



February 2, 2020

The Honorable Anna Eshoo
Chairwoman
U.S. House of Representatives
272 Cannon HOB
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member
U.S. House of Representatives
2434 Rayburn HOB
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Guthrie:

On behalf of the Healthcare Leadership Council (HLC), we thank you for holding a hearing on, "Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. We are uniquely positioned to address disaster preparedness comprehensively from all perspectives in the healthcare industry.

The COVID-19 health pandemic has been an unprecedented challenge to all Americans. Over 25 million Americans have tested positive for COVID-19 and over 400,000 have tragically lost their lives. Stay-at-home orders have resulted in millions of job losses. However, due to the outstanding cooperation between the private sector and federal, state and local officials, significant progress has been made in confronting the pandemic. These efforts have enabled the development and distribution of two vaccines, with more completing clinical trials. Manufacturers and suppliers of personal protective equipment (PPE) working together with government, have been able to distribute essential items for frontline workers. While these efforts are admirable and represent the potential successes such partnerships can achieve, we can do more to strengthen our disaster readiness infrastructure to be prepared for future pandemics and other health emergencies.

HLC, through its National Dialogue for Healthcare Innovation (NDHI) initiative on Disaster Preparedness and Response has partnered with the Duke-Margolis Center for Health Policy to recommend future strategies that will lead to better disaster readiness efforts. In this report, we focus on three different areas: improving data and evidence generation, strengthening innovation and supply chain readiness and improving care delivery approaches. The report

highlights many of the current challenges public and private entities have had in responding to the COVID-19 health pandemic and makes recommendations on how to ease future burdens.

One of the greatest challenges of the COVID-19 health pandemic has been the difficulty of coordination among a diverse set of public and private stakeholders. Each of these groups is uniquely situated to respond to disaster scenarios. Leveraging their individual strengths in a systemic, coordinated manner will lead to greater successes. One critical area where such coordination could be used is in data collection and exchange. Public health officials require real-time information on a variety of metrics (e.g. PPE levels, hospital bed count, number of individuals vaccinated) so that they can tailor their responses as necessary. Private sector healthcare organizations stand at the ready to provide input to government officials on how best to share information in times of emergency to support supply chain management and surge redeployment.

HLC applauds federal, state and local officials for their support in easing regulatory barriers to allow for swift approval of vaccines and therapeutics, assistance in scaling testing capacity and providing flexibilities for healthcare employees to assist in other communities. These flexibilities are essential for the private sector to swiftly respond to disaster events. We encourage Congress to work with regulators to make these flexibilities permanent, while keeping important safeguards in place to ensure public trust.

HLC looks forward to working with you on steps to better improve our disaster response efforts. We are pleased to share a copy of our final NDHI report that is attached. Please feel free to contact Tina Grande at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

A handwritten signature in cursive script, reading "Mary R. Grealy".

Mary R. Grealy
President



**NATIONAL DIALOGUE FOR
HEALTHCARE INNOVATION:**
*Framework for Private-Public Collaboration
on Disaster Preparedness and Response*



FEBRUARY 2021



NATIONAL DIALOGUE FOR
Healthcare Innovation

Duke | MARGOLIS CENTER
for Health Policy

Executive Summary

During the COVID-19 pandemic, the private sector responded with unprecedented urgency to emerging needs, including ramping up production for medical products and pharmaceuticals, re-tooling assembly lines to develop new products, ensuring swift and efficient distribution of those products, sharing information to increase coordination and situational awareness, and adapting care delivery to manage surges in disease. Successful response efforts during the pandemic generally required significant private-public collaboration and within-industry data sharing and partnerships, even where proprietary concerns or intra-sector competition would normally restrict such collaboration. Despite these successes, the COVID-19 pandemic also revealed vulnerabilities in the United States health care system, such as shortages, distribution bottlenecks, and conflicting or unclear regulatory guidance that delayed and hampered response efforts.

To support the healthcare sector's capacity to prepare for and respond to the next public health emergency, the **Healthcare Leadership Council (HLC)**, an alliance of leaders from all sectors of American health care, and the **Duke-Margolis Center for Health Policy** collaborated on an initiative aimed at strengthening the U.S. health care sector's capacity to prepare for and respond to future disasters. The **Disaster Preparedness and Response Initiative** brought together expertise from across public and private sectors to highlight lessons learned from the response to the COVID-19 crisis, identify innovations that can be maintained or strengthened, and develop recommendations for how the private and public sectors can better collaborate to prepare and respond to the next emergency.

This initiative was well positioned to help clarify, shape, and coordinate the execution of that strategy among governmental and private sector leaders. It was unique in its focus on private-public coordination; in developing recommendations applicable to a broader spectrum of disaster responses beyond pandemics (including natural disasters, bioterrorism, cybersecurity, and others); and in creating targeted, bold recommendations that private sector leaders, the new Congress, and incoming Biden Administration can adopt in the immediate term. Although HLC's work to support improved disaster preparedness started before the COVID-19 global pandemic, it has naturally taken on greater urgency as the pandemic continues to cause widespread mortality and economic disruption.

Throughout the initiative, public and private stakeholders consistently identified the need to strengthen coordination and collaborations, harmonize conflicting requirements during emergencies to improve health care mobility and surge capacity, improve equity, increase transparency for emergency management, and leverage innovations that were developed during the pandemic. To accomplish these cross-cutting objectives, the initiative focused on actions that could be taken in each of the following areas:

- Improving data and evidence generation, and
- Strengthening innovation and supply chain readiness, and
- Innovating care delivery approaches.

In each area, the report outlines key actions private sector leaders can commit to accomplishing together and identifies recommended actions for public sector leaders to improve coordination and collaborations for public health emergencies.

Recommended Private Sector Actions to Improve Disaster Preparedness, Resilience, and Response

- Review regulatory reforms that worked well during the pandemic and identify areas for further improvement.
- Identify best practices in care delivery, supply chain, innovation, and data that were learned during this pandemic, especially understanding how to increase adoption of these best practices for future emergencies.
- Identify specific financing mechanisms to support capacity building for preparedness, public health, and emergency response efforts.
- Establish new approaches to supply chains to help prevent significant disruptions, such as using virtual stockpiles based on “time to inventory” for selected products; geographically diversifying product sourcing (including domestic manufacturing for high-priority medical products); and establishing pre-certified relationships, such as through pre-defined contract mechanisms, between manufacturers, distributors, and end users that identify organizations that have the capability to produce and distribute products to meet potential demand during emergencies.
- Expand data and evidence generation practices for biomedical innovation.
- Invest in tools that can address health disparities and make equity a greater priority.
- Ensure health care payments support resilience, and identify resources to build capacity and capabilities.

