

January 13, 2021

The Honorable Joseph R. Biden  
President-Elect of the United States of America  
Office of the President Elect

The Honorable Kamala Harris  
Vice President-Elect of the United States of America  
Office of the President Elect

Dear President-Elect Biden and Vice President-Elect Harris:

On behalf of Premier Inc., the nation's leading healthcare performance improvement company, I write to express our **steadfast commitment to ensuring a safe, effective and expeditious process for mass COVID-19 vaccinations of the American people.**

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. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

Many of Premier's network hospitals and non-acute facilities have been selected by their states as vaccination hubs and are actively working on the front lines to ensure priority populations receive the vaccination safely and equitably. Premier assists these sites by ensuring they have access to the supplies and staffing they need to carry out the mass vaccination campaign. In addition, Premier helps collate and share best practices amongst these sites to help maximize vaccination efforts.

Despite tireless efforts on the part of our frontline caregivers, **Premier and our members believe that vaccinations must be administered much more quickly in order to reduce the national infection rate and alleviate the systemic strain new cases and viral mutations place on the healthcare system.** Swift intervention from the Federal government is needed. While some delays can be attributed to holiday schedules and the newness of the vaccination process, other issues are indicative of challenges in the current system that must be addressed lest they become catastrophic limitations later.

As a national convener of vaccination sites across the nation, **Premier recognized early on that a mass vaccination effort would be the biggest logistical challenge of the pandemic.** As such, we have been regularly speaking with and polling our members to understand the evolving on-the-ground realities and obstacles that could continue to limit the vaccine rollout. Now a month in, we have identified at least five systemic issues in need of immediate remediation:

- **Vaccine hesitancy:** Given the newness of the vaccine and its emergency use status, on the ground reports suggest that a consistent 30<sup>1</sup>-50<sup>2</sup> percent of healthcare workers eligible to receive the vaccine have not been vaccinated. More than three weeks into the vaccination campaign,

<sup>1</sup> <https://nypost.com/2021/01/05/around-30-of-ny-medical-workers-refusing-covid-19-vaccine-official/>

<sup>2</sup> <https://www.desertsun.com/story/news/health/2021/01/05/half-riverside-county-hospital-workers-refusing-covid-19-vaccine/4118966001/>

some hospitals are seeing as much as 80% of the staff hesitant to be vaccinated.<sup>3</sup> **This hesitancy rate was largely unanticipated and has caused significant confusion as providers grapple with the ethical dilemma of scrambling to find willing persons to accept the vaccine in the short timeframe that it remains viable.** This dilemma has also disrupted the Centers for Disease Control and Prevention's (CDC) prioritization pathway, as the search for willing candidates has led to vaccinations of individuals who otherwise would not have qualified at this point in time. This problem of refusal could be exacerbated by the two-dose nature of the current vaccines, as even more people may elect to forgo a second dose if they have an unpleasant reaction or experience with the first.

- **Clinical staffing limitations:** Clinical staff qualified to administer vaccines are extremely scarce and on the verge of burnout. **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.** Premier members similarly report a nearly 30 percent attrition rate in clinical staff as frontline workers buckle under the strain of the response and quit. Lack of qualified staff is leading to bottlenecks at some vaccination sites, particularly those where demand is high.
- **Distribution challenges:** The current Operation Warp Speed distribution process is decentralized, with limited end-to-end visibility. As a result, **providers report an uneven process, with some sites getting clear, advance notice of shipments, quantities and arrival schedules, while vaccines and supply kits show up at other locations almost by surprise.** Absent clear information, some vaccination sites are questioning how, when or even if they will receive their second dose shipments and are holding back half their supply in order to accommodate second dose administration. Not only does this limit the initial numbers of people getting vaccinated, it could also lead to an overabundance once second doses do arrive, creating throughput limits and/or wastage.

Furthermore, vaccination sites are beginning to report gray market offers for vaccines proliferating concerns about an emerging counterfeit market for vaccines and the integrity of the distribution channel.

