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Case No.: 2020-01155-FOIA-OS

September 16, 2020

Sent via Email

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A representative from the Assistant Secretary for Preparedness and Response (ASPR) conducted a search for responsive records and located 73 pages. After a careful review of these pages, I have determined to release them to you in their entirety.

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ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE**

**CRIMSON CONTAGION 2019 FUNCTIONAL EXERCISE
AFTER-ACTION REPORT**

JANUARY 2020



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HANDLING INSTRUCTIONS

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2. Reproduction of this document, in whole or in part, without prior approval from the U.S. Department of Health and Human Services (HHS) is prohibited.
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4. For more information about the exercise and this report, please email: ASPRExercises@hhs.gov.



MESSAGE FROM THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

DATE: December 9, 2019
FROM: Assistant Secretary for Preparedness and Response
SUBJECT: Crimson Contagion 2019 Functional Exercise

In following with the Assistant Secretary for Preparedness and Response's (ASPR) ongoing mission of "Saving Lives. Protecting Americans," HHS/ASPR conducted the Crimson Contagion 2019 Exercise Series. The Crimson Contagion 2019 Exercise Series was a multi-state, whole-of-government effort focused on the response and policy issues of workforce viability, critical infrastructure protection, economic impact, social distancing, scarce resource allocation, prioritization of vaccines and other countermeasures, and medical surge operations.

The Crimson Contagion 2019 Functional Exercise, conducted from August 13 to August 16, 2019, exercised the Nation's ability to respond to a large-scale outbreak of a novel avian influenza virus (H7N9) strain, which quickly spreads via human-to-human transmission around the world and across the continental United States with high rates of morbidity and mortality. The ASPR Exercise Branch managed the design, planning and conduct of this four-day exercise, which involved 19 Federal Departments/Agencies; 12 states; 74 local health departments and coalition regions; 15 tribal nations and pueblos; 87 hospitals; over 100 healthcare and public health private sector partners; and the White House National Security Council.

This After-Action Report provides feedback and recommendations on six distinct capabilities. Our purpose with this After-Action Report is to provide state, local, regional, federal, non-governmental and private sector partners with a summary of the strategic findings from the Crimson Contagion 2019 Functional Exercise. A short synopsis of the strategic findings is below, but I encourage you to read the full After-Action Report.

It was my great pleasure to participate and manage the Crimson Contagion 2019 Functional Exercise as the Exercise Director. The level of participation in the exercise from all levels of government and the collaboration and genuine concern for pandemic preparedness throughout the planning process and ramp-up exercises demonstrated a national commitment to excellence that will translate into lives saved when we encounter a severe pandemic.



As you collectively work through the key findings in this After-Action Report, please keep in mind that we are seeking workable solutions that can be codified and written into policies, plans, procedures, and systems. As solutions are agreed upon, ensure that the next step is taken by updating documents and socializing the solutions across the lifeline sectors.

Respectfully,

A handwritten signature in black ink, appearing to read "R. P. Kadlec". The signature is fluid and cursive, with a large initial "R" and "K".

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

Synopsis of Strategic Findings: Conduct of the Crimson Contagion 2019 Functional Exercise confirmed three strategic gaps in public health preparedness efforts with respect to authorities and capabilities:

1. **Authorities:** Presidential Policy Directive-44 (PPD-44, November 2016) allows for a non-traditional Federal Department to serve as the lead federal agency in response to a unique threat, such as an influenza pandemic, but it does not provide requisite mechanisms or processes to effectively lead coordination of the Federal Government's response to an influenza pandemic.
 - a. HHS has no mechanism to coordinate across or task other Federal Departments and Agencies during an influenza pandemic or other biological incident response. Although significant strides were made during the exercise to address this finding, the Federal Government needs to codify policy and procedure during a non-Stafford event.
2. **Funding:** HHS has limited funds associated with the Public Health Service Act, and it is not sufficient to fund the Federal Government's response to an influenza pandemic of this magnitude.
 - a. An influenza pandemic is not defined as a major disaster under the Robert T. Stafford Act; therefore, funding from the FEMA Disaster Relief Fund is likely not available for responding to this type of event.
 - b. If using the authorities under the Economy Act, HHS (the requesting Agency) does not have funding readily available to reimburse servicing Federal Agencies, requiring HHS to submit a supplemental funding request to Congress.
3. **Capabilities (Procurement of medical countermeasures):** In the event of a pandemic, initiating vaccine development, and procuring other medical countermeasures requires rapid, substantial funding from the United States. Delays in this funding mean delays in both vaccine availability and ability to compete with other buyers (countries) for scarce medical countermeasures, such as personal protective equipment (PPE), vaccines, diagnostics, and antivirals.
 - a. Delays in starting vaccine manufacturing will subsequently delay vaccine availability, putting more individuals at risk for infection.
 - b. Delays in procurement of PPE and other medical countermeasures will allow other buyers to procure available supplies.
 - c. HHS will require in excess of \$10B in new funding immediately upon identification of a novel pandemic influenza strain to secure medical countermeasures, including manufacturing capabilities for a vaccine in an influenza pandemic of this magnitude.
4. **Capabilities (raw materials and domestic manufacturing capability):** The United States lacks sufficient domestic manufacturing capacity and/or raw materials for almost all pandemic influenza medical countermeasures, including vaccines, therapeutics, PPE, needles and syringes, and N95 masks. Further, in the event of a pandemic, global manufacturing capacity will not be sufficient to meet demand, resulting in an inability to import adequate quantities of medical countermeasures.
 - a. The lack of domestic manufacturing capacity for these medical countermeasures in a severe pandemic with high morbidity and high rates of workforce absenteeism will

require (1) a prioritization strategy for the distribution and allocation of scarce resources nationwide, (2) prioritization of Continuity of Operations (COOP) and Continuity of Government (COG) efforts, and (3) consideration of creating domestic capabilities, including supplies of raw materials, to support manufacture of medical countermeasures, diagnostics, PPE, and other medical supplies in quantities sufficient to respond to an influenza pandemic in an adequate and timely manner.

CRIMSON CONTAGION 2019 FUNCTIONAL EXERCISE KEY FINDINGS AND OUTCOMES

Below is a list of the high-level, cross-cutting issues discussed in the Key Findings and Outcomes section of this report.

1. Statutory Authorities and Policies

- Existing statutory authorities and policies tasking HHS to lead the federal government's response to an influenza pandemic are insufficient, and policies are often in conflict with one another, which resulted in confusion among exercise participants.

2. Funding

- Currently, there are insufficient funding sources designated for the federal government to use in response to an influenza pandemic.
- It was unclear if and how states could repurpose HHS and the Centers for Disease Control and Prevention (CDC) grants, as well as other federal dollars to support the response to an influenza pandemic.

3. Planning

- The *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and the *Pandemic Crisis Action Plan Version 2.0* (January 2018) do not outline the organizational structure of the federal government response when HHS is designated as the lead federal agency.
- The extent of crisis standards of care planning and implementation varies across local, state, territorial, tribal, and federal stakeholders.
- State and federal entities identified challenges in implementing remote work/telework policies (as a workforce protection measure) to maintain operational capacity.
- The exercise provided an opportunity for state and local entities to test and validate their pandemic influenza plans.

4. Operational Coordination

- The HHS Disaster Leadership Group and the White House National Security Council Domestic Resilience Group have the infrastructure and capabilities to

successfully conduct virtual meetings during incidents necessitating social distancing.

- Exercise participants lacked clarity on federal interagency partners' roles and responsibilities during an influenza pandemic response.
- HHS and Emergency Support Function #8 partner liaisons in the Secretary's Operations Center and National Response Coordination Center played a critical role in providing subject matter expertise and coordination support to meet the public health and medical mission.
- HHS and the U.S. Department of Homeland Security (DHS)/Federal Emergency Management Agency (FEMA) collaborated closely throughout the exercise in an effort to enhance their understanding of one another's operational capabilities and facilitate a more efficient and effective response to a pandemic.
- Confusion regarding the purpose of and target audience for national conference calls hampered coordination among state and federal response partners.
- States lacked clarity on which channels they should use to request information from and report information to federal partners throughout the response.
- At times, HHS' Operating Divisions and Staff Divisions provided inconsistent and inaccurate response guidance and actions to healthcare and public health private sector partners.
- Representatives of Emergency Support Function #14 – Long-Term Community Recovery successfully supported cross-sector coordination among infrastructure owners and operators, businesses and government partners.

5. Situational Assessment

- Federal interagency partners conducted a productive crisis action planning session to develop key leader decisions, critical information requirements, and essential elements of information for a pandemic influenza response.
- HHS and DHS/FEMA's use of disparate information management systems (i.e. SharePoint and WebEOC) hampered their ability to establish and maintain a national common operating picture.
- Both HHS and DHS/FEMA submitted senior leader briefs to the White House National Security Council during the exercise, which caused confusion regarding the official source of senior leader briefs.
- Response partners lack clarity on CDC's data sharing policies.
- Federal partners did not provide state, local, tribal, and territorial public health and medical and emergency management partners with a standard template to report information across the full spectrum of community lifelines.
- HHS' regional staff lack clear guidance on the distribution of federal information

management products to state and local partners.

- CDC's State Health Official and Regional Emergency Coordinator calls provided state health officials with valuable insight into pandemic response activities at the national, regional, and state levels; however, the amount and types of information shared, as well as the existing limited mechanisms to share information were insufficient.
- Inconsistent use of terminology regarding vaccine types and stockpiles caused confusion among response partners at all levels of government.

6. Resources

- The current medical countermeasure supply chain and production capacity may not meet the demands imposed by countries during a global influenza pandemic.
- Federal exercise participants were not clear on the applicability or use of Title I, Priorities and Allocations Authority, of the Defense Production Act to mitigate medical countermeasure and ancillary supply shortages during an influenza pandemic response.
- States experienced multiple challenges requesting resources from the federal government due to a lack of standardized, well-understood, and properly executed resource request processes.
- The majority of participating states¹ indicated that they were unclear on pre-pandemic vaccine and the Strategic National Stockpile asset distribution in response to an influenza pandemic.
- States questioned the rationale behind federal decisions to decline resource requests.