Recommended Governmental Actions to Improve Private-Public Coordination and Collaborations for Public Health Emergencies

- Ensure private sector health care leaders can coordinate during emergencies by ensuring adequate legal protections.
- Streamline regulations based on what has been learned during the COVID-19 pandemic, especially on capacity challenges, virtual care expansions, and licensure and scope of practice for workforce mobility across states.
- Establish mechanisms to quickly convene and coordinate senior decisionmakers and subject matter experts from private sector health care organizations before and during public health emergencies.
- Clearly define the roles and responsibilities of federal and state regulatory agencies and establish improved coordination and communication channels between public and private sectors.
- Use various tools to both build up and maintain emergency preparedness, resilience, response, and recovery, such as mandatory appropriations, zero interest loans, bond debt service, or health care payment models with upfront payments and more flexible payment structures.
- Reform data collection, coordination, and utilization approaches to support disaster response efforts, and modernize national health IT systems and capabilities, and strengthen data reporting and transparency around supply chains.
- Create standards for what should be stored in stockpiles, including how much and how long in the stockpile, regularly updating the standards based on most recent science and with active care delivery system and provider engagement.
- Develop mechanisms for collecting supply chain information (both upstream and downstream) to identify vulnerabilities, including by building on new authorities and learnings coming out of implementation of the CARES Act, in a manner that protects confidential commercial information, trade secret information, and other information that is considered classified.

The accompanying report contains more detailed recommendations to operationalize this multi-faceted vision, with specific strategies for private sector, federal, and state leaders to bolster preparedness, resilience, response, and recovery.

Improving Preparedness and Response for All Future EMERGENCIES



Strengthen Private-Public Coordination and Collaboration

The private sector responded to the COVID-19 pandemic with unprecedented efforts, such as ramping up production for medical products, re-tooling assembly lines to developing new products, and rapidly adapting care delivery to manage surges in pandemic cases. Further, successful responses to COVID-19 generally required significant private-public collaboration and within-industry data sharing and partnerships, even in areas normally considered competitive or proprietary. However, the COVID-19 pandemic also revealed vulnerabilities in the United States health care system, such as shortages, distribution bottlenecks, and conflicting or unclear regulatory guidance that delayed and hampered response efforts.

- Ensure adequate legal protections for private sector coordination
- Improve stakeholder engagement with private sector, especially senior leaders
- Harmonize conflicting requirements to improve surge capacity
- Improve equity
- Transparency as backbone of emergency management
- Leverage innovations developed during pandemic



IMPROVE Data and Evidence Generation

- Promote real-time data collection, reporting, and sharing,
- Leverage interoperability of health information technology and public health data systems
- Generate real-world evidence
- Provide sustained support for infrastructure investments
- Harmonize regulatory requirements
- Ensure privacy and security

INNOVATE Care Delivery Approaches

- Streamline regulations to implement delivery best practices
- Improve equity
- Ensure health care payment supports resilience
- Strengthen private/public communication and coordination

STRENGTHEN Innovation and Supply Chain Readiness

- Strengthen stockpiles and prevent supply shocks by focusing on “time to inventory” and diversifying supply chains
- Improve supply chain transparency
- Expand supply chain capacity, especially for ancillary supplies

Introduction

The Healthcare Leadership Council (HLC), an alliance of leaders from all sectors of American health care, and the Duke-Margolis Center for Health Policy collaborated on an initiative aimed at strengthening the U.S. health care sector's capacity to prepare for and respond to future disasters. Although HLC's work to support improved disaster preparedness started before the COVID-19 global pandemic, it has naturally taken on greater urgency as the pandemic continues to cause widespread mortality and economic disruption. Leveraging lessons learned from the response to the COVID-19 crisis, this initiative sought to bring together expertise from across public and private sectors to highlight lessons learned, identify innovations that can be maintained or strengthened, and develop recommendations for how the public and private sectors can collaborate to better prepare and respond to the next emergency.

This initiative was well positioned to help clarify, shape, and coordinate the execution of that strategy among governmental and private sector leaders. It was unique in its focus on private-public coordination; in developing recommendations applicable to a broader spectrum of disaster responses beyond pandemics (including natural disasters, bioterrorism, cybersecurity, and others); and in creating targeted, bold recommendations that private sector leaders, the new Congress, and incoming Biden Administration can adopt in the immediate term.

While the issues confronting disaster preparedness and response are complex and interrelated, the initiative concentrated on three primary areas where the pandemic has highlighted significant challenges. For each of the three areas, we outlined a vision for future emergency preparedness, resilience, and response:

- **Improving data and evidence generation:** We highlighted opportunities for better private-public coordination on data to improve patient care response during an emergency or disaster, strengthening public health surveillance, and accelerating biomedical innovation while protecting the privacy of individuals.
- **Strengthening innovation and supply chain readiness:** The initiative identified strategies for a disaster-ready supply chain that can ensure our nation's needs are met. Using the current pandemic as a case study, we need to ensure that personal protective equipment, supplies, treatments, vaccines, and devices can be delivered equitably, safely, and efficiently.
- **Innovating care delivery approaches:** The project developed approaches and policy strategies to respond to extraordinary escalations and changes in patient needs, which included how to encourage rapid uptake of clinical and treatment advancements; accelerate adaptations of delivery models in response to emergency needs, such as leveraging telehealth and virtual care models; deploy clinicians and care delivery resources where they are needed; and implement measures to ensure resiliency, equity, and financial stability for health care providers during periods when normal revenue streams are disrupted.

Throughout 2020, the initiative brought together multiple experts, leaders, and multisector perspectives from across the public and private sector to develop consensus recommendations through interviews, multi-stakeholder meetings, and a large national summit in October 2020. The resulting report contains practical and actionable recommendations to strengthen our nation's preparedness and response for future health crises, as well as strategies that federal, state, and private sector leaders can take to bolster preparedness, resilience, response, and recovery.

Cross-Cutting Principles for Strengthening Disaster Response and Preparedness

Several key themes have emerged from discussions with public and private sector leaders, stakeholders, and experts, drawing on the lessons learned during the COVID-19 pandemic and other public health emergencies. The principles aim to be useful for the wide spectrum of types of disasters and their varying scope (local, statewide, or national). The following section synthesizes those concepts into cross-cutting principles that will guide all recommendations for the initiative.

- **Strengthen Private-Public Coordination and Collaborations:** Successful responses to COVID-19 have required significant private-public collaboration and within-industry data sharing and partnerships, even in areas that are normally considered competitive or proprietary. This type of private sector accountability and commitment should be encouraged and supported by public sector leaders for future emergencies through the following actions:

 - Convene private sector organizations to identify best practices and metrics for emergency preparedness, response, and recovery, leveraging the private sector's ability to identify important metrics to judge accountability.
 - Improve collaboration and coordination across the private sector in health care for future emergencies by creating stronger and more transparent communication channels across the private sector and between the public and private sectors.
 - Expand private-public collaborations for future public health emergencies, drawing where appropriate from experiences in other industries (e.g., aviation, national electrical grid), and building on and improving existing stakeholder engagement efforts (e.g., HHS Sector Coordinating Councils and FEMA voluntary agreements).
 - Create a standard set of legal and regulatory guidances and waivers (e.g., antitrust, anti-collusion) that allow for collaborative action across the private sector and could be implemented quickly by specified government agencies or officials during public health emergencies.
 - Institute dedicated, efficient financing mechanisms, contingent on meeting certain standards and performance metrics, that support public and private sector capacity building for preparedness, public health, and emergency response efforts.
 - Support a more collaborative process for future emergencies by building trust and relationships between private sector health care organizations and local non-profit and community groups outside the health system for disaster response and recovery.
- **Harmonize Conflicting Requirements During Emergencies to Improve Health Care Mobility and Surge Capacity:** As public health emergencies often cross state and local government boundaries, health care organizations can face conflicting regulations and laws during their emergency response. Further, conflicting regulations can limit the ability of the health care system to quickly deliver supplies, human capital, and direct care to areas with greatest need. To address these challenges during emergencies, public sector leaders can:

 - Harmonize regulations and have quickly implementable, uniform waivers for local, state, and federal regulations on policies such as provider licensure and scope of practice; public health reporting; stockpiles for PPE, devices, and other supplies; data use, disclosures, exchange, and sharing; and telehealth.
 - Coordinate government response with clear roles and responsibilities across levels of government (state and federal), federal agencies (e.g., CDC, OCR, DHS, ASPR, FEMA, FDA, DoD, CMS), different data reporting systems and requirements, and federal emergency response legal frameworks (e.g., Stafford Act, National Emergencies Act, Public Health Emergencies under the Public Health Service Act).

- **Improve Equity and Address Disparities in Access and Outcomes:** The COVID-19 pandemic has disproportionately affected many groups that are already experiencing poor outcomes across the health system. Equity and access issues must be proactively monitored on an ongoing basis and inform all areas and phases of preparedness and response. Planning, coordinating and collaborating should also ensure that the perspectives of vulnerable populations and diverse communities, including racial and ethnic minorities, the uninsured, and people with disabilities, are represented.
- **Increase Transparency as Backbone of Emergency Management:** Data and technology are needed for the private and public sectors to quickly deliver supplies and human capital to the areas that need it; technology such as regional dashboards on current and predicted capacity can support improved transparency and responsiveness. Transparency of research findings is also important. Significant research has been conducted across a variety of stakeholder groups. These findings need to be shared and readily available at local and state levels.
- **Leverage Innovations Developed During Pandemic:** Given the substantial innovation that has occurred during the pandemic, public and private sector leaders should work to identify those processes and flexibility that should be continued, with adequate funding and organizational commitments, to build capacity and respond to future emergencies.

General Recommendations for Improving Disaster Preparedness and Response

Building on the cross-cutting principles identified above, the following specific recommendations for private and public sectors leaders are critical to advancing preparedness, resilience, response, and recovery. Building these capabilities is integral to American national security, the health of the American public, and future economic stability and growth; as such they merit further investment and attention by private and public sector leaders.

- **Strengthen Private-Public Coordination and Collaborations**

There is general agreement that better coordination is needed between government agencies and the private sector; between government agencies; and across federal, state, and local governments.

- Ensure private sector health care leaders can coordinate during emergencies by guaranteeing adequate legal protections.
 - There are opportunities to build on and improve antitrust safe harbors for private sector collaborations during the current pandemic, such as the Critical Infrastructure Partnership Advisory Council or FEMA voluntary agreements. Existing safe harbors should be clearly articulated and publicized so that health care organizations know of them before an emergency occurs, and new safe harbors should be created and similarly publicized.
- Establish mechanisms to quickly convene and coordinate senior decisionmakers from private sector organizations across the health care system (e.g., acute care delivery, outpatient and community clinics, post-acute providers, health plans, accrediting organizations, laboratories, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, group purchasing organizations, independent and chain pharmacies, information technology companies, state and local health officials) before and during public health emergencies.
 - *Coordinate stakeholder engagement:* DHS, HHS, and DoD should develop one formal health care stakeholder engagement plan that identifies how to best coordinate the multiple existing stakeholder engagement initiatives inside various agencies to promote strong communications, coordination, and engagement during an emergency.
 - *Ensure senior decisions makers from private sector organizations receive needed communications and are engaged:* DHS, HHS, and DoD should examine existing stakeholder engagement channels to identify whether an existing channel can be modified to engage senior decisionmakers from private sector health care industry sectors, or, if not, create new channels for such senior-level engagement.
 - This senior decisionmaker stakeholder engagement process can be modeled after C-suite level engagement in the electricity sector, such as the CEO-led Electricity Subsector Coordinating Council.

- *Expand opportunities to involve senior decision makers from private sector health care organizations in preparedness:* Senior decisionmakers in private sector stakeholder organizations should engage with DHS, HHS, and DoD to conduct regular preparedness exercises and tabletop scenarios on private-public emergency response. The information gathered from these efforts, which may also involve frontline health care workers and patients, should be used to update emergency preparedness and response plans.
 - Private sector leaders should coordinate to create a playbook that outlines private sector coordination in health care during an emergency. This can be modeled after a similar playbook for the financial services industry under their Sector Coordinating Council and Information Sharing and Analysis Center.
 - *Coordinate stakeholder engagement with states and localities:* DHS, HHS, and DoD should coordinate stakeholder engagement with private stakeholders, local or regional government leaders, and state government leaders (especially Governors) in order to expand stakeholder engagement with private sector health care organizations operating inside their state or region.
 - This can build on regional collaborative efforts, such as ASPR's Regional Disaster Health Response System that has piloted capacity building and network development with Massachusetts General Hospital and the University of Nebraska Medical Center. Such engagement is particularly important in rural or underserved regions.
 - *Increase access to subject matter expertise from private sector health care stakeholders:* To ensure all agencies involved in emergency preparedness and response have access to subject matter expertise in health care, the White House should create a new, or modify an existing group that includes private sector subject matter experts from each health care sector important for emergencies, such as production capacity, supply chain and distribution, acute care delivery, community delivered care, and others, with multiple experts from each sector.
 - This could be implemented through a Federal Advisory Committee seated before an emergency or as an advisory council for the HHS Assistant Secretary for Preparedness and Response. Regardless of the structure, the group should serve multiple agencies across the federal government.
 - If implemented as a Federal Advisory Committee, the Congress should review the Federal Advisory Committee Act to identify statutory requirements that could be waived during an emergency.
 - *Identify key governmental contacts for private sector during emergencies:* Guided by stakeholder engagement with senior private sector health leaders, DHS, HHS, and DoD should develop a publicly accessible inventory of key federal government contacts, drawing on private sector leaders' experiences during COVID and where they had the greatest need for federal government information, waivers, or coordination.
- Clearly define the roles and responsibilities of federal and state regulatory agencies and establish improved coordination and communication channels between public and private sectors.
- *Communicate roles and responsibilities of federal agencies involved in public health emergencies:* Outside of any emergency and at the beginning of a public health emergency, the White House should publicly communicate the expected roles and responsibilities of the federal agencies relevant to public health emergency preparedness, response, resilience, and recovery, which will help promote coordination and engagement with the private sector during an emergency.
 - *Improve coordination between federal agencies involved in public health emergencies:* The White House should identify a mechanism for coordinating among federal departments during public health emergencies, whether tasking a single federal agency to serve as coordinator, tasking a well-defined interagency task force, or implementing another mechanism. During a given emergency, the President should appoint one person that remains the leader throughout the course of the disaster, and that person either has experience with health care for health care-related emergencies or has access to health care advisors.