- **Supply shortages:** Most of the vaccines shipping today are in “overfilled” vials, a standard practice that allows providers to extract more doses than are indicated on the FDA-approved labeling. Not anticipating usable overfill, Operation Warp Speed ancillary kits contain enough needles and syringes to administer labeled dose counts only, leaving providers to dip into their own stocks of needles and syringes for the precious, overfill doses. **Premier members report an inability to order more of these needles through their traditional distributors, which has caused spot shortages.**

As a second concern, **Premier data shows that gloves have been backordered for months with members citing gloves as their second major supply chain challenge even after implementing conservation protocols as recommended by Premier.** Hospitals note struggling with maintaining mandatory 90-day stockpiles of exam gloves prior to the

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<sup>3</sup> [https://www.modernhealthcare.com/providers/vaccine-rollout-hits-snap-health-workers-balk-shots?utm\\_source=modern-healthcare-covid-19-coverage&utm\\_medium=email&utm\\_campaign=20210110&utm\\_content=article4-headline](https://www.modernhealthcare.com/providers/vaccine-rollout-hits-snap-health-workers-balk-shots?utm_source=modern-healthcare-covid-19-coverage&utm_medium=email&utm_campaign=20210110&utm_content=article4-headline)

December surge, which is being further compounded by the additional strain placed on the glove supply chain due to vaccination needs. Currently, Premier data shows that glove demand has increased by 40 percent since vaccination began and the average lead time to receive nitrile exam gloves is currently approximately 35 days. Although gloves are not *required* to administer the vaccine and therefore were not provided by Operation Warp Speed in the ancillary kits, 78 percent of Premier members report their vaccinators prefer gloves given the current circumstances and feel safer with them, and some may refuse to provide vaccines without them.

Both of these shortages are obstacles limiting the speed of vaccination.

- **Communication gaps:** Operation Warp Speed is a large-scale effort, involving multiple state and federal agencies, 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.** There is poor understanding of the command structure detailing the roles and responsibilities of the various actors, nor is there a consistent mechanism for providers to provide direct feedback to decision makers for remediation. Similarly, there are no established best practices or learning mechanisms for providers to ask questions and get advice about how to handle common problems such as spot shortages, population targeting, essential worker definitions, distribution and other common challenges. The net result is that providers can waste valuable time and resources and struggle with the significant inter-jurisdictional variability surrounding all aspects of vaccine distribution and administration. Finally, there is no single source of truth for communicating with the public which is leading to mass confusion amongst Americans.

Premier believes that with the right corrective action, all of these barriers can be overcome. However, actions must be urgently undertaken now, before misconceptions gain traction as fact, before additional vaccines reach the market, and before approved manufacturers start to reach scale. With this in mind, we respectfully submit the following recommendations that can be implemented in the short-term to streamline and expedite the vaccination process throughout the country. Premier believes these recommendations are actionable, sustainable, and practical opportunities to improve the nation's response.

- **Vaccine hesitancy:** The key to overcoming vaccine hesitancy is education coupled with appropriate incentives to encourage Americans to receive the vaccine.
  1. 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. Therefore, **we urge the Food and Drug Administration (FDA) and vaccine manufacturers make the totality of evidence available supporting the safety and efficacy of COVID-19 vaccines publicly available as would normally occur for a new drug.** This would permit healthcare providers, academics, and other experts to peer-review the data and support broader education efforts amongst healthcare providers based upon scientific integrity. A peer-to-peer approach amongst healthcare providers is also highly encouraged with early adopters and recipients of the vaccine helping to educate others who may have reservations.
  2. For the general public, broader education and communication efforts are

necessary to explain the necessity of the vaccine and answer individualized questions. **A concerted national public awareness campaign on COVID-19 vaccines is needed.** The campaign should be evidence-based and aggressively debunk myths and other rumors while addressing vaccine safety, efficacy, their role in society, and their importance in our return to normal. The campaign should foster a multi-media approach (e.g. print, radio, television, internet, etc.) and ensure health literacy is accounted for to help Americans obtain, read, understand, and use the pertinent healthcare information in order to make appropriate health decisions around vaccination.