7. Public Information and Risk Communications

- CDC used multiple information-sharing channels to successfully provide the public and responders with information about the influenza pandemic response, as well as guidance on safe work practices, and personal protective equipment for first responders.
- The implementation of school closures among some participating states highlighted the many cascading impacts to communities; and the variation in timing of school closures caused confusion among exercise participants.
- The reasons for HHS' decision to halt seasonal influenza administration and distribution were unclear to state participants.²

¹ During the exercise, three of the twelve participating states indicated that this was a challenge. This was later confirmed as a challenge by nearly all of the participating states during the After-Action Meeting.

² While this decision was made prior to exercise conduct, the level of discussion and concern raised during conduct of the Crimson Contagion 2019 Functional Exercise warranted its inclusion in this report.

-
- Despite initial technical issues, the National Incident Coordination Conference Line call enabled federal government response partners to coordinate on the development of public messages.
 - State government public information officers found the State Incident Coordination Conference Line calls useful to create state-based public messaging.

CRIMSON CONTAGION 2019 EXERCISE SERIES

Background

The lessons learned from HHS’ response to the 2009 Influenza Pandemic and the Ebola and Zika outbreaks highlighted the need for the nation to better prepare for incidents in which DHS/FEMA is not the lead federal agency. As such, HHS/ASPR/Office of the Principal Deputy Assistant Secretary/Exercise, Evaluation and After Action Division developed the Crimson Contagion 2019 Exercise Series (hereafter referred to as “Series”).

The Series included two tabletop exercises, a seminar, and a functional exercise to examine issues related to response structures, information exchange, coordination of resources, and policy decisions—with a non-traditional lead federal agency³—in accordance with the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and the *Pandemic Crisis Action Plan Version 2.0* (January 2018). These events involved all levels of government, private industry partners, and nongovernmental organizations. Table 1 below provides an overview of the Series’ exercises, excluding the Crimson Contagion 2019 Functional Exercise, which is included in this report below.

Table 1. Overview of the Crimson Contagion Exercise Series

Exercise Name	Date	Participants	Purpose
Internal HHS Pandemic Influenza Tabletop Exercise	January 23-24, 2019	HHS	Provided the opportunity to: <ol style="list-style-type: none"> 1. Examine current HHS/ASPR pandemic influenza planning efforts; 2. Understand relevant national-level and HHS plans, policies, and procedures; and 3. Synchronize response efforts in accordance with the new operational structures and concepts in HHS/ASPR Incident Response Framework.

³ For the purposes of this report, a non-traditional lead federal agency is defined as a federal agency that leads and manages the federal government’s response to a “complex and unique” incident, as identified in Presidential Policy Directive-44 (source: *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017)).



Exercise Name	Date	Participants	Purpose
Chicago and Illinois Pandemic Influenza Tabletop Exercise	April 10, 2019	City of Chicago, State of Illinois, HHS, Regional Federal Interagency Partners	Provided an opportunity for participants to: <ol style="list-style-type: none"> 1. Examine current city, state, and regional pandemic influenza planning efforts; 2. Better understand existing plans, policies, and procedures; 3. Identify any pandemic influenza response issues and/or challenges at the local, state, and regional levels; 4. Synchronize city, state, and regional response plans with federal response plans; and 5. Discuss the extent of federal support and capabilities.
Crimson Contagion 2019 Federal Interagency Seminar	May 14-15, 2019	White House National Security Council, federal interagency partners, and Functional Exercise participating jurisdictions	Provided a forum for participants to discuss: <ol style="list-style-type: none"> 1. How the federal government will organize to manage a nationwide pandemic influenza response; 2. Anticipated local and state pandemic influenza response challenges; and 3. The federal government's capabilities and available resources to support local and state response efforts during a nationwide influenza pandemic.

The culminating event of the Series—the Crimson Contagion 2019 Functional Exercise—was a four-day, multi-state, and multi-regional exercise that focused on whole-of-community response and policy issues of workforce viability; critical infrastructure protection; economic impact; social distancing; scarce resource allocation; prioritization of vaccines and other countermeasures; available (or potentially available) funding streams or mechanisms to fund the response; and medical surge operations. The exercise began on August 13, 2019 and concluded on August 16, 2019.

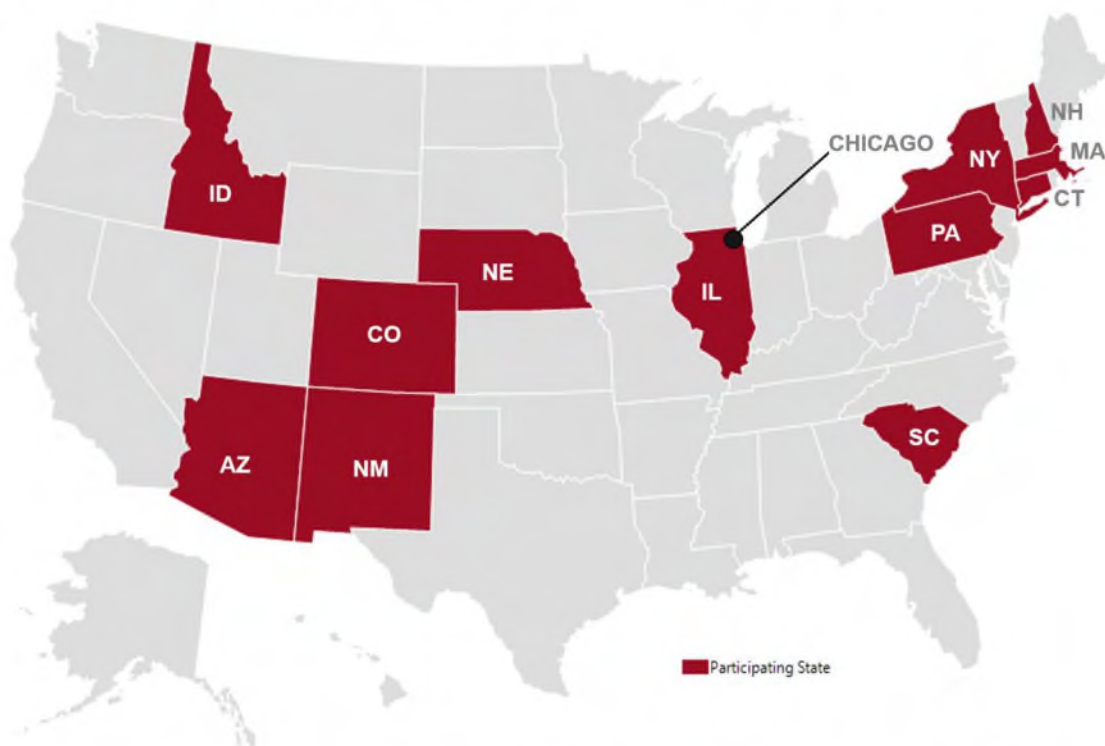
On each day of the Crimson Contagion 2019 Functional Exercise, participating federal organizations examined and tested capabilities related to that day's and the previous days' overarching federal focus areas. **Table 2** below depicts the overarching federal focus areas for each day of the exercise.

Table 2. Overarching Federal Focus Areas

Tuesday, 13 August	Wednesday, 14 August	Thursday, 15 August	Friday, 16 August
<ul style="list-style-type: none"> Operational Coordination Risk Messaging 	<ul style="list-style-type: none"> Situational Awareness, Information Sharing, and Reporting 	<ul style="list-style-type: none"> Finance 	<ul style="list-style-type: none"> Continuity of Operations

The Crimson Contagion 2019 Functional Exercise included robust participation from federal, state, local, territorial, and tribal communities, as well as from private sector partners including the White House National Security Council. Participation included approximately 19 federal departments and agencies, 12 states, 15 tribal nations and pueblos, 74 local health departments and coalition regions, 87 hospitals, and over 100 healthcare and public health private sector partners. At least one state from each of HHS' ten regions participated in the exercise, as illustrated in **Figure 1**. These states included: the Commonwealth of Massachusetts (Region 1); State of New Hampshire (Region 1); State of Connecticut (Region 1); State of New York (Region 2); Commonwealth of Pennsylvania (Region 3); State of South Carolina (Region 4); State of Illinois (Region 5); State of New Mexico (Region 6); State of Nebraska (Region 7); State of Colorado (Region 8); State of Arizona (Region 9); and State of Idaho (Region 10). As the host city, the City of Chicago was a key participant throughout the Crimson Contagion Series – demonstrating the impact of an influenza pandemic on a major U.S. city. For a full list of participating organizations, see **Appendix A**.

Figure 1. Jurisdictions Participating in the Crimson Contagion 19 Functional Exercise



Over 35 operations centers activated for the exercise, including state and local emergency operations centers, state and local public health and medical operations centers, nongovernmental organizations' operations centers, the HHS Secretary's Operations Center, the CDC Emergency Operations Center, the DHS/FEMA National

Response Coordination Center, and the DHS/FEMA Region 1 Regional Response Coordination Center. **Figure 2** below depicts the operations centers activated for exercise conduct.

Figure 2. Participating organizations' emergency operations centers activated for the Crimson Contagion 2019 Functional Exercise



Crimson Contagion 2019 Functional Exercise Scenario Overview

The Crimson Contagion 2019 Functional Exercise scenario was based on a novel influenza A(H7N9) virus that originates in China and is antigenically distinct (not matched) from stockpiled H7N9 vaccines.

The scenario starts off with tourists becoming ill in China with non-severe acute respiratory illness and then departing the Lhasa airport to other cities in China before flying back to their respective countries. During their flights home, additional tour group members, who were not ill when they embarked on their return flights from China, begin to experience the onset of respiratory symptoms and some develop fever. **Figure 3** below shows how the virus begins to spread around the world, as the ill tourists fly back to their countries of origin.