- *Streamline legislative authority for public health emergencies:* The Congress should ensure federal disaster response legislative authority can be used for public health emergencies, like pandemics, such as by amending the disaster definition in the Stafford Act to explicitly define pandemics and other public health emergencies in major disaster declarations.
 - *Develop inventory of governmental emergency planning and response policies and documents:* DHS and HHS should develop a comprehensive and easily accessible inventory of federal, state, and local emergency planning and response documents, drawing on prior inventory efforts like AHRQ's [guidelines.gov](https://www.aahrq.gov/guidelines), so that private health care organizations can find the most recent and relevant policies in one location.
- Identify specific financing vehicles to support capacity building for preparedness, public health, and emergency response efforts.
- *Facilitate private sector leadership and investment in emergency preparedness:* Encourage private sector leadership and investment in health care emergency preparedness, drawing on the lessons learned about private sector investment and leadership in emergency preparedness such as in fire protection.
 - Drawing on multi-stakeholder input and review, identify how to leverage and develop private sector-focused performance standards and metrics for emergency preparedness.
 - While each emergency is unique, there are categories of disasters with common preparedness needs, challenges, and health care impacts. Accordingly, performance standards, metrics, and best practices for health care can be identified for each category of emergencies and disasters. There are also opportunities to learn from other experiences with standards in emergency preparedness, such as the PS-Prep program, launched by FEMA after the 9/11 Commission Act of 2007, that established voluntary private sector preparedness accreditation and certification, as well as partnerships between ASPR and the National Quality Forum on a Healthcare System Readiness Framework.
 - Private-sector standards and metrics could be simple through non-regulatory, industry led approaches.
 - *Increase investments in emergency preparedness, resilience, response, and recovery:* The Congress should use various tools to both build up and maintain emergency preparedness, resilience, response, and recovery, such as mandatory appropriations, zero interest loans, bond service, or health care payment models with upfront payments and more flexible payment structures.
 - Any financing would be contingent on meeting certain standards and performance metrics and would seek to build capacity across public and private sectors.
 - Key preparedness agencies, such as the HHS Assistant Secretary for Preparedness and Response, should be adequately funded during non-emergency times so that there is active infrastructure and processes in place for emergencies. It is also important to have adequate and sustained funding for state and regional preparedness agencies.
- **Harmonize Conflicting Requirements During Emergencies to Improve Health Care Mobility and Surge Capacity**
- There is broad agreement that regulatory barriers and other administrative policies should be amended or waived during times of emergencies.*
- Drawing on stakeholder engagement channels, private sector leaders and relevant federal and state agencies should review regulatory reforms that worked well and identify areas for further improvement.
 - The Congress and state legislatures should update disaster response legislation to provide for fast waivers that can grant needed flexibility during emergencies, such as those allowing for licensure portability, greater telehealth accessibility, temporarily lift communications restrictions to allow for coordination of care and with public health, and to quickly access PPE stockpiles.
 - These waivers could be implemented through multiple approaches: the legislation could outline which types of emergencies warrant certain waivers or flexibilities, all waivers or flexibilities could go into effect shortly after an emergency has been declared unless specifically not needed as noted in the emergency declaration, or the legislation could identify a tiered or categorized approach that could be specified by the emergency declaration.

Principles and Recommendations for Improving Data and Evidence Generation

Overarching Considerations for Improving Data and Evidence Generation

Preparing for and responding to a health-related disaster will require steady, trusted streams of data capable of supporting multiple components of a private-public response, including:

- Identifying, evaluating, and protecting at-risk populations.
- Measuring clinical outcomes to monitor treatments and interventions to learn what works and to educate clinicians.
- Ensuring data supports the needs of policy makers and other stakeholders in coordinating, planning, and responding in a timely, effective way.

To support public health disaster response (including syndromic and disease syndromic surveillance, case identification, mitigation, and monitoring), supply chain coordination, and other long-term efforts for achieving sustained health impacts, the recommendations below should be informed by the following general principles:

- **Promote Real-time Data Collection, Reporting, and Sharing:** Support real-time and consistent data collection and reporting to ensure availability on key dimensions critical for disaster response by a variety of public and private stakeholders.
- **Leverage and Support Interoperability of Health Information Technology and Public Health Data Systems:** Identify and coordinate existing health information technology (health IT) initiatives and data systems that help contribute flows of information to response efforts (e.g., electronic case reporting for reportable conditions to public health, health system data, electronic prescribing, electronic lab reporting, NEMSIS for EMS data) – ideally leveraging existing health IT and data sources to help address challenges of interoperability between health care and public health.
 - Relying on the recently released guidance from OCR, develop permanent policies for emergency situations and public health infrastructure that builds off of existing health IT sources and data infrastructure, including health information exchanges (HIEs).
- **Generate Real-World Evidence:** Ensure that response efforts, particularly those that are ongoing over the course of several months, produce understandable data and recommendations that contribute to collective learning and sharing of best practices.
- **Provide Sustained Support for Infrastructure Investments:** Create an ongoing funding stream to support Federal, state, tribal, territorial, and local public health data systems, such as immunization information systems, including supporting staff who maintain and update these systems and who make decisions informed by these data systems.
- **Harmonize Regulatory Requirements:** Review and harmonize requirements for data collection and reporting across Federal, state, tribal, territorial, and local public health authorities. Allow increased flexibility in response efforts if new national requirements are necessary. Address potential conflict between state or local regulations and national requirements.
- **Privacy and Security:** Plan for and create contingencies for data privacy challenges, including modifying existing federal and state policies to allow appropriate data sharing before and during public health emergencies while still protecting the privacy of patient data. This should include parallel plans to protect the security of health data and any necessary data sharing. Address potential conflict between state policies and national policies.

Recommendations

• Reform Data Collection, Coordination, and Utilization Approaches to Support Disaster Preparedness and Response Efforts

- HHS, coordinating across relevant HHS agencies (such as ONC, CDC, FDA) and in consultation with agencies from other departments (such as FEMA and agencies involved in emergency response efforts), should work with private sector stakeholders to:
 - Develop an improved process by which consistent, standardized data is collected and reported across the public health and health care ecosystem, including among providers/clinicians and federal, state, tribal, territorial, and local health authorities. This information can be used and visualized uniquely by each state, but the data should be complete and standardized at the national level without requiring additional data reporting by providers/clinicians, distributors, health plans, or other health care sectors.
 - Enhance existing advisory processes to ensure participation of health care and public health organizations in efforts to define the data and measures necessary for disaster response efforts. Processes should ensure privacy and security of the information, and clear, rapid identification of data collection and reporting for public health disasters or health-related emergencies, including:
 - What data is needed to inform disaster response efforts.
 - Which organizations must submit it and how often.
 - Which central or coordinating entity receives it.
 - Which entities can access it.
 - What training is needed to support data reporting.
 - How the data is organized, reviewed, and merged.
 - Clear guidelines on specific use cases for individual and aggregate health data to support disaster response efforts, accounting for variability in use cases across different types of disasters and response efforts.
 - Safeguards to protect the privacy and security of any information collected.
 - Define measures necessary for disaster response and monitoring efforts, including measures from across public health and health care delivery that capture both health care demand, resources, health outcomes, and health and health care disparities. Use standard data definitions and transmission mechanisms whenever possible.
 - Build a 21st century public health early warning system that is able to:
 - Collect, exchange, report and use a uniform set of data from inpatient, ambulatory, pharmacy, and long-term care electronic health records.
 - Designate, adopt, and implement data and technology standards for public health data, with deference given to those published by consensus-based standards development organizations, and with priority given to standards adopted by ONC.
 - Enhance and expand current public health data collection and systems from ambulatory and outpatient settings (including labs, pharmacies, and long-term care) for syndromic surveillance, threat detection, and surge prediction, monitoring, and mitigation.
 - Ensure that any data collection and reporting efforts informing disaster readiness and response include race, ethnicity, and sociodemographic characteristics to help identify high risk vulnerable populations and direct resources accordingly.