3. Employers will also play a critical role in educating their employees about vaccine availability and safety as they prepare for the return to normal. Employers should be encouraged to leverage and repurpose materials from the national public awareness campaign for their employees. In addition, **employers should be encouraged to create internal peer-to-peer educational opportunities amongst employees with early adopters and recipients of the vaccine helping to educate others who may have reservations.** Our member health systems have been receiving requests for materials they can repurpose in their educational programs as well as make available to local businesses.
4. For all Americans, it is critical to understand how the long-term safety and efficacy of the vaccine will be studied given its current emergency use status. Therefore, **transparency regarding how data will be collected to further demonstrate vaccine safety and efficacy during phase IV clinical trials, ongoing surveillance for adverse events, and real-world evidence will be critical to overcoming vaccine hesitancy.** In addition, it is important for the FDA to be transparent regarding the level of evidence and potential timeline needed to move a vaccine from emergency use authorization to full FDA approval as many Americans may be hesitant to receive the vaccine until it formally meets the FDA's gold standard for approval.
5. **As reports from other nations suggest vaccination approaches that deviate from the FDA issued EUA such as providing a half-dose or delaying the second dose, it is critical that the FDA provide clear guidance and educate both providers and the public on why such approaches are not yet recommended in the US.** In addition, the FDA should be clear about how, if at all, alternate approaches are being studied in the US, the level of evidence that is required for a shift, and the potential implications to patients.

For example, the potential recommendation of delaying the second dose of the vaccine is causing consternation amongst healthcare providers as clinical trial data demonstrated a 52% efficacy rate for the Pfizer vaccine and an 80.2% efficacy rate for the Moderna vaccine after the first dose.<sup>4</sup> However, there

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<sup>4</sup> <https://blogs.bmj.com/bmj/2021/01/06/john-p-moore-how-do-you-take-your-vaccine-one-lump-or-two/>

were significant caveats given the small sample size, lack of follow up, and vaccine mechanism of action that render this data difficult to extrapolate across the larger population. In addition, insufficient data was available to understand the potential for viral mutation after a single dose. Healthcare providers need to understand how these types of recommendations are being studied by the FDA and how they align with supply chain logistics to ensure doses are available when they are needed and can provide maximum protection.

6. Healthcare providers are an instrumental and trusted resource for providing one-on-one education to patients and responding to patient-specific questions to alleviate healthcare concerns. However, these are also scarce resources at this time. To overcome this barrier and provide Americans with access to healthcare providers to help answer their questions, **the Centers for Medicare and Medicaid Services (CMS) should temporarily permit the use of Medication Therapy Management (MTM) services for vaccine-related education.** Commercial payers who support MTM-type services should also expand the ability of providers to bill for these services for vaccine-related education. By leveraging the national MTM network of pharmacists, nurses, doctors, and other healthcare providers, patients can be educated on the value of a vaccine, notified when they are eligible to receive it, and understand any vaccine-related complications they may experience based upon their comorbidities and medication profiles. This also provides an opportunity for patients to ask any specific questions they may have about the vaccine and gain confidence in the vaccination process. MTM providers can also work directly with patients to help locate a vaccination clinic upon eligibility and schedule appointments.
7. In the United States, direct-to-consumer (DTC) advertising is a unique mechanism utilized to help educate the public about disease states and therapies available to treat them. To help bolster educational efforts around the vaccine, **the FDA should consider permitting unbranded DTC advertising on vaccine availability, safety, and efficacy.** Premier recommends that DTC advertising be permissible for pharmaceutical manufacturers granted an EUA for a COVID-19 vaccine. However, DTC advertising should remain unbranded and focus on overarching vaccination principles to help avoid brand recognition where patients may insist upon being vaccinated with a particular manufacturer's product which can impede mass vaccination.
8. 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:
  - **Patient incentives:** Current Stark and anti-kickback laws limit the ability of healthcare providers and manufacturers to provide patients with something of value to induce the purchase of items or services payable by a federal health care program. While the Stark and anti-kickback laws were recently modernized to align with