Figure 3. Map of Ill Tourists Flying Back to Their Countries of Origin



The virus rapidly spreads via human-to-human transmission around the world and to the continental U.S., where the virus is first detected in Chicago, Illinois. The virus continues to spread to other metropolitan areas across the U.S. **Figure 4** below shows the extent of the outbreak across the U.S. at the start of the exercise.

Conduct of the Crimson Contagion 2019 Functional Exercise began **47 days after the identification of the first case of H7N9 in the U.S.** By this point in the scenario, the HHS Secretary has declared a national public health emergency and the World Health Organization has declared an influenza pandemic—the 2019 H7N9 Influenza Pandemic. The federal government has decided to use stockpiled H7N9 vaccines as a

priming dose for selected persons at high risk of complications from influenza and designated critical workforce groups, but vaccination has not yet been implemented.

Figure 4. Influenza-Like Illness Activity Indicator by State

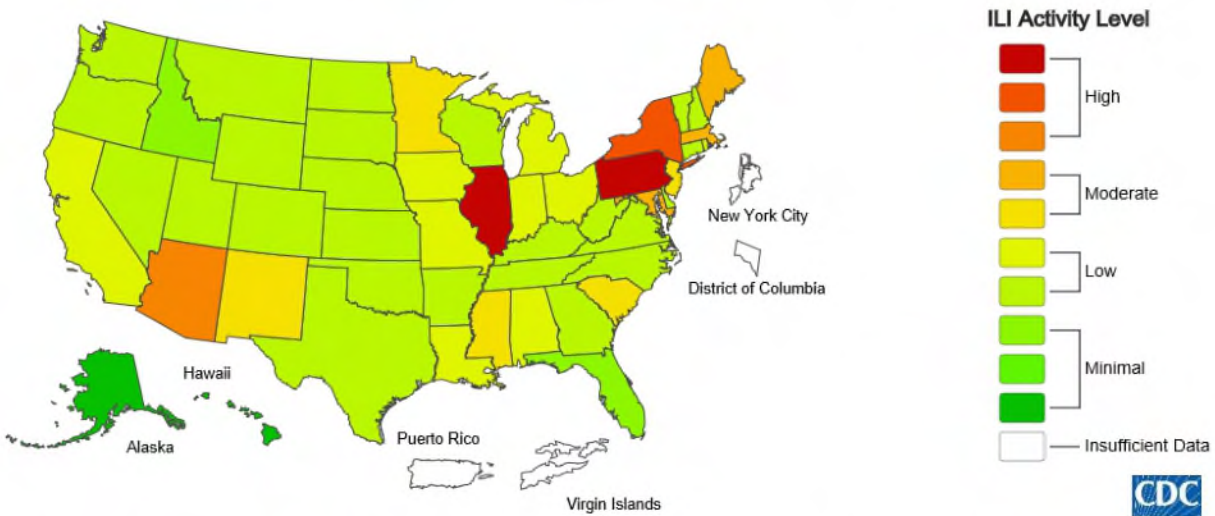


Figure 5 below depicts the epidemiological curve associated with the outbreak. During the Crimson Contagion 2019 Functional Exercise, the H7N9 pandemic is in the “acceleration phase”, the phase during which the number of cases consistently increases. **Figure 6** below depicts the virus’ high transmissibility and clinical severity, resulting in high-morbidity, and how the H7N9 pandemic compares to other historical pandemics. In addition, as part of the exercise scenario, forecasts projected a 90% chance that the pandemic will be of very high severity, with 110 million forecasted illnesses, 7.7 million forecasted hospitalizations, and 586,000 deaths in the U.S. alone.

Figure 5. Crimson Contagion Scenario: Progression Along the Epidemiological Curve

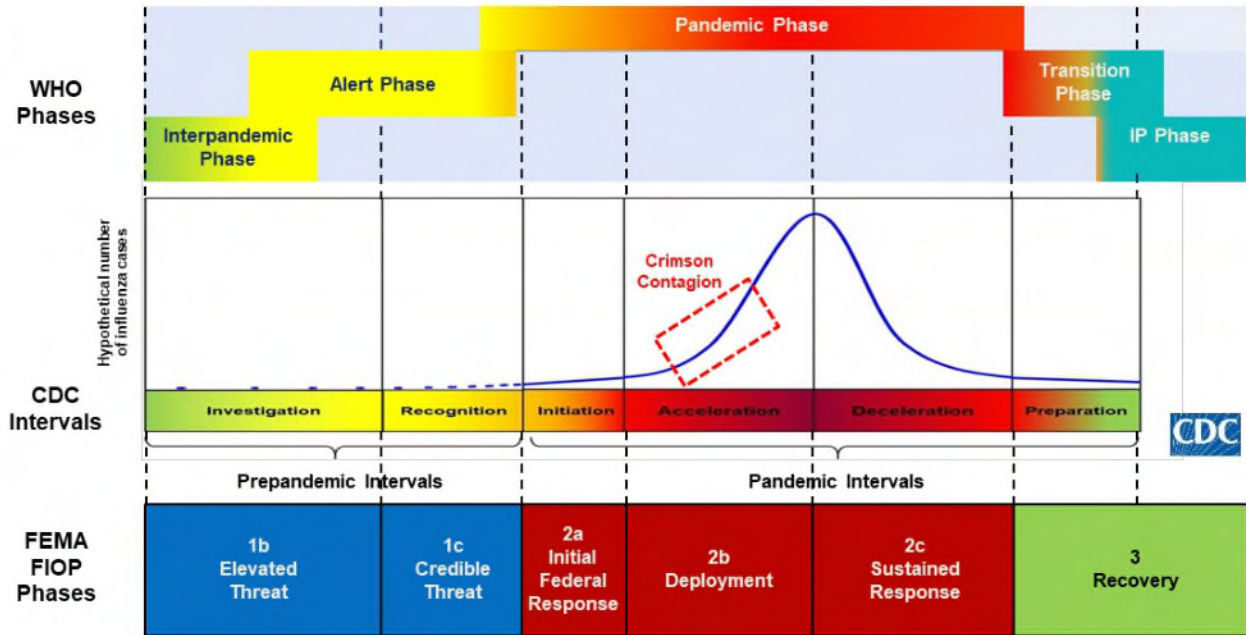
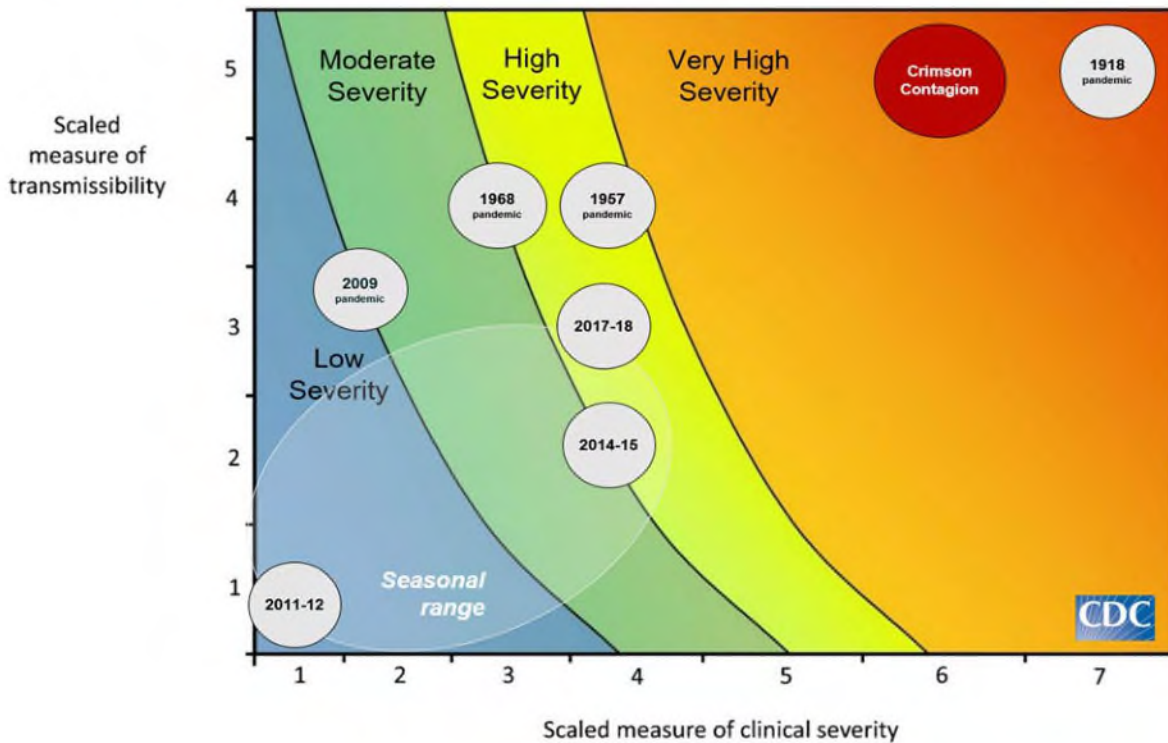


Figure 6. Crimson Contagion Scenario: Pandemic Severity Assessment Framework⁴



⁴ Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. *Emerg Infect Dis*. 2013;19(1):85–91. doi:10.3201/eid1901.120124

Crimson Contagion 2019 Functional Exercise Control and Evaluation Methodology

To coordinate and oversee the entire extent of exercise play, HHS stood up a Master Control Cell in Washington, DC. Participating organizations provided representatives to the Master Control Cell to monitor control and evaluation activities at their respective exercise venues. Additionally, HHS stood up a robust Simulation Cell to simulate nonparticipating states, federal departments and agencies, private sector organizations, and nongovernmental organizations, as needed.

Following the exercise, players and evaluators participated in hotwashes at their respective venues. Evaluators used Evaluator Logs, After-Action Report Analysis Forms, and Exercise Evaluation Guides to record their observations, and HHS also gathered player feedback using HHS's Corrective Action Program Electronic Feedback Form.