- Establish key technology requirements for public health authorities (e.g., state and county health officials), including the ability to:
 - Send and receive patient level and aggregate data.
 - Ensure the privacy and security of data.
- Pursuant to these goals, the Congress and HHS should ensure that existing programs are leveraged wherever possible and, absent available programs or resources, should augment existing efforts with new programs and funding streams to support all activities identified in this section.
- Congress should update national privacy legislation for all health information, building on HIPAA to protect the use and disclosure of health data during public health emergencies.
- **Modernize National, State, and Local Health IT Systems and Capabilities**
 - The Congress should pass legislation that funds public health data and IT modernization, sets targets and benchmarks, and improves workforce capacity – including federal agencies, state, tribal, territorial, and local public health authorities.
 - Pursuant to the goals above, Congress, HHS, and state and local leaders should leverage existing programs or create new programs that provide opportunities and incentives for hospitals, health systems, laboratories, and other private organizations to improve their ability to report necessary data for disaster response efforts.
 - This should include identifying opportunities to more routinely engage these entities in state and local preparedness planning activities.
 - Both public and private sector entities should adopt common baseline standards harmonized and updated across national, state and local levels to improve patient identification.
 - Providers, software developers, payers, and other health care organizations should collaborate, with technical assistance from HHS, to identify and collect a common set of data elements using federally adopted standards, to improve accurately matching patients to their health records.
- **Strengthen Data Reporting and Transparency Around Supply Chains**
 - Consistent with the recommendations in the following section on supply chain transparency, stakeholder groups should provide input to help HHS establish mechanisms for private sector health care entities to share confidential, aggregate, organization-specific data in an emergency with the federal and state governments or an authorized coordinating body to support supply chain management and surge redeployment.
 - Could focus on specific types of products and/or supply chains likely to be disrupted.
 - May require reporting and visibility both up- and downstream and bi-directionally between government and private sector in the supply chain.
 - Ensure information is shared in a manner that protects confidential commercial information, trade secret information, and any other information that is considered classified information.
 - HHS should develop the ability to create a dashboard on short notice with the above data that can inform disaster response efforts by the federal and state governments or an authorized coordinating body. This dashboard should reflect a bi-directional flow of information between the government and private sector.

● **Expand Data and Evidence Generation Practices for Biomedical Innovation**

- The private sector and federal government should identify ways to provide incentives or enable researchers, health information technology vendors, manufacturers, health care providers, and health plans to utilize their data for research that specifically advances care delivery and treatment through the rapid deployment of clinical trials or observational studies.
 - This could include incentives for internal research activities utilizing an organization’s own data or incentives for making data available to third party organizations.
- Manufacturers, academic researchers, participating health systems, and the NIH should leverage and adapt existing platform trial designs and tools to rapidly establish practical trial networks for generating evidence on new or repurposed treatments for the health emergency.
 - These networks should include clinical care settings (e.g., community hospitals and practices) and patient populations (e.g., older and minority populations) not typically represented in traditional clinical trials.
- Manufacturers, academic researchers, participating health systems, and the NIH should identify strategies for incorporating virtual care, remote monitoring, and telehealth into clinical research, particularly during a long-lasting health-related disaster.
- Health systems, payers, manufacturers, and researchers should support the use of observational data that can rapidly identify effective care approaches to inform best practices or serve as hypothesis generation for additional randomized studies.
- HHS, CDC, public health authorities, and private sector entities should apply innovative and breakthrough technologies and analytics approaches (including artificial intelligence, natural language processing, and machine learning) to strengthen public health predictive and forecasting capabilities (demands for health care, supplies and resources) and to inform evidence-based practices.
- HHS should ensure that federal information blocking penalties are appropriately enforced, with robust input from the stakeholder community as enforcement policy is developed, to ensure data liquidity among health systems, health plans, research organizations, and patients, and support broad access to timely and accurate data under a unified privacy law.

Principles and Recommendations for Strengthening Innovation and Supply Chain Readiness

Overarching Principles and Recommendation Concepts

The private sector has responded to the COVID-19 pandemic with unprecedented efforts to meet medical product needs, from ramping up production to re-tooling assembly lines to developing new products. However, the COVID-19 pandemic has also revealed vulnerabilities in the United States health care supply chain, with shortages, distribution bottlenecks, and conflicting or unclear regulatory guidance that delayed and hampered response efforts. To develop a resilient, responsive, and robust supply chain for the next emergency, it is imperative that the United States better leverage the unique capabilities of the private and public sectors. The following key principles should be considered to support a coordinated private-public response:

- **Improve Communication and Coordination:** Create a national strategy and roadmap for medical product innovation, rapid production, and distribution chains with strong engagement from the private sector; improve coordination across federal, state, and local agencies; expand robust private-public sector collaboration with systematic communications and data sharing; and remove regulatory barriers that impede rapid production and distribution of medical products during emergencies.
- **Strengthen Stockpiles and Prevent Supply Shocks:** Establish new approaches to supply chains to help prevent significant disruptions, such as using virtual stockpiles based on “time to inventory” for selected products; geographically diversified product sourcing (including domestic manufacturing for high-priority medical products); create standards for what should be stored in stockpiles, including how much and how long in the stockpile, regularly updating the standards based on most recent science and with active care delivery system and provider engagement; and establish pre-certified relationships, such as through pre-defined contract mechanisms, between manufacturers, distributors, group purchasing organizations, and end users to identify organizations that have the capability to produce and distribute products to meet potential demand during emergencies.
- **Improve Visibility into Supply Chains:** Develop mechanisms for collecting supply chain information (both upstream and downstream) to identify vulnerabilities, including by building on new authorities and learnings coming out of implementation of the CARES Act, in a manner that protects confidential commercial information, trade secret information, and other information that is considered classified.
- **Expand Supply Chain Capacity:** Ensure sustained funding to meet the nation’s supply chain needs, identify needed ancillary supplies for important emergency purposes (such as nasal swabs for testing, syringes for vaccines, and active pharmaceutical ingredients to quickly scale up drug production), provide strategic incentives to bolster supply chain resilience, and protect against gray and black-market vendors.