the movement towards value-based care, pharmaceutical companies were excluded from those changes. **To encourage patients to receive the COVID-19 vaccine, the Office of Inspector General (OIG) and CMS should temporarily waive Stark and anti-kickback requirements as it relates directly to the administration of the COVID-19 vaccine.** CMS should provide guidance on a monetary limit that it considers permissible and reasonable as an incentive and examples of the type of incentives (e.g. gift cards, items depicting an individual has been vaccinated such as a button or bracelet, etc.) that could be leveraged by healthcare providers and manufacturers to encourage vaccination.

In addition, **Medicare Advantage (MA) plans should be encouraged to leverage CMS guidance from May 2020<sup>5</sup> permitting the implementation of Rewards and Incentive Programs for enrollees in connection with the COVID-19 outbreak.** The guidance provides MA organizations with considerable flexibility with regard to what may be offered as a reward or incentive. For example, gift cards are a permissible form of reward or incentive as long as they are not redeemable for cash and meet the applicable limits in the regulation. Therefore, Rewards and Incentive Programs should be leveraged to encourage MA enrollees to receive the COVID-19 vaccine.

- **Payer incentives:** Payers are a critical player in the healthcare ecosystem and traditionally play a very important role from a population health perspective to ensure broad preventative measures are implemented across large patient populations. Therefore, **CMS should consider bonus payments to payers based upon simple performance-based measures for vaccinating a specified percentage of their patient population by the end of fiscal year 2021.** A bonus payment structure of this nature will encourage payers to play an active role in educating and encouraging patients to be vaccinated.
- **Provider incentives:** Similarly to payers, **CMS should consider bonus payments to providers, including those in Accountable Care Organizations and risk-sharing arrangements, based upon simple performance-based measures for vaccinating a specified percentage of their patient population by the end of fiscal year 2021.** A bonus payment structure of this nature will encourage providers to play an active role in educating and encouraging patients to be vaccinated.

For providers responsible for administration of the vaccine, additional bonus payments should be considered for the percentage of patients who complete the second dose of the vaccine, percentage of wasted vaccine, and other elements tied to rewarding efficient and complete vaccination protocols.

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<sup>5</sup> <https://www.cms.gov/files/document/updated-guidance-medicare-advantage-organizations-5132020.pdf>

- **Employer incentives:** Employers will also play a critical role in encouraging their employees to be vaccinated in support of a healthy workplace. **Temporary tax incentives should be considered for employers, including small businesses, based upon simple performance-based measures for vaccinating a specified percentage of their employee population by the end of fiscal year 2021.** A bonus payment structure of this nature will encourage employers to play an active role in educating and encouraging patients to be vaccinated.
- **Clinical staffing limitations:** The key to overcoming clinical staffing limitations is to identify new cohorts of vaccinators coupled with best practices and guidelines for how to integrate new clinical sources into practice.
  1. To help augment the number of licensed vaccinators, **states should recruit retired pharmacists and pharmacy technicians who have maintained active licensure and vaccination credentials.** A similar approach was used to help recruit physicians and nurses during surges in the spring and proved to be successful. By focusing recruitment efforts on retired pharmacists and pharmacy technicians with active licensure and vaccination credentials, retired nurses and physicians can continue to focus on helping to augment frontline care for COVID-19 patients while pharmacists and pharmacy technicians can focus on helping to augment vaccination efforts.
  2. Student pharmacists who have undergone training to provide immunizations are also an untapped resource that states can leverage. Therefore, **states should collaborate with local schools of pharmacy to identify and deploy student pharmacists who have successfully completed coursework related to the administration of vaccines to assist with the mass vaccination campaign.** A similar approach was used by several states during the height of the pandemic to identify and deploy student nurses who had completed a sufficient portion of their coursework to complete certain tasks associated with the care of COVID-19 patients and proved to be successful.
  3. In times of need, a major barrier to quickly moving licensed healthcare personnel to an area of need is state specific licensure requirements that can often take weeks to months to complete. To overcome this barrier, **a concerted effort should be made to collaborate with states to temporarily waive reciprocity requirements for vaccinators if they are licensed vaccinators in good standing in another state.** The temporary licensure should be limited to a very narrow scope of practice associated with vaccine administration only. This could apply to all healthcare licenses with vaccination training such as pharmacists, pharmacy technicians, nurses, physician assistants, physicians, etc. In addition, a temporary licensure of this nature would also be critical to deploy military spouses who are licensed healthcare professionals who may have recently been relocated to a state where they are not yet licensed and therefore cannot otherwise assist with COVID-19 vaccination efforts.