The Evaluation Team compiled all exercise data to construct a comprehensive picture of the major actions taken and decisions made during exercise play, comparing player decision and actions with applicable plans, policies, and procedures to identify gaps and issues. The purpose of this report is to provide an overview of the Crimson Contagion 2019 Functional Exercise and identify high-level, cross-cutting issues among the full range of stakeholders with a role in responding to an influenza pandemic.

CRIMSON CONTAGION 2019 FUNCTIONAL EXERCISE OVERVIEW

Exercise Name	Crimson Contagion 2019 Functional Exercise
Exercise Dates	August 13 – 16, 2019
Scope	<p>The Crimson Contagion 2019 Functional Exercise was a four-day, multi-state exercise that focused on the whole of community response and policy issues of workforce viability; critical infrastructure protection; economic impact; non-pharmaceutical interventions; scarce resource allocation; prioritization of vaccines and other countermeasures; and medical surge operations. Organizations participating in the Crimson Contagion Functional Exercise included local, state, and federal departments and agencies, as well as private-sector and nongovernmental organizations. At least one state from each of HHS' ten regions and the City of Chicago participated in the exercise.</p>
Core Capabilities	<ul style="list-style-type: none"> • Community Resilience • Critical Transportation • Environmental Response/Health and Safety • Fatality Management Services • Infrastructure Systems • Logistics and Supply Chain Management • Long-term Vulnerability Reduction • Mass Care Services • Operational Communications • Operational Coordination • Planning • Public Health, Healthcare, and Emergency Medical Services • Public Information and Warning • Risk and Disaster Resilience Assessment • Situational Assessment • Threats and Hazards Identification
Principals' Strategic Priorities	<ul style="list-style-type: none"> • Operational Coordination and Communications • Stabilization and Restoration of Critical Lifelines • National Security Emergencies • Public Health Emergencies • Continuity

Health Care Preparedness and Response Capabilities	<ul style="list-style-type: none"> • Foundation for Health Care and Medical Readiness • Health Care and Medical Response Coordination • Continuity of Health Care Service Delivery • Medical Surge
Emergency Support Function #8 Functional Areas	<ul style="list-style-type: none"> • Planning and Coordination • Assessment of Public Health, Human Services, and Medical Needs • Communications and Outreach • Patient Care • Health, Medical, and Veterinary Equipment and Supplies • Public Health and Medical Information
Overarching Exercise Objectives	<ul style="list-style-type: none"> • Examine the ability of federal, state, and local governments, as well as private industry, nongovernmental organizations, and members of the public, to take coordinated protective actions during a pandemic influenza outbreak in accordance with applicable plans, policies, and procedures. • Examine current gaps in capabilities and policies needed to determine risks to the affected population and the processes to manage, treat, and care for an overwhelming number of patients with an emphasis on people, pharmaceuticals, transportation requirements, and standards of care. • Test and identify gaps in applicable plans, policies, and procedures to maintain a viable workforce in order to minimize disruptions to critical infrastructure systems and supply chains. • Examine current mechanisms to integrate federal, state, and local decision-making and public messaging processes during a pandemic influenza response.
Overarching Exercise Outcomes	<ul style="list-style-type: none"> • Further understand HHS' and Emergency Support Function #8 partners' roles and responsibilities in response to a pandemic influenza outbreak. • Compare response actions and decisions during the exercise to identify any gaps / shortfalls within current applicable local, state, regional, and federal pandemic influenza plans. • Identify and address policy issues associated with a pandemic influenza response.
Threat or Hazard	Pandemic Influenza

Scenario

A large-scale outbreak of a novel avian influenza (H7N9) originates in China, but quickly spreads around the world and to the continental U.S., where the virus is first detected in Chicago, Illinois. The virus rapidly spreads via human-to-human transmission to other metropolitan areas across the U.S. Stockpiled H7N9 vaccines do not match the pandemic virus but can be used as a priming dose. The H7N9 virus is susceptible to neuraminidase inhibitor drugs, but resistant to adamantane antiviral drugs.

Participants

For a full list of participating organizations, see **Appendix A**.

KEY FINDINGS AND OUTCOMES

This report identifies the high-level, cross-cutting strengths and areas for improvement related to the Crimson Contagion 2019 Functional Exercise. The findings are organized into the following sections: Statutory Authorities and Funding; Planning; Operational Coordination; Situational Assessment; Resource Management; and Public Information and Risk Communications.

1. Statutory Authorities and Policies

1.1. Existing statutory authorities and policies tasking HHS to lead the federal government's response to an influenza pandemic are insufficient and policies are often in conflict with one another, resulting in confusion among exercise participants.

The *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January 2018) designate HHS as the lead federal agency for a nationwide pandemic influenza response, with DHS/FEMA coordinating support for the broader incident response.⁵ This operational construct was confirmed during Crimson Contagion lead-up events such as the Senior Officials Exercise 18-5⁶ and the Crimson Contagion 2019 Federal Interagency Seminar.

However, existing executive branch policies and statutory authorities related to an influenza pandemic (or other naturally occurring biological incident) do not provide the requisite mechanisms for HHS to serve successfully as the lead federal agency for the federal government's response to a severe influenza pandemic, as explained below.

- **Presidential Policy Directive-44 (November 2016).** Presidential Policy Directive-44 allows for a nontraditional federal department or agency to serve as the lead federal agency in response to a unique threat, such as an influenza pandemic, but it does not provide the requisite mechanisms or processes to effectively lead the coordination of the federal government's response. Specifically, Presidential Policy Directive-44 includes no mechanisms for a nontraditional lead federal agency, such as HHS, to mission assign, fund, or otherwise task other federal departments

⁵ Federal Emergency Management Agency, *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans*, January 2017.

⁶ Departments and agencies participated in a 90-minute tabletop exercise designed to examine the authorities, policies, capabilities, and structures in place for domestic response to a large-scale, naturally occurring human pandemic of avian influenza.

and agencies during the response to a unique threat (similar to how DHS/FEMA would during a disaster).

- **Defense Production Act of 1950.** The Defense Production Act provides a number of important authorities to expedite the supply of materials and services from the U.S. industrial base to support national defense. National defense is defined in Section 702 of the Defense Production Act to mean programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity (including preparing for or responding to an influenza pandemic). During the exercise, participants were unclear as to how the Defense Production Act could be used to compel or influence the private sector industry to acquire or produce critical resources.
- **Economy Act of 1932 (hereafter referred to as the “Economy Act”).** The Economy Act authorizes HHS to request support from and provide reimbursement to other federal agencies to respond to a biological incident, however, it does not provide HHS with the mechanisms necessary (or funds to reimburse supporting federal departments and agencies) to execute its roles and responsibilities as lead federal agency in response to an influenza pandemic. Specifically, HHS cannot request services or supplies from other federal agencies that HHS has no authority to conduct or procure.
- **Public Health Service Act.** Under this act, the HHS Secretary leads the federal public health and medical response to public health emergencies and incidents covered by the National Response Framework and may enter into an interagency agreement under which the HHS Secretary shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency, with the exception that members of the armed forces and assets under the authority of the Secretary of Defense remain under the U.S. Department of Defense. The ASPR, as the HHS Secretary’s principal advisor on all matters related to federal public health and medical preparedness and response for public health emergencies, may coordinate with federal, state, tribal and local entities. The act, however, provides only limited authorities for the HHS Secretary to facilitate this coordination among other federal departments and agencies. For example, if the Secretary declares a public health emergency, he or she may exercise the authority to (1) enable the Secretary of Defense to deploy military trauma care providers—which is not relevant in an influenza pandemic scenario—and (2) allow the U.S. Department of Labor to issue dislocated worker program

grants for disaster relief employment pursuant to 29 U.S.C. § 3225.⁷ The Public Health Service Act does not provide HHS with the requisite authorities or mechanisms (or access to funds) to task and coordinate other federal departments and agencies in order to lead a whole-of-government response to a public health emergency that results in cascading impacts to non-public health and medical sectors.

- **National Emergencies Act.** A declaration of a national emergency under the National Emergencies Act authorizes the President to declare a “national emergency”. As with previously mentioned acts, this act does not provide HHS with additional authorities (or funding) to lead the response to an influenza pandemic. Rather, the National Emergencies Act relies on emergency authorities provided in other statutes and does not provide specific emergency authority on its own.⁸
- **Robert T. Stafford Disaster Relief and Emergency Assistance Act (hereafter referred to as the “Stafford Act”).** The exercise reaffirmed previous exercise series participants’ confusion regarding the applicability of the Stafford Act for an influenza pandemic. During the “snap” Domestic Resilience Group Policy Coordination Committee meeting (hereafter referred to as the “‘snap’ Domestic Resilience Group meeting”)⁹, participants discussed the possibility of providing states with assistance through an “emergency” or “major disaster” declaration under the Stafford Act, but expressed uncertainty surrounding the legal possibilities of a declaration under the Stafford Act, noting the lack of historical precedent for issuing a declaration in response to a naturally occurring biological incident. Further, the definition of a “major disaster” under the Stafford Act does not explicitly refer to an influenza pandemic.¹⁰¹¹ In the absence of a Stafford Act declaration, DHS/FEMA cannot access the Disaster Relief Fund to provide funding to mission assign other federal departments and agencies, leaving HHS to use or create alternative mechanisms or routes in order to serve as the lead federal

⁷ The U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response Public Health Emergency Q&As, <http://www.phe.gov/Preparedness/legal/Pages/phe-ga.aspx#faq1>.

⁸ Association of State and Territorial Health Officials, <http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Authority-and-Immunity-Toolkit/National-Emergencies-Act,-Sections-201-and-301-Fact-Sheet/>.

⁹ Given the social distancing recommendations during the exercise, the National Security Council decided to hold a “snap” Domestic Resilience Group meeting that took place virtually.