In addition to these principles, the group highlighted the great diversity in medical products and noted that supply chain issues often differ for different products (such as diagnostics versus personal protective equipment versus durable medical equipment versus pharmaceuticals versus others).

Recommendations

● **Improve Communication and Coordination**

In addition to the cross-cutting recommendations, the following actions can strengthen coordination of the supply chain response:

- Clearly define the roles and responsibilities of federal and state regulatory agencies with respect to the supply chain, including critical inputs and delivery of countermeasures or medical products.
 - The White House should publicly communicate expected roles and responsibilities of federal agencies to facilitate private sector engagement to manage the manufacturing, storing, and distribution of critical supplies needed during a public health emergency.
- Leverage expanded stakeholder engagement channels (*as discussed in the cross-cutting recommendation section*).
 - The private sector should provide input to DHS, HHS and DoD on supply chain resilience. This may include defining what drugs, equipment, and other products are “critical;” establishing stockpile standards (e.g., quantity, quality, and duration), and inventory reporting requirements.
- Reduce regulatory barriers.
 - FEMA should clearly communicate – during normal operations and emergencies – protocols and plans to utilize existing authority (e.g., Section 708 of the Defense Production Act) or other regulatory waivers during emergencies (e.g., such as for antitrust laws, anti-collusion, technology transfer, or export controls) that can help improve supply chain coordination during an emergency. While recognizing the need for greater speed, any waivers or safe harbors should continue to support market functioning, patient privacy, and continue to ensure protection of trade secrets and confidential commercial information.
 - FDA should promote expedited regulatory approvals during emergencies, with further opportunities for communication between the FDA and manufacturers to evaluate and approve submissions (e.g., leverage technology and virtual protocols to expedite processes and optimize needed documentation).
 - The FDA should continue to release updated Emergency Use Authorizations (EUA) guidance for emergencies, including the underlying decision-making in issuing EUAs, to provide appropriate consistency in EUA use and encourage rapid production response (recognizing that different products might appropriately be subject to different standards).

● **Strengthen Stockpiles and Prevent Supply Shocks**

- Modernize and optimize the stockpile of critical medical supplies and drugs.
 - Existing stakeholder engagement channels, like the Sector Coordinating Councils, should be leveraged by DHS, HHS and DoD to identify specific critical medical products and pharmaceuticals that could be transitioned to a virtual stockpile or transitioned to a “flow-through” inventory model (constant replenishment of newer stock as older stock moves into distribution). Medical products and pharmaceuticals that are candidates for a virtual stockpile approach will have sufficient production capacity, so that a portion of capacity can be stored in an ongoing way. Further, a virtual stockpile approach will require greater coordination between federal agencies and supply chain organizations that either hold inventory or help in inventory procurement.

- ASPR should coordinate with other federal agencies, state leaders, and private sector leaders to prevent proliferation of and competition for local stockpiles with explicit coordination between federal and state governments through a “hub-and-spoke” stockpile model. ASPR should clearly communicate expectations for how the Strategic National Stockpile should be utilized during emergencies.
 - The Congress should ensure adequate, sustained funding for the Strategic National Stockpile.
 - ASPR should coordinate with existing stakeholder engagement channels, like the Sector Coordinating Councils, to update standards for medical products in stockpiles (e.g., quantity needed, shelf life, time to ramp up production level for product, and time for distribution) with regular reviews based on updated science and industry trends, with standards sensitive to products types needed for various public health emergencies.
- Private sector health leaders should coordinate with DHS, HHS and DoD to develop best practices for private sector modernization of the supply chain through digitalization, automation, and predictive analytics; develop best practices for private sector manufacturers to transition to advanced manufacturing practices (e.g., continuous manufacturing, modular manufacturing); and develop policies that support a “just-in-case” manufacturing approach balanced with the need for “just-in-time” efficiency, sensitive to medical product types.
 - DHS, HHS, and DoD should establish pre-certified relationships between manufacturers, distributors, and end users that have the capability of producing pre-defined critical medical products of a minimum standard in the least amount of time. Federal agencies may establish pre-certified relationships, create pre-defined contract mechanisms for use during emergencies, or establish contingency contracts that can easily be activated in order to be responsive with a shorter time to inventory. Private sector distributors or end users may develop best practices to aid in developing pre-certified relationships. *Participants in the initiative generally agreed that other approaches (e.g. a list of pre-contracted suppliers or creating a national clearinghouse to vet and connect manufacturers and distributors) would not be feasible.*
 - ASPR should conduct biannual tests of the supply chain readiness to ensure the systems are in place with manufacturers, distributors, GPOs, and providers to activate as needed.

• **Improve Visibility into Supply Chains**

There was a general consensus that more visibility is needed into the supply chain – both upstream and downstream, which includes informing key stakeholders about usage, levels, and dispositions, while maintaining protection of confidential commercial information and trade secrets and protecting any information that is sensitive from a national security perspective. The following areas emerged as actionable recommendations:

- Stakeholder engagement groups should work in partnership with HHS to review existing reporting protocols, identify opportunities for improving reporting and tracking of critical products in a coordinated or centralized approach, provide feedback on how to transition to automatic reporting versus manual reporting on medical product capacity, identify strategies for bi-directional data sharing (to ensure that industry has access to actionable information), and outline opportunities for engendering trust with end users that would encourage greater coordination and data sharing. The goal should be to have an information system that can be quickly utilized during emergencies containing specific information on critical products in terms of manufacturing capacity, speed and product availability, product availability and location with distributors and available inventory in hospitals.

- FEMA should leverage existing mechanisms to enhance appropriate information exchanges. For instance, FEMA's voluntary agreement can assist with coordination between the federal government and commercial entities in specific supply chain networks, providing anti-trust safe harbors for businesses within the same sub-sector. The Critical Infrastructure Partnership Advisory Council (CIPAC) can also facilitate coordination by shielding businesses from publicly disclosing sensitive information.
 - Consistent with the recommendations in the data section of this report, a private-public process should define what information or data is needed to provide practical and actionable insights into inventory levels and use rates for various medical products in a way that is feasible and does not impose undue burden.
 - ASPR, in coordination with FEMA, should conduct tabletop exercises to assess key vulnerabilities in the ability of private and public sectors to develop, procure, store, and distribute critical medical products and make this information available for industry use, with appropriate safeguards to protect against unauthorized disclosures.
 - This exercise should consider all critical linkages in the supply chain. For instance, strengthening transportation lines (e.g., trucking/shipping/rail/air freight) and addressing trade restrictions to prevent disruptions.
 - ASPR, in consultation with existing stakeholder engagement channels and other HHS agencies, should develop a standardized approach for allocating resources based on need and equity, with clear communications and expectations for how end users can procure and access supplies prevent counterproductive bidding wars and profiteering.
 - DHS and FDA should coordinate to identify a system that can be quickly utilized during emergencies that will provide a centralized means to manage gray and black-market vendors, providing a means to centralize vetting and approval of products that are being offered by these vendors.
- **Expand Supply Chain Capacity**
- Congress should provide strategic incentives (e.g., zero percent and expedited low-finance loans, federally-guaranteed purchase commitments) to bolster supply chain resilience, incentivize health suppliers to invest in new technologies where appropriate (e.g., digitalization), and increase domestic manufacturing capacity of critical medical products to improve availability during emergencies.
 - A private-public process should identify additional strategies to strengthen the resilience of supply chain networks, including enhancing supply chain redundancies, investing in workforce development programs to support manufacturing needs, encouraging geographic diversification for critical medical products, and improve critical medical product inventory (while meeting quality standards) during emergencies.
 - Congress should ensure sustained funding for research and development, especially for products with national security utility or limited commercial potential, such as through federal research channels (e.g., RADx, BARDA).
 - Given that supply chains are only as resilient as their weakest link, ASPR, FEMA, FDA, and DHS (supported by the cross-sector coordinating groups) should identify critical ancillary supplies common to different emergency scenarios (e.g., nuclear disasters, pandemics, natural disasters, etc.).