4. Another potential new cohort of vaccinators is licensed healthcare professionals who are not employed in a frontline healthcare role. Therefore, **employers should be encouraged to support licensed healthcare workers who are in non-healthcare roles to return to the frontlines.** Premier is currently supporting several licensed healthcare professionals that we employ as they return to the frontlines to help vaccination efforts in their home states and other employers should be encouraged to do the same.
5. In addition to staffing support, logistical and on-the-ground support is also needed to help vaccination efforts at the state level. **States should leverage Title 32 federal funds to deploy the National Guard to assist with logistical support such as setting up temporary vaccination clinics, inventory management, and providing additional vaccinators through active and reserve healthcare professionals.** States should collaborate with designated vaccine hubs to determine need and how to best leverage the National Guard to provide maximum benefit to the community.

To further enable the National Guard and maximize their utility, **the Biden administration should develop a blueprint for how the National Guard can best support hospitals, retail settings, and community physicians to achieve mass vaccination.** The blueprint should include details such as: 1) the roles and responsibilities of various entities throughout the healthcare continuum; 2) best practices for partnering with industries that have been significantly impacted by the pandemic (e.g. airlines, hospitality, entertainment) to repurpose physical locations and staff to create vaccination clinic space with non-clinical staff trained to support registration, throughout, and inventory management; 3) best practices for integrating new cohorts of vaccinators expeditiously and efficiently into vaccination clinics; and 4) how to create a command and control infrastructure driven by data for vaccine outages, overages, and physical logistics.

- **Distribution challenges:** The key to overcoming distribution challenges is building a true end-to-end supply chain that is transparent and resilient.
  1. To overcome distribution challenges associated with the current decentralized system with limited end-to-end visibility, **a centralized national real-time tracking and tracing system must be implemented expeditiously to provide visibility into the complete vaccine supply chain.** The current process of states independently reporting this information is archaic, delayed, and prone to error. Instead, we need to modernize the data infrastructure that is being leveraged to track vaccine doses to eliminate the current delay in reporting, inability of several states to notify hospitals when to anticipate vaccine delivery, and other logistical challenges.

It is critical for the US to be aware of exactly where vaccine doses are currently being held and in the exact quantities. This information will become even more critical if all available vaccine doses are released with the hope that manufacturing will be able to meet future demand as a transparent and clear mechanism will be necessary to proactively determine any potential bottlenecks for patients receiving the second dose.

2. Vaccine distribution is currently based upon state census and not based upon the number of eligible individuals in the state that qualify for Phase 1a prioritization. This has resulted in some states being able to vaccinate all eligible patients in phase 1a and move to subsequent phases whereas other states continue to struggle to vaccinate all phase 1a eligible patients due to insufficient supply. This results in inequalities in vaccine distribution and access that could have been avoided. **To ensure equitable vaccine distribution and access, a data-driven dynamic allocation process should be implemented moving forward to match vaccine allocation with the number of eligible patients in the state based upon the prioritization pathway.** A dynamic allocation process is necessary to ensure the right doses are distributed to the areas of greatest need.
3. During the pandemic, lack of clear visibility of distributor fulfillment lead 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. Unfortunately, the high demand of vaccine coupled with the insufficient supply has resulted in some hospitals already receiving gray market offers from entities claiming to have COVID-19 vaccine available. 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:
    - Hold all payments in escrow until testing is validated;
    - Test lot samples through a certification process;
    - Permit the sale of products that are validated; and
    - 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 vaccine security** to minimize diversion

from vaccination sites.