¹⁰ 42 U.S.C. 5122

¹¹ States must request a major disaster declaration under the Stafford Act for assistance.

agency for an influenza pandemic.¹²

To further compound matters, existing policies of the executive branch are often contradict one another, providing differing guidance as to which federal department or agency assumes lead or supporting roles during a domestic incident. Specifically, Homeland Security Presidential Directive-5 (February 2003)—which assigns the Secretary of Homeland Security as the lead federal agency and authority to coordinate federal operations—does not align with the operational constructs outlined in Presidential Policy Directive-44. As a result, exercise participants, as seen among those in attendance at the “snap” Domestic Resilience Group meeting, remained uncertain as to which federal department or agency was the lead federal agency—DHS/FEMA or HHS—and whether their respective agency would receive tasks from DHS/FEMA through the Mission Assignment process or from HHS through some other means, such as interagency agreements.

Recommendations:

- The federal government should codify policies and procedures for HHS to lead, direct, and source funding in response to all kinds of public health emergencies.
 - Failing modification to the Stafford Act, HHS should work with Congress to establish and appropriate an emergency fund to provide immediate funding for the response to a biological incident(s). See 1.2.1 for additional information on funding.
- The White House National Security Council should consider assembling a working group to review and clarify Presidential Policy Directive-44, including its purpose and how its operational constructs relate to those outlined in other policies, such as Homeland Security Presidential Directive-5. HHS should develop a comprehensive plan and approach to integrate authorities and policies (either through Executive Order or with new legislation) to more efficiently respond to an influenza pandemic.
- HHS should collaborate with DHS/FEMA to examine the applicability of recovery-related authorities and executive orders outlined in the National Disaster Recovery Framework during an influenza pandemic.

¹² In 2019, however, the President shifted approximately \$155 million from DHS/FEMA’s Disaster Relief Fund to support his policy of returning some migrants to Mexico and support DHS’ immigration enforcement agency (source: <https://www.cnn.com/2019/08/27/politics/fema-immigration-enforcement-dorian/index.html>).

2. Funding

2.1. Currently, there are insufficient funding sources designated for the federal government to use in response to an influenza pandemic.

During the “snap” Domestic Resilience Group meeting, participants noted that the manufacturing of vaccines alone cost \$6.2 billion dollars. Additional several billions of dollars would be required to increase the production of antivirals and the production of ancillary supplies, such as personal protective equipment and syringes. However, there are limited funds available in the Public Health Emergency Fund and, historically, Congress has rarely appropriated funds to the Public Health Emergency Fund. In the rare instances when Congress has appropriated funds, the amount has been minimal and would be insufficient to fund the federal government’s response to a severe influenza pandemic. Thus, as seen in previous pandemics and other public health and medical incidents, HHS would need to request and receive supplemental appropriations from Congress, which can often take upwards of two months from the time a request is made to the time the funds are available for use.

A presidential declaration under the Stafford Act could allow HHS access to DHS/FEMA’s Disaster Relief Fund appropriated by Congress.¹³ The definition of an “emergency” under the Stafford Act is broad and could encompass a biological incident, such as an influenza pandemic; however, the definition of “major disaster” is more specific and does not explicitly refer to an influenza pandemic. Thus, the President could choose to declare an “emergency” under the Stafford Act in response to an influenza pandemic, allowing HHS access to funding from the Disaster Relief Fund for covered expenditures not typically provided under HHS’ regular appropriations. However, a State Governor or Tribal Chief Executive must request an emergency declaration unless the emergency involves federal primary responsibility. Thus, there is unlikely to be a nationwide emergency declaration and the President is likely to make a determination on a state-by-state basis when requested. Further, it is unlikely that the Disaster Relief Fund could be used for expenditures that HHS traditionally receives appropriations for (including supplemental appropriations), such as procurement of vaccines, as any “assistance” through the Disaster Relief Funds with respect to medicine is limited to: (1) providing financial assistance to individuals to obtain medicine; or (2) paying for the federal government or the impacted state government to distribute medicine. In addition, given the limited historical precedence for a Stafford Act declaration in response to an infectious disease

¹³ DHS/FEMA, <https://www.fema.gov/media-library/assets/documents/15271/>.

outbreak¹⁴, a great deal of uncertainty exists surrounding the likelihood of this occurring in a future influenza pandemic.

Without access to the money within the Disaster Relief Fund or access to other readily available funding sources, exercise participants noted several challenges and cascading impacts, including but not limited to delays in pandemic vaccine availability and an inability of HHS to compete with other buyers (e.g., countries) for scarce medical countermeasures such as personal protective equipment, raw materials, diagnostics, and antivirals, most of which are produced offshore. Such a delay in funding means delays in vaccine availability, which puts more Americans at risk for infection and increases hospitalizations and fatalities. The exercise demonstrated that the lack of authorities provided to HHS coupled with a lack of funding associated with said authorities hinders the ability of HHS to provide timely assistance in response to an influenza pandemic.

Recommendations:

- The Office of Management and Budget and Congress should consider creating a \$10B contingency fund for medical countermeasure procurement for an emerging virus with pandemic potential, including vaccine development and ancillary supplies.
- As directed in the September 2019 *Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health*¹⁵, HHS/ASPR should estimate the cost of:
 - Expanding and diversifying domestic vaccine-manufacturing capacity to use innovative, faster, and more scalable technologies;
 - Expanding domestic production capacity of adjuvants in order to combine such adjuvants with both seasonal and pandemic influenza vaccines;
 - Expanding domestic fill-and-finish capacity to rapidly fulfill antigen and adjuvant needs for pandemic response; and
 - Evaluate incentives for the development and production of vaccines by

¹⁴ In 2000, the President declared Stafford Act Emergency Declarations for New York and New Jersey in response to the West Nile virus. Other than these two, there have not been any other Stafford Act declarations for disease control measures.

¹⁵ The full text of the executive order is available at <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-influenza-vaccines-united-states-promote-national-security-public-health/>.

private manufacturers and public-private partnerships.

- HHS should consider authorizing the development of a legislative proposal to support the investment in and development of a domestic capability to manufacture therapeutics, personal protective equipment, medical supplies, and other medical countermeasures, and take action to increase access to drugs, equipment, supplies, and raw materials, many of which are produced offshore.
- Congress should update the 1983 Public Law authorizing the Public Health Emergency Fund, starting with an annual appropriation equivalent to anticipated state and local needs (this would potentially provide funds for immediate use during an influenza pandemic response, prior to any supplemental funding is provided through Congress). Providing more technical and financial resources to HHS requires operationalizing existing mechanisms and capacities, including improving coordination among HHS and other federal agencies, as well as revitalizing the Public Health Emergency Fund.
- When requesting additional funds from Congress to respond to an emerging pandemic, HHS should include the following information in its request: (1) the funding streams and resources HHS is using in response to the emerging pandemic, (2) the benefits of said resources, and (3) the anticipated benefits of receiving additional funds from Congress. This information may help expedite the approval process, allowing Congress to act quickly and provide the requisite funds necessary to meet the needs of the response.

2.2. It was unclear if and how states could repurpose HHS and CDC grants, as well as other federal dollars to support the response to an influenza pandemic.

During the exercise, participating states discussed the lack of clarity on how CDC's Public Health Crisis Notice of Funding Opportunity—a funding mechanism that enables CDC to expedite funding, through the establishment of a corresponding approved but unfunded list, to state, local, tribal, and territorial public health agencies in the event of a public health emergency¹⁶—could support an influenza pandemic response. By the end of the exercise, participating states did not receive any information on how CDC planned to use the Public Health Crisis Notice of Funding Opportunity or how quickly the states would have access to emergency funds.

States were also unclear on how to use Public Health Emergency Preparedness funds during an emergency. The Public Health Emergency Preparedness cooperative

¹⁶ Centers for Disease Control and Prevention, "Public Health Crisis Response NOFO", <https://www.cdc.gov/cpr/readiness/funding-crisis.htm>.

agreement is a critical source of funding for state, local, tribal, and territorial public health departments. Since 2002, the Public Health Emergency Preparedness cooperative agreement has provided assistance to public health departments across the nation.¹⁷ This helps health departments build and strengthen their abilities to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events.² The State of Illinois and the City of Chicago requested waivers in several existing funding streams, including Public Health Emergency Preparedness and the Hospital Preparedness Program, to allow for already available money to be re-directed for use during the pandemic response. The State of Illinois also requested guidance from CDC on how Public Health Emergency Preparedness and Hospital Preparedness Program funds could be used for response efforts. During the exercise, HHS/ASPR and CDC verbally approved to release restrictions on the Public Health Emergency Preparedness and Hospital Preparedness Program grants for a 30-day period for response efforts; however, they did not provide written approval or an acknowledgement that an amended Notice of Award would be forthcoming. Without written approvals, local jurisdictions and states would be unable to utilize grant monies outside of their intended use. The State of Colorado also requested information regarding the use of Public Health Emergency Preparedness funds during the exercise, but never received guidance from CDC on the use of these funds in an emergency response. It is critical for states to understand the availability of funds, and how they can use them, in order to adequately respond to the needs of the community during a public health emergency.

Recommendations:

- HHS/ASPR and CDC should continue to collaborate to create and issue written guidance to recipients on acceptable uses of their respective grant funds during an emergency response. Future grant applications and awards should include language in the grant agreement indicating the potential “changes in intent of original deliverables” based on developing emergency events, and how those changes will be enacted.
- HHS/ASPR should clarify the intent and use of the CDC Public Health Crisis Notice of Funding Opportunity during a pandemic.
- HHS/ASPR’s Management Finance and Human Capital Division should consider developing an algorithm for HHS senior leaders to decide on how grant monies get repurposed for an incident response.

¹⁷ Centers for Disease Control and Prevention, “Public Health Emergency Preparedness (PHEP) Cooperative Agreement, <https://www.cdc.gov/cpr/readiness/phep.htm>.

3. Planning

3.1. Federal Plans

3.1.1. The organization of the federal government response when HHS is the lead federal agency is not sufficiently outlined in the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans (January 2017)* or the *Pandemic Crisis Action Plan Version 2.0 (January 2018)*.