Principles and Recommendations for Innovating Care Delivery Approaches

Overarching Considerations for Improving Care Delivery

While the COVID-19 pandemic has stressed health systems across the country, it has also shown their resilience and resourcefulness in delivering care under unusual circumstances. The goal of this initiative was to identify how organizations can build on the lessons learned during the pandemic, such as how to rapidly adopt clinical and treatment advances; adapt delivery models to take advantage of telehealth and virtual care models; deploy clinicians and care delivery resources to where they are needed; and implement measures to ensure resilience, equity, and financial sustainability for health care providers during periods when normal revenue streams are disrupted. Multiple organizations will need to be involved to allow for widespread, sustainable improvement, such as hospitals and independent clinician practices, primary and specialty care, civilian and military health care organizations, health care and public health, acute and post-acute and long-term care, payers and providers and patients, group-purchasing organizations and distributors and life science industry, and public and private sector. To improve responsiveness during future emergencies, private-public initiatives should primarily focus on the following principles:

- **Identify and Increase Adoption of Care Delivery Best Practices:** Innovation in many areas has accelerated, with organizations modifying facilities, integrating new types of care, and reorienting workforces to respond more effectively. Identifying best practices learned both in the current pandemic and previous emergencies will allow the health system to better respond to future emergencies while maintaining continuity of care for patients with acute conditions.
- **Strengthen Public/Private Communication and Coordination:** Support efforts that foster more effective two-way, continuous communication and collaboration between the public and private sectors.
- **Streamline Regulations to Allow for Implementation of Standardized Delivery System Best Practices:** Federal and state regulations should be streamlined based on what has been learned during the COVID-19 pandemic, especially on capacity challenges, virtual care expansions, and licensure and scope of practice for workforce mobility across states. The private sector can identify opportunities to specify best practices and standards for care delivery that can be used instead of regulatory requirements.
- **Improve Equity:** As the COVID-19 pandemic shone a spotlight on disparities, public and private sectors should invest in tools and develop communication strategies that can address health disparities and prioritize equity.
- **Identify Resources to Build Capacity and Capabilities:** To improve emergency preparedness, management, and response capabilities and ensure a diverse, resilient workforce, public and private sectors should identify necessary resources, such as bonds, payment, loans, and grants.
- **Ensure Health Care Payment Supports Resilience:** COVID-19 has shown that consistent, reliable funding is critical to maintain operational functioning during emergencies. Policymakers should encourage payment models that support financial resilience and overall flexibility in emergencies.

Recommendations

• Identify and Increase Adoption of Care Delivery Best Practices

- Professional associations should identify areas where new standardized training modules may be needed to help organizations efficiently re-train and re-deploy providers into new fields. Associations should work with ASPR TRACIE (Technical Resources, Assistance Center, and Information Exchange) to provide open access to these modules. This can also draw on the lessons learned from the National Emerging Special Pathogens Training and Education Center (NETEC), funded by ASPR and CDC, that has launched regional training centers around the country with leadership from Emory Medicine, University of Nebraska Medical Center, and Bellevue Hospital (part of NYC Health+Hospitals).
- Health care delivery organizations should develop tools and best practices to prevent provider fatigue through creative work schedules, childcare accommodations, and necessary system contingencies.
- Health care delivery organizations should develop best practices for improving coordination between care delivery staff and public health organizations.

• Strengthen Public/Private Communication and Coordination

- FEMA, ASPR, and CDC, the agencies leading the National Response Coordination Center, should collaborate with relevant public and private stakeholders to:
 - Determine where new policies and initiatives could improve coordination among health care coalitions, state and regional emergency management teams, incident command centers, alternate care sites, and other critical systems, especially ensuring strong coordination with payers, clinicians, and health care delivery organizations.
 - Identify key gap areas where improved coordination and communication could streamline emergency response, such as between public and private organizations and between organizations within the health care system.

• Streamline Regulations to Allow for Implementation of Standardized Delivery System Best Practices

- Capacity
 - HHS should develop a single, common set of shared reporting requirements for hospitals and other health care settings as relevant to the emergency that includes standardized metrics such as available beds, essential supplies, pharmaceuticals, patient transfer protocols, and others.
 - The reporting requirements should ensure these data can be automatically generated from electronic health record systems and other existing data systems.
 - HHS should draw on broad stakeholder input, review, and comment to ensure feasibility of the reporting requirements.

— Virtual Care

- A private-public process focused on virtual care should conduct the following:
 - Inventory key regulatory constraints in virtual care, and conditions for determining how and where waivers can allow such regulations to be changed or relaxed during an emergency;
 - Identify geographic regions where limited broadband capabilities could inhibit access to care;
 - Develop best practices for virtual care provision, with a specific focus on behavioral health; and
 - Identify opportunities to standardize definitions and terminology for federal programs in policies and regulations in areas such as:
 - Definition of telehealth (to include audio only and not just video).
 - Site of service provisions (such as originating sites).
 - Allowable tools.
- The FDA should evaluate how regulations can encourage better deployment of digital technology during public health emergencies, drawing on the regulatory discretion used already for mobile apps and other software. CMS, state Medicaid agencies, and commercial payers should examine how payment and coverage policies affect uptake of virtual care technologies, with special consideration of how flexibility on using virtual care technologies could be included in alternative payment models.
- Drawing on coordinating functions of national associations when feasible, state agencies, state legislatures, and state professional associations, should collaborate to identify opportunities to align definitions and terminology in virtual care policy and regulation, including areas such as:
 - Definition of telehealth (to include audio-only and not just video);
 - Site of service provisions (such as originating sites);
 - Allowable tools; and
 - Scope of practice for telehealth delivery.

— Licensure and Certification

- The Congress should establish and enact a national emergency licensure policy for emergencies, addressing the following:
 - Cross-state licensure allowing for health care delivery organizations to address workforce needs more efficiently by using out-of-state providers; and
 - A national uniform process to allow medical, nursing, pharmacy, and allied professional school graduates to enter the health system quickly in appropriate roles.
- Professional associations should work with state health and human services agencies to identify best practices for workforce mobility given varying licensure and scope of practice laws, with the goal of developing processes that ensure health care delivery organizations have regular access to most recent scope of practice laws and regulations.