4. A potential complicating factor to distribution challenges is the threat of cybersecurity attacks on the distribution channels associated with vaccines. Cybersecurity threats can take on a number of different forms such as impacting the freezers used to store vaccine, registration and appointment systems, electronic health records, vaccination tracking systems, etc. Therefore, **a national approach is needed to monitor and protect the US healthcare system and vaccine distribution channel from cybersecurity threats.** It is critical that cybersecurity be monitored at a national level to account for all incoming threats, track and trend across the country, and proactively respond. While states and local health systems may have their own cybersecurity programs in place, a national and coordinated approach would augment local approaches and provide a whole of nation view.
- **Supply 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.
    1. To ensure all viable vaccine is being leveraged and that no overfill doses go to waste, **the ancillary kits accompanying vaccine should be reconfigured moving forward to include additional needles and syringes assuming the maximum number of doses per vial with overfill will be administered.** Operation Warp Speed should consult with healthcare providers to determine that maximum number of doses that can be anticipated for each manufacturer and ensure ancillary supply kits support this new calculation.
    2. To ensure healthcare providers administering the vaccine have access to gloves to feel confident that they are protected against any inadvertent transmission of COVID-19 during the vaccination process, **the ancillary kits accompanying vaccine should be reconfigured moving forward to include nitrile exam gloves.** The kits should include gloves in a variety of sizes to accommodate differing needs amongst vaccinators. Should a strain on nitrile exam gloves preclude this recommendation from moving forward, the inclusion of latex exam gloves can also be considered as an alternate solution as it can be a viable option for vaccinators and patients with no history of a latex allergy.
    3. To ensure adequate supply of needles and syringes and nitrile exam gloves, **the Strategic National Stockpile should release any existing supply to Operation Warp Speed to support vaccination efforts.** However, it is also critical to ensure an adequate stockpile of critical supplies exists and therefore the Defense Production Act should be leveraged to expeditiously refill inventory in the Strategic National Stockpile and provide additional supply for future vaccination efforts.
    4. To provide visibility into potential supply chain issues in the future, **a public-private partnership should be leveraged to monitor the rollout, collaboratively discuss challenges, and work proactively to resolve any supply chain challenges that**

**may arise such as spot shortages.** This group should utilize a data-driven approach to proactively identify supply chain challenges and collectively brainstorm and provide recommendations regarding how to address forthcoming challenges in a manner that best supports the mass vaccination campaign with minimal disruption. Similar public-private partnerships were leveraged by FEMA during the COVID-19 pandemic and proved to be successful in addressing shortages of PPE, ventilators, and critical medications and therefore should be mimicked for the vaccine rollout.

5. Section 3121 of the CARES Act, which was passed by Congress in March 2020, created new authority for the FDA to help prevent or mitigate medical device shortages during a public health emergency. The provision includes requirements for manufacturers of certain devices to notify the FDA "of a permanent discontinuance in the manufacture of the device" or "an interruption in the manufacture of the device that is likely to lead to a meaningful disruption in supply of that device in the United States" during a declared public health emergency. In addition, FDA is required to maintain a publicly available, up-to-date list of the devices the FDA has determined to be in shortage.

While FDA has expeditiously implemented these new provisions and published the list of device shortages in September 2020, **the FDA should liken the device shortage list to more closely resemble the drug shortage list which is more specific around the exact product and manufacturer that is impacted.** This information is key to enable purchasers to identify alternatives and adjust buying. Premier also hopes the FDA will work with private sector partners to get a better sense of real-time supply and surge demand. This specificity is also key to incent more domestic manufacturing and potential leveraging of the Defense Production Act, where companies and the government need to understand the market and the potential demand so that they can feel confident in business plans and investments.