As previously mentioned (Observation 1.1.1), according to the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans (January 2017)* and the *Pandemic Crisis Action Plan Version 2.0 (January 2018)*, “when federal public health and medical support is required for response and recovery efforts, HHS is the lead agency and originator for federal agency-to-agency operational support tasks” (p. 14). During Senior Officials Exercise 18-5, deputies agreed that HHS would serve as the lead federal agency for a nationwide pandemic influenza response, with support from DHS/FEMA and other federal agencies. However, in the lead-up to the Crimson Contagion 2019 Functional Exercise, interagency representatives articulated a variety of interpretations of HHS as the lead federal agency. The two main interpretations are (1) HHS is designated as the sole lead federal agency, or (2) HHS serves as the lead for all public health and medical aspects of the response while the DHS/FEMA serves as the lead for consequence management. Given DHS/FEMA’s experience as the lead federal agency during disasters, the plans assign DHS/FEMA to assist HHS by coordinating support for the broader incident response, as a nationwide influenza pandemic will affect sectors beyond the public health and medical sector. During the exercise, participants applied the latter of the two interpretations and encountered challenges with respect to operational coordination and reporting.

When exercising this interpretation, it was not clear to federal interagency and state participants how HHS and DHS/FEMA’s bifurcated lead roles applied to their coordination and reporting channels. Although HHS explicitly claimed responsibility for leading response coordination meetings (e.g., DHS/FEMA’s 1230 Video Teleconference) and developing products for senior-level decision-makers (e.g., Senior Leader Briefs [SLBs]), supporting federal departments and agencies and state partners were uncertain as to how and to whom they should provide informational inputs.

Further adding to the confusion, the respective roles between HHS/ASPR and CDC were not well-understood. From the state-level perspective, it was not clear which of HHS’ components were leading the various aspects of the response. Moreover, several states sought to gain state-federal coordination efficiencies by mirroring the federal response structure, but were unable to do so because they were not provided with guidance on

how the federal government organizes during a pandemic response. Lacking an understanding of the federal response structure, many states engaged in limited coordination with federal agencies, relying primarily on CDC staff in the state and their Regional Emergency Coordinators as federal conduits.

Recommendations:

- HHS partner with FEMA to assemble a taskforce to revise the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January 2018) to provide the specific coordinating structures and processes that should be followed when there is a nontraditional lead federal agency. The federal interagency would then operate under a unified command and also leverage DHS/FEMA's national and regional structures and processes.
- HHS, in collaboration with DHS/FEMA, should re-examine organizational structures initially proposed by DHS/FEMA when drafting the first versions of the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January 2018).

3.2. State and Local Plans

3.2.1. The exercise provided an opportunity for state and local entities to test and validate their pandemic influenza plans.

The exercise allowed state and local entities to identify gaps in and shortfalls of their pandemic influenza plans. Following the exercise, states reported that they will use the findings and outcomes of the exercise to enhance various elements of their pandemic influenza plans, including processes and protocols related to topics such as antiviral and vaccine distribution; community mitigation; emergency risk communication; infection control and personal protective equipment; and fatality management.

3.3. Crisis Standards of Care

3.3.1. The degree of progress made with respect to crisis standards of care planning and implementation varies across local, state, territorial, tribal, and federal stakeholders.

Development and implementation of crisis standards of care plans, policies, and procedures has occurred to varying degrees over the past decade. In 2009, during the height of the H1N1 Influenza Pandemic, the Institute of Medicine of the National



Academies, at the request of HHS/ASPR, issued *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*.¹⁸ In 2012, the Institute of Medicine Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations released a second report entitled *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*.¹⁹ The second report was commissioned by HHS, the U.S. Department of Veterans Affairs, and the National Highway Transportation Safety Administration, with the express purpose of providing concepts and guidance to help state and local officials apply the Crisis Standards of Care framework developed for the first report. Taken in combination, the two Institute of Medicine reports provide a framework for considering, developing, and implementing Crisis Standards of Care plans.

Although the framework provided to date has resulted in some progress, state and local participants reported varying degrees of development and implementation of crisis standards of care, ranging from the absence of plans, to having some focused concepts developed, such as the allocation of specific resources, (e.g., ventilators), to relatively mature implementation plans. Additionally, the exercise highlighted that deliberate coordinated planning efforts integrating a range of stakeholder perspectives have not occurred to a sufficient extent.²⁰

Recommendations:

- Entities with no or minimal standards of care plans should examine models from other states, with an eye toward potentially adapting those models to meet their specific circumstances, and assess existing executive-level authorities and determine what, if any, current authorities allow for a transition to population-based care.
 - States should codify in existing incident response plans the requirement to

¹⁸ Institute of Medicine (US) Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations; Altevogt BM, Stroud C, Hanson SL, et al., editors. *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*. Washington (DC): National Academies Press (US); 2009. [Letter to Nicole Lurie, M.D., M.S.P.H.] Available from: <https://www.ncbi.nlm.nih.gov/books/NBK219946/>.

¹⁹ Institute of Medicine. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*. 2012. Washington, DC: The National Academies Press. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*. Accessed March 29, 2012.

²⁰ On the first day of the exercise, ASPR Region 1 submitted a request for information on behalf of the Region 1 states, seeking assistance in determining how to implement crisis standards of care, as ASPR is responsible for providing recommendations for Crisis Standards of Care, in accordance with the Draft Area Response Pocket Guide: Pandemic Influenza (2019). Although this request for information was referred to the HHS Disaster Leadership Group, no response was provided by the end of the exercise.

immediately report to CDC a shift from normal operations to implementation of crisis standards of care.

3.4. Continuity Planning

3.4.1. State and federal entities identified challenges in implementing remote work/telework policies (as a workforce protection measure) and to maintain operational capacity.

The exercise revealed several workforce protection challenges under conditions where medical countermeasures, such as the pandemic vaccine, antiviral medications, and personal protective equipment, are limited. To protect the public prior to vaccine distribution, public health officials issued guidance on the implementation of non-pharmaceutical interventions intended to slow the spread of the virus. In keeping with non-pharmaceutical intervention recommendations, employers—including government entities—sought to practice social distancing by having a significant portion of their employees work remotely. Employers encountered cascading impacts associated with making, communicating, and implementing such work-distancing decisions.

At multiple levels of government, officials wrestled with identifying employees who are essential and those who are nonessential in the context of an incident forecasted to span many months. In addition, officials faced challenges in determining which employees could perform their duties remotely and hierarchical organizations, such as most state and federal departments and agencies, were uncertain as to the process for determining and implementing remote-workforce decisions. Similarly, several state agencies were unclear as to how remote-workforce decisions would be made and communicated uniformly across the state government workforce. Federal participants posited, but did not validate, that HHS/ASPR's Continuity of Operations team, in coordination with DHS/FEMA's National Continuity Programs, would propose remote workforce policies to the HHS Disaster Leadership Group (see 3.1.1. for more information on the HHS Disaster Leadership Group). The HHS Disaster Leadership Group would in turn forward the recommendation to the HHS Secretary, who would then forward this recommendation, if approved, to the White House National Security Council through the Domestic Resilience Group for action and the Office of Personnel Management would communicate those policies to the civil service workforce.

Some officials noted that traditional continuity of operations plans assume a shorter period in which specific mission essential functions must be performed to maintain the structure and function of an organization at a basic level. However, a global influenza pandemic may last a year or more, and organizations will likely need to adapt to be able

to perform organizational tasks and functions above the most basic level of their essential functions.

Participating organizations also found that their employees were not uniformly or reliably able to perform their duties remotely and, in turn, sustain performance of their agency's tasks and functions. Many of the hurdles stemmed from technology and equipment issues, including an uneven distribution of laptop computers and mobile devices among the workforce, user volume limitations on virtual private network systems, and insufficient internet bandwidth or connectivity. Little or no training on remote systems further hindered their performance of essential tasks and functions. Participants also reported inefficiencies associated with having to log in and log out of different response management systems (e.g., Web Emergency Operations Center, SharePoint) when using a single laptop, as opposed to having multiple screens and operating systems in an emergency operations center environment. In addition to technology and equipment challenges, participants lacked standard operating procedures and staff communications plans for remote operations.

Recommendations:

- Based on lessons learned, the HHS/ASPR Continuity of Operations team, in coordination with DHS/FEMA's National Continuity Programs and the Office of Personnel Management, should develop and issue best practices and recommendations for continuity of operations during pandemics and longer-term incidents for organizations to consider as they review and update their plans.
- HHS and DHS/FEMA should coordinate to ensure that the *Biological Incident Annex to the Response and Recover Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January (2018) specify the role of the Office of Personnel Management during a pandemic influenza response and emphasize the importance of ensuring the resilience of government services during an influenza pandemic.

4. Operational Coordination

4.1. Senior Leadership Meetings

4.1.1. The HHS Disaster Leadership Group and Domestic Resilience Group have the infrastructure and capabilities to successfully conduct virtual meetings during incidents necessitating social distancing.

According to the *HHS/ASPR Incident Response Framework*, the HHS Disaster Leadership Group is a policy committee convened by HHS/ASPR when incident or event

conditions are expected to raise significant policy issues that require increased surveillance, coordination, and/or information sharing across HHS or throughout the U.S. government.²¹ While the HHS Disaster Leadership Group is primarily a forum for HHS' senior leaders, some incidents/events may require expertise from other federal interagency partners or external subject matter experts.²² As demonstrated during the exercise, the HHS Disaster Leadership Group convened on August 13 and 16, 2019, and involved HHS' Operating Divisions and Staff Divisions, and federal interagency partners to discuss policy issues of senior leadership concern. The successful execution of the HHS Disaster Leadership Group confirmed that, when needed, HHS/ASPR leadership can convene the HHS Disaster Leadership Group to discuss policy issues during a critical response incident in both in-person and virtual settings.