— Scope of Practice

- State legislatures should establish and enact automatic standards for scope of practice flexibility during emergencies to ensure providers are practicing at the top of their license.
 - Efforts should allow health systems to more easily create diverse health care teams that include social workers, community health workers, and others.
- State agencies and state legislatures should collaborate with state medical and pharmacy boards to identify areas where permanent regulatory flexibility and scope of practice expansion could improve public health emergency response and reduce inter-state variability to allow for a more consistent, comprehensive and efficient national strategy during a public health emergency response.

— Implementation

- The private sector should convene a group to review current processes for administering uniform care delivery policies and initiatives during an emergency and recommend areas to HHS where efficiency or coordination could be improved.
 - Specific focuses could include updating standards and regulations, or processes such as updating ICD-10 codes.
 - The group should solicit input on pain points during the COVID-19 pandemic and other recent public health emergencies

• **Improve Equity**

- Stakeholders, in collaboration with the CDC, CMS, and ONC, should identify and develop measures that can track progress in improving equity and addressing disparities during a public health emergency and build on the CDC's COVID-19 Response Health Equity Strategy.
 - The measures should inform disaster readiness and response by focusing on race, ethnicity, and sociodemographic characteristics to help identify high risk, vulnerable populations and direct resources accordingly.
- Researchers should create a vulnerability index to help health systems prioritize the most important groups for targeted outreach and support
- States and local public health agencies should provide community education to vulnerable populations on public health prevention measures and how to access preventive care and treatments.
- Ensure that new payment approaches include payment/funding of services outside of healthcare delivery that address social determinants of health.

• **Identify Resources to Build Capacity and Capabilities**

— Infrastructure Investment

- The private sector should work with HHS through its stakeholder engagement channels, as described in the general recommendations section, to review where policies can be modified to support a “just in case” approach balanced with the need for “just in time” efficiency and lean streamlining, which should include the following approaches:
 - Exploring strange bedfellow collaborations outside the health care community (e.g., investment banks).
 - Tax structures, risk ratings, reinsurance, and liability waivers to provide incentives for private sector readiness.

- HHS should identify financing mechanisms, technical assistance, and other supports that can help organizations expand their emergency preparedness and response capabilities and infrastructure.
 - Efforts should specifically focus on where greater flexibility may be needed in grant administration that would allow organizations to increase capability more quickly.

— Preparedness and Response Capacity

- Congress should increase grant funding for already existing disaster preparedness and response programs (e.g., Regional Disaster Health Response System, Hospital Preparedness Program).
- HHS should identify areas where additional grant funding or greater flexibility around who can receive this funding could increase preparedness.

• **Ensure Health Care Payment Supports Resilience**

— Payment Models

- CMS, state Medicaid agencies, and private payers should prioritize alternative payment models that allow for greater financial flexibility in emergencies, aligning model components to reduce administrative burden when possible.
 - The models should include built-in contingency policies for emergency periods, such as upfront payments to help organizations manage through crisis periods and transition to alternative payment models over longer terms.
 - Specifically focus on models that effectively engage providers across the continuum of care and meet the needs of primary and behavioral health, with increased regulatory flexibility for those clinicians practicing under alternative payment models.

APPENDIX - ABBREVIATIONS, AND ACRONYMS

AHRQ – Agency for Healthcare Research and Quality

ASPR – Assistant Secretary for Preparedness and Response

BARDA – Biomedical Advanced Research and Development Authority

CARES ACT – The Coronavirus Aid, Relief, and Economic Security Act

CDC – Centers For Disease Control and Prevention

CIPAC – Critical Infrastructure Partnership Advisory Council

CMS – Centers for Medicare and Medicaid Services

DHS – Department of Homeland Security

DoD – Department of Defense

DPA – Defense Production Act

EHR – Electronic Health Record

EMS – Emergency Medical Services

FDA – Food and Drug Administration

FEMA – Federal Emergency Management Agency

GPO – Group Purchasing Organization

HHS – Health and Human Services

ICD – International Classification of Diseases

NEMESIS – National EMS Information System

NETEC – National Emerging Special Pathogen Training and Education Center

NIH – National Institutes of Health

NRCC – National Response Coordination Center

OCR – Office for Civil Rights

ONC – Office of the National Coordinator for Health Information Technology

PPE – Personal Protective Equipment

RADx – Rapid Acceleration of Diagnostics

SCC – Sector Coordinating Council

SNS – Strategic National Stockpile

TRACIE – Technical Resources, Assistance Center, and Information Exchange

VUA – Voluntary Use Agreement

Contributors

AdvaMed
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Aledade
American Academy of Pediatrics
American Clinical Laboratory Association
American College of Emergency Physicians
American Health Care Association
American Hospital Association
American Medical Association
American Pharmacists Association
American Public Health Association
America's Blood Centers
America's Health Insurance Plans
AmerisourceBergen
Amgen
AMN Healthcare
Anthem
Ascension
Association for Behavioral Health and Wellness
Association of American Medical Colleges
Atrium Health
Baxter
Biogen
Biotechnology Innovation Organization
Bipartisan Policy Center
BlueCross BlueShield of North Carolina
BlueCross BlueShield of Tennessee
Bristol Myers Squibb
Business Roundtable
CDC Foundation
Change Healthcare
Cigna/Express Scripts
City of Hope
Civica Rx
Cleveland Clinic
ConnectiveRx
Cotiviti
Deloitte

ELITE Strategic Services
Epic
Fairview Health Services
Federation of American Hospitals
Genentech
Guardant Health
HCA Healthcare
Healthcare Distribution Alliance
Health Industry Distributors Association
Health Management Systems
Healthcare Leadership Council
Healthcare Ready
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IQVIA
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Merck
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National Alliance on Mental Illness
National Association of Chain Drug Stores
National Association of Manufacturers
National Center for Disaster Medicine and Public Health, Uniformed Services University of the Health Sciences
National Governors Association
National Health Council
National Minority Quality Forum
NewYork-Presbyterian Hospital
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Pfizer
Pharmaceutical Care Management Association
Pharmacy HIT Collaborative
PhRMA
Premier healthcare alliance
Primary Care Collaborative
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About the National Dialogue for Healthcare Innovation

NDHI was created by the Healthcare Leadership Council, an alliance of chief executives of the nation's leading healthcare companies and organizations representing all health sectors. The purpose of NDHI is to bring together leaders from private sector healthcare, government, academia, business, and patient organizations to focus on issues affecting the course for healthcare's future. For more information, visit: www.ndhi.org

About the Duke-Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy is a focus area within Duke University that addresses critical health policy challenges and delivers practical, innovative solutions to **improve health and the value of health care or all**. The Center brings together faculty and staff from across Duke's schools of medicine, nursing, law, public policy, business, and engineering, and engages them in academic research and in developing practical solutions to health policy's most pressing problems.

Duke-Margolis faculty and researchers contributing to this report include:

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- Mark Japinga

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