- **Communication gaps:** The key to overcoming communication gaps is the creation of a single source of truth.
  1. To address the fragmented communication channels and ongoing confusion, **it is essential that a single source of truth is established for both healthcare providers and the general public.** We need 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. Today, it's a large bureaucracy and many are very unclear about which agencies, authorities or regulators are responsible for what actions.

The establishment of single source of truth should include the appointment of a formal vaccination spokesperson by the Biden administration that will be considered the commander in chief for all vaccine-related issues and will be responsible for correcting any misinformation. Provider and public facing websites should also be established that collate all vaccine-related information in a single and centralized manner such that it is easy to navigate and differentiate fact from fiction. Furthermore,

for patients who may not have access to the internet, toll-free numbers should be established for patients to call and receive additional information from real-life individuals.

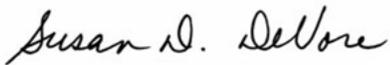
2. To provide the US with a better picture of current vaccination rates, **the CDC vaccine reporting website should be reconfigured to provide data on the first and second dose administered.** Providing information on the administration of the second dose will provide a more accurate picture of national administration rates and protection from COVID-19. This information will also be critical to understand why patients may not be returning for the second dose and the impact of any supply chain challenges in delaying administration of the second dose.
3. To avoid patients returning day after day with no luck to receive vaccines, **all vaccinations should be moved to an appointment-based system with an active waitlist that can be leveraged if there are no shows.** As appointment-based system helps avoid the confusion patients are facing in first come first serve jurisdictions by ensuring they receive an appointment that aligns with their place on the prioritization pathway coupled with available supply. An appointment-based system also helps providers appropriately maximize the number of vaccines given in a day by aligning appointments with available staff and vaccine. Furthermore, a pre-established wait list helps ensure that no dose is wasted and avoids the last-minute scramble of trying to find a willing patient prior to expiration of the vaccine.
4. The identification and sharing of best practices are a key component of a strong communication channel. **The Biden administration should lead a fact-finding process to understand why there are jurisdictional differences in vaccination administration rates.** The analysis should include a review of what are the educational, operational, or systematic differences that make some jurisdictions more successful than others. **The Biden administration should also establish standardized reporting of key administration metrics or features that will allow for governmental and non-governmental organizations to mine the data to look for best practices to improve vaccination rates in the future.** It is essential that the reporting of this data be automated and not place an additional burden on healthcare providers.
5. A lack of standardized definitions and various interpretations of the prioritization pathway has created confusion to date. To avoid this confusion in the future, **standardized definitions (e.g. “essential worker”) should be created that are applicable across jurisdictions.** Guidance should also be developed that outlines circumstances where deviation from the prioritization pathway or standardized definition is acceptable (e.g. administering a soon to expire dose outside of the prioritization pathway vs wasting the dose) and how, if at all, deviations should be documented.

In addition to the recommendations above, it is critical that the public and private sector continue to collaborate throughout the mass vaccination campaign to identify additional challenges, areas for improvement, and bottlenecks and collectively brainstorm opportunities to overcome them. The power of

the public-private sector partnership has been integral during the COVID-19 pandemic response and will continue to be a powerful tool as we work together to vaccinate the American people.

In closing, Premier and our members appreciate the opportunity to share our recommendations for ensuring a fast and equitable process for mass vaccination against COVID-19. If you have any questions regarding our comments or need more information, please contact Blair Childs at [Blair\\_Childs@premierinc.com](mailto:Blair_Childs@premierinc.com) or 202.879.8009 or Soumi Saha at [Soumi\\_Saha@premierinc.com](mailto:Soumi_Saha@premierinc.com) or 732.266.5472.

Sincerely,



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