Similarly, the National Security Council Domestic Resilience Group—a policy group charged with discussing the authorities, policies, capabilities, and structures in place for a domestic responses—also successfully convened and executed a single “snap” forum on August 15, 2019, to discuss a range of topics related to the federal government's response to the influenza pandemic.²³ The National Security Council staff scheduled and structured the meeting to be held virtually in accordance with the social-distancing guidance issued by CDC. Of the 29 federal departments and agencies invited, 24 (83 percent) virtually participated in the discussion. Throughout the forum's duration, no significant technology issues occurred.

Recommendations:

- The White House National Security Council should consider examining the capabilities of the Domestic Resilience Group when meeting with federal stakeholders in a classified, virtual environment.

4.2. Federal-level Coordination

4.2.1. Exercise participants lacked clarity on federal interagency partners' roles and responsibilities during an influenza pandemic response.

Influenza pandemics, just like other infectious disease outbreaks (e.g., 2014 Ebola outbreak), are a less familiar threat to and less exercised on a large scale or a regular basis by the U.S. government than more frequently occurring disasters such as

²¹ U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response, *Incident Response Framework Version 2.1*, April 2, 2019, 11.

²² *Ibid.*

²³ Immediately following the meeting, the National Security Council produced a Domestic Resilience Group Summary of Conclusions that outlined the participants' discussion and action items.

hurricanes, earthquakes, or wildfires. As a result, federal interagency partners lack practice implementing the intra- and interagency coordination mechanisms necessary to manage an influenza pandemic response.

For intra-agency coordination, many federal participants had limited knowledge of the pandemic response roles and responsibilities of the various components within their own agency, which hampered their ability to integrate their agency's response activities effectively. For example, DHS participants noted that while some DHS components, such as DHS/FEMA and the National Operations Center, have clearly defined roles within the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January 2018), other components—such as the Office of Public Affairs, Countering Weapons of Mass Destruction Office, Customs and Border Protection, Transportation Security Administration, and Immigration and Customs Enforcement—do not. Rather, their pandemic response roles are less clearly defined, or not defined, within current plans.²⁴ As a result, DHS participants were unsure how these components should coordinate during a pandemic response. Similarly, some of HHS' components lacked familiarity with the Biomedical Advanced Research and Development Authority's response capabilities to an influenza pandemic and encountered challenges integrating the Biomedical Advanced Research and Development Authority into the overarching HHS' incident response structure.

For interagency coordination, the exercise revealed that federal partners also lack clarity on one another's roles and responsibilities during an influenza pandemic. As previously mentioned (Observation 2.1.1.), the respective roles between HHS/ASPR and CDC were not always well-understood. In another example, during the exercise planning process, it was unclear to planners how HHS and the Office of Personnel Management would coordinate to develop and disseminate guidance to the federal workforce. The *Pandemic Crisis Action Plan Version 2.0* (January 2018) states that the Office of Personnel Management will provide guidance to assist federal departments and agencies in identifying appropriate social distancing protective measures, including assignment to alternate facilities or telework locations; however, the plan does not specify how the Office of Personnel Management will work with HHS and other partners to develop this guidance. Similarly, the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) states that the Office of Personnel Management may be involved in the response to a biological incident but it does not

²⁴ The Federal Emergency Management Agency, National Operations Center, and Countering Weapons of Mass Destruction Office actively participated in the exercise, while Customs and Border Protection, the Transportation Security Administration, and Immigration and Customs Enforcement were available to provide reach back support, as needed.

specify how the agency would be involved. In addition, Emergency Support Function #13 partners lacked clarity on the kind of support they should expect to provide during a pandemic influenza response. According to the *Pandemic Crisis Action Plan Version 2.0* (January 2018), the role of the U.S. Department of Justice during an influenza pandemic response is to provide security for the Strategic National Stockpile, coordinate with state, local, tribal, and territorial partners to provide security for vaccine production facilities, and provide credible threat information regarding Strategic National Stockpile transportation and vaccine distribution.²⁵ During the exercise, Emergency Support Function #13 participants submitted a request for information to HHS requesting information on the type of Federal Operational Support missions they should expect to receive. However, Emergency Support Function #13 participants did not receive the level of detail they needed to support their planning.

Recommendations:

- HHS and DHS/FEMA should coordinate to ensure that the *Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans* (January 2017) and *Pandemic Crisis Action Plan Version 2.0* (January 2018) capture the key roles and responsibilities of all federal departments and agencies that will be involved in managing a pandemic influenza response.
 - HHS, the U.S. Department of Justice, and other Emergency Support Function #13 partners should hold discussions to determine (1) the roles and responsibilities of ESF #13 partners during a pandemic influenza response, (2) the applicability of existing MOAs and IAA, and (3) protocols for vaccination of frontline law enforcement personnel.²⁶
- Federal departments and agencies should update their agency-specific pandemic influenza response plans to detail the roles and responsibilities of all relevant components. Departments and agencies should then socialize these plans through trainings and exercises.

4.2.2. HHS and Emergency Support Function #8 partner liaisons in the Secretary's Operations Center and National Response Coordination Center played a critical

²⁵ U.S. Department of Homeland Security. *Pandemic Crisis Action Plan*, 2018, p. 17.

²⁶ The CDC identifies front-line law enforcement personnel as a one of the highest priority population groups to receive vaccination of there is limited vaccine supply for any level of pandemic severity. More information is available at <https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/pandemic-severities-tier-1.html>.

role in providing subject matter expertise and coordination support to meet the public health and medical mission.

During an emergency, the Secretary's Operations Center may draw upon agency representatives from HHS' Operating Divisions and Staff Divisions and interagency partners to serve as action officers on specific matters within their areas of expertise.²⁷ Agency representatives are intended to serve as a central point of coordination and communication for their respective department, agency, office, or function. During the exercise, DHS, the U.S. Department of Defense, CDC, the Biomedical Advanced Research and Development Authority, and the U.S. Department of Veterans Affairs provided agency representatives to the Secretary's Operations Center, and exercise participants noted that these representatives played a vital role in supporting operational coordination and information-sharing. Participants recognized great value in having agency representatives in the Secretary's Operations Center, particularly those with knowledge and expertise related to seasonal and pandemic influenza responses. To build on this strength, participants recommended that the Secretary's Operations Center request agency representatives from additional agencies during a pandemic influenza response, including, but not limited to, the National Institutes of Health, the Food and Drug Administration, and the U.S. Department of Agriculture.

In addition, HHS/ASPR deployed an Emergency Support Function #8 Support Team to the National Response Coordination Center to serve as a link between the National Response Coordination Center, Secretary's Operations Center, and relevant Emergency Support Functions, as described in the *HHS/ASPR Incident Response Framework*.²⁸ Exercise participants commended the Emergency Support Function #8 Support Team for providing valuable technical support to response partners in the National Response Coordination Center. However, participants agreed that the limited number of Emergency Support Function #8 staff deployed to the National Response Coordination Center was insufficient to meet the needs of the response or attend the various, concurrent meetings in the National Response Coordination Center throughout the exercise. Participants also identified the need for additional Emergency Support Function #8 staff in the National Response Coordination Center to support information management and planning, and it remains unclear what level of support other lifelines would require from HHS during a pandemic influenza response, which could necessitate additional Departmental personnel. Thus, the exercise revealed a robust National Response Coordination Center

²⁷ U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response *Incident Response Framework*, 2019, p. 39.

²⁸ U.S. Department of Health and Human Services/Office of the Assistant Secretary for Preparedness and Response *Incident Response Framework*, 2019. p. 25.

Emergency Support Function #8 Support Team is needed to facilitate federal public health and medical coordination during a pandemic influenza response.

During the exercise, CDC provided a liaison to the National Response Coordination Center. Having someone with the necessary technical expertise and knowledge physically present at the National Response Coordination Center was beneficial to quickly address requests for information, especially given the time-consuming request and tracking process (see 3.2.2. for additional information).

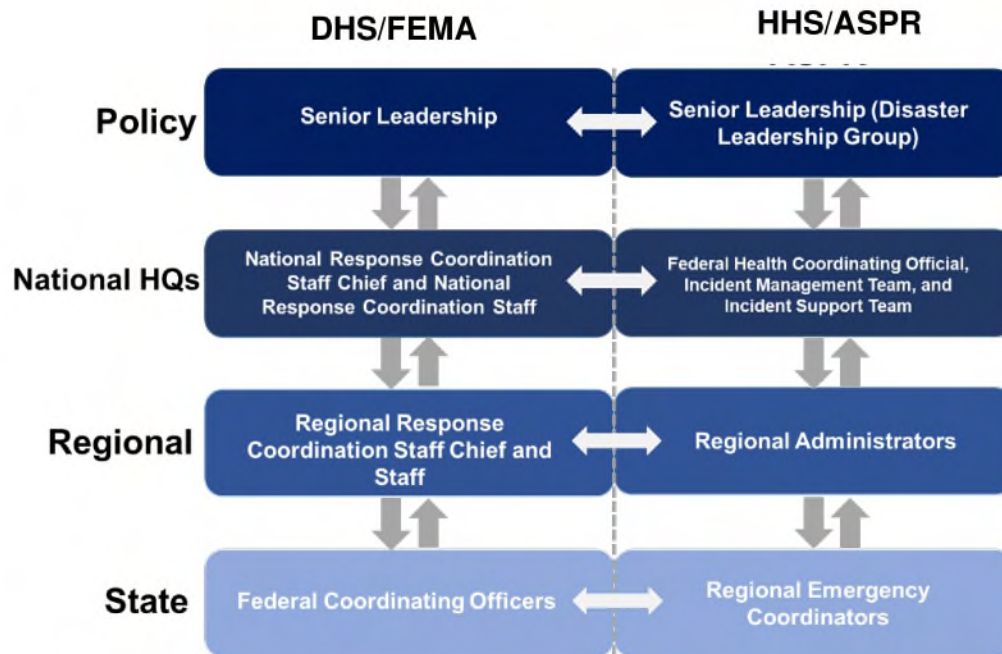
Recommendations:

- HHS should codify in plans and procedures the agencies that should send representatives to the Secretary's Operations Center during a pandemic influenza response and communicate this future requirement to said agencies.
- HHS and DHS/FEMA should coordinate to determine what level of Emergency Support Function #8 support would be needed in the National Response Coordination Center during a pandemic influenza response, and identify staff to fill key positions on the Emergency Support Function #8 Support Team.

4.2.3. HHS and DHS/FEMA collaborated closely throughout the exercise in an effort to enhance their understanding of one another's operational capabilities and facilitate a more efficient and effective response to a pandemic.

The exercise provided an opportunity for HHS and DHS/FEMA to collaborate closely in order to execute their respective roles and responsibilities in response to a unique threat, in which DHS/FEMA is not the lead federal agency. Throughout the exercise, HHS Region 1 and DHS/FEMA Region 1 met daily to provide regional-federal coordination and leadership, and HHS and DHS/FEMA Headquarters-level operational leadership met daily in the National Response Coordination Center to discuss ongoing response challenges (e.g., supply chain shortages, vulnerable populations, and workforce absenteeism) and their respective agency's operations. On the first day of the exercise, HHS' and DHS/FEMA's operational leadership met to discuss and sketch out the operational construct specific to an incident in which DHS/FEMA is not the lead federal agency, highlighting key coordination nodes and the flow of operations across the various levels of the response. Engaging in these discussions helped bridge knowledge gaps among both agencies. See **Figure 7** below for the aforementioned operational construct.

Figure 7. DHS/FEMA and HHS/ASPR Response Key Operational Nodes and Flow of Operations



To ensure a smooth exchange of information and to address any scheduling conflicts of key coordination calls, HHS invited DHS/FEMA to take part in what are normally Emergency Support Function #8-only coordination calls, such as CDC’s State Health Official call, the Secretary’s Operations Center morning briefing, and the Public Health and Medical call. Both agencies also adjusted their respective operational rhythms, as needed. For instance, the National Response Coordination Staff Chief suggested moving the National Response Coordination Center’s morning briefing to after the Secretary’s Operations Center morning briefing call at 0800 EDT. This allowed the National Response Coordination Staff Chief and National Response Coordination Staff an opportunity to make adjustments to their daily objectives and/or informational updates, as needed.

As mentioned previously, the Federal Health Coordinating Officer and Incident Management Team floated between DHS/FEMA and HHS’ Headquarters, which was easy enough to do given the close proximity of the two agencies’ headquarters. The likelihood of HHS and DHS/FEMA responders co-locating at either the National Response Coordination Center or in the Secretary’s Operations Center during an influenza pandemic would lead to discussions between HHS and DHS/FEMA operational leadership on approaches to help maintain a healthy and functioning workforce in the midst of a response to an influenza pandemic, including the implementation of sanitation measures (e.g., mandatory wipe downs of desks, shared

work spaces, phones, and key boards) and having security or other personnel perform a temperature check at the building entrances.

DHS/FEMA also notionally deployed a National Incident Management Assistance Team to the National Response Coordination Center to create a Unified Coordination Group in order to further enhance information-sharing, coordination, and operational decision-making between HHS and DHS/FEMA. Utilizing the Unified Coordination Group structure, HHS immediately identified the following key objectives: (1) determine the distribution/transportation plan for the H7N9 pre-pandemic vaccine to be used as a priming dose (e.g., phased distribution); (2) begin to identify the minimum personnel requirements to continue critical infrastructure services (e.g., water, power, transportation); (3) identify/address state shortfalls; and (4) evaluate and revise public messaging.

Despite HHS and DHS/FEMA's close collaboration throughout the exercise, both agencies remained uncertain on how best they could support one another. Most often, discussions centered on how DHS/FEMA should support HHS as the lead federal agency. DHS/FEMA looked to HHS for guidance on areas beyond the public health and medical lifelines and for guidance on what kinds of support DHS/FEMA should task other federal departments and agencies to provide states with emergency declarations. However, oftentimes these requests for guidance went unanswered within the timeframe of the exercise, as providing accurate guidance requires the knowledge of an influenza pandemic subject matter expert and its second and third order effects.

Recommendations:

- HHS should consider deploying a subject matter expert (in this instance, an influenza subject matter expert) alongside the Federal Health Coordinating Officer for responses to incidents requiring specialized knowledge and a thorough understanding of the potential cascading impacts to other, non-public health and medical sectors.
- HHS and DHS/FEMA should continue to engage in preparedness activities to ensure a mutual understanding of their respective roles and responsibilities during an incident with a nontraditional lead federal agency.
- HHS and DHS/FEMA should continue to explore the feasibility of virtually operating their respective operational coordination centers.

4.3. State and Federal Coordination

4.3.1. Confusion regarding the purpose of and target audience for national conference calls hampered coordination among state and federal response partners.

Federal interagency partners conducted a variety of conference calls over the course of the exercise in order to synchronize response activities and promote situational awareness. DHS/FEMA and HHS hosted several calls that commonly take place during national responses, including DHS/FEMA's 1230 Video Teleconference and the Center for Disease Control and Prevention's State Health Official call. However, in an effort to address the complexities and unique features of a pandemic influenza response, partners modified various aspects of these standard calls, including the call titles, formats, and target audiences.²⁹ For example, the title of DHS/FEMA's 1230 video teleconference was changed to "Senior Leader Video Teleconference," and while DHS/FEMA facilitated the video teleconference logistics and sent out invitations, HHS/ASPR served as the formal host of the meeting. Similarly, the title of CDC's State Health Official Call was changed to the "State Health Official and Regional Emergency Coordinator Call," and CDC invited the Federal Health Coordinating Officer to also join the call and provide an update on the federal interagency response posture.

While the Secretary's Operations Center and National Response Coordination Center published daily call schedules, the schedules included only the call titles and times and provided limited information about the call purpose and target audience. Exercise participants noted that several calls were titled with acronyms or had ambiguous titles that did not clearly convey the purpose of the calls. Given the modifications to standard calls and the lack of detail provided in the call schedule, exercise participants at both the state and federal levels struggled to determine in which national calls they should participate. Participating state organizations that are frequently understaffed found that keeping up with the number of calls and the rapidly shifting nature of calls was difficult. Furthermore, participants reported that distribution lists for several calls were not updated to include all relevant partners with key roles in pandemic influenza response operations. Consequently, some partners missed calls or received last-minute invitations and were therefore inadequately prepared to participate in calls.

²⁹ This may be partially due to an exercise artificiality, as the specifics regarding each of the calls would most likely have been determined by day 47 of the response; however, this finding highlights the probability of this occurring at the beginning of a response, with a nontraditional lead federal agency.

Recommendations:

- In an incident response in which HHS is the lead federal agency, HHS should coordinate with DHS/FEMA to develop and publish a national conference call schedule that includes clearly titled calls. For each call, the schedule should include the call's purpose, target audience, time, and dial-in information. HHS and DHS/FEMA regional staff should also establish clear expectations about which calls include state participation and what information (essential elements of information), if any, state partners should prepare to provide on each call.
- HHS should coordinate with DHS/FEMA to ensure that the distribution lists for national pandemic influenza coordination calls include all key stakeholders, across all levels of government. HHS and DHS/FEMA should also develop a distribution plan that details who is responsible for distributing conference call information and how the information should be distributed.
- HHS should continue to maintain relationships with the Association of State and Territorial Health Officials, National Association of County and City Health Officials, and Council of State and Territorial Epidemiologists to ensure all local health departments are receiving information from federal response stakeholders.

4.3.2. States lacked clarity on which channels they should use to request information from and report information to federal partners throughout the response.

During the course of the exercise, it was not clear to state participants which federal agencies and points of contact they should send requests for information. For example, exercise participants sent requests for information to the U.S. Food and Drug Administration that should have been directed to the U.S. Department of Agriculture. In practice, most states directed requests for information to their respective Regional Emergency Coordinators or, in some cases, directly to CDC. The Regional Emergency Coordinators then directed many of the requests for information regarding technical guidance to CDC. The majority of Regional Emergency Coordinators expressed concern about an overreliance on their position as the primary state-federal coordination node due to their limited familiarity with certain aspects of the response (e.g., Strategic National Stockpile assets and capabilities) and HHS/ASPR regional offices' limited personnel capacity. At the same time, states had direct access to technical guidance from CDC via the State Health Officer and Regional Emergency Coordinator calls, leaving state-level participants to question whether they should submit requests for information directly to CDC.

Several states submitted requests for information that went entirely unanswered over the course of the exercise, despite direct reminders to the recipients and exercise control staff intervention. Further contributing to the confusion, some states received requests for information (e.g., on State Declarations and emergency declarations under the Stafford Act) from federal agencies for information that had already been provided to other federal response partners (e.g. HHS/ASPR's regional personnel, DHS/FEMA).

Recommendations:

- Consistent with the aforementioned recommendations in the planning section, HHS should identify the federal response structure that will apply to an influenza pandemic and widely socialize the structure among state, local, tribal, and territorial partners. Include a flow diagram for requests for information and the essential elements of information that may be requested of states during an influenza pandemic.
- HHS should develop processes for efficient and timely sharing of state-provided information among federal partners to reduce burdens on state agencies and Regional Emergency Coordinators.
- HHS should develop processes for responding to requests for information in a timely manner and provide request for information status updates, or a system that provides updates, to state partners to provide them with a sense of where their requests for information are in the process.

4.4. Private Sector Coordination

4.4.1. At times, HHS' Operating Divisions and Staff Divisions provided inconsistent and inaccurate response guidance and actions to healthcare and public health private sector partners.

According to the *HHS/ASPR Incident Response Framework* and the *Pandemic Crisis Action Plan Version 2.0* (January 2018), the appropriate HHS' Operating Divisions and Staff Divisions provide information and decision support to private sector partners regarding the operating status and critical needs of the healthcare and public health sector during incident responses, with a focus on critical facilities and interconnected supporting infrastructure.³⁰

³⁰ U.S. Department of Health and Human Services: Office of the Assistant Secretary for