoming communication gaps is establishing a single source of truth with:

- A clear and consistent command and control structure that explains the roles and responsibilities of the various entities involved in the rollout, what decision-making authority they have, and how to engage with them;
- A reconfigured CDC vaccine reporting website to provide data on the first and second dose administered;
- An appointment-based vaccination system with an active waitlist that can be leveraged if there are no shows;
- An administration-led fact-finding process to understand why there are jurisdictional differences in vaccination administration rates and standardized reporting of key administration metrics to allow for data mining to identify best practices to improve vaccination rates in the future; and
- Standardized definitions (e.g. “essential worker”) that are applicable across jurisdictions.

Creating Upstream and Downstream Visibility

COVID-19 has exposed one of healthcare’s fundamental weaknesses: the fragmented and siloed nature of care delivery and the lack of centralized coordination when it comes to managing and preventing disease spread. The public health system continues to rely on flawed data and obsolete technology that consistently fails to accurately identify and track current cases, monitor disease progression, or predict future surges. Not only do these blind spots create opportunities for the disease to spread, they also undermine the ability to safely plan for economic recovery and re-opening of the country.

The COVID-19 emergency underscores the need for:

- Investing in a robust, real time HIT infrastructure that will provide an on-call, nimble data collection infrastructure that the nation can call upon in any future major crises. Rather than standing up an inadequate and duplicative system as we experienced during the pandemic, the nation needs a system that can track critical product availability - from the raw materials, to manufacturer, to distribution, to hospital inventory. This system would exist behind the scenes and be ready to be "turned on" in a moment's notice. This information would inform dynamic and appropriate product allocation and distribution strategies, minimize hoarding, and enable powerful and accurate prediction, enabling the nation to manage supplies during the crisis.
- Modernizing the nation's public health syndromic surveillance system so that infected patients can be identified earlier through symptom information. Reliance on testing, particularly early on in an emergency, can delay insights for and misinform public health officials.

Expanding Infection Prevention Clinical Surveillance

COVID-19 has brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus has accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of the 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 every year in these facilities and as many as 380,000 people die of the 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. Nursing homes should have the same access to tools that will help them combat infection spread during any future outbreaks of COVID-19 and during their day-to-day operations, but unfortunately funding remains a significant barrier. Nursing homes are already challenged with meeting their more visible needs, such as testing and securing adequate PPE levels at their sites, but a comprehensive approach is additionally needed to ensure data collection is efficient, non-duplicative and being analyzed in ways that are helpful for facilities.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the House Energy and Commerce Health Subcommittee hearing on ramping up COVID-19 vaccines, testing, and medical 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, Vice President of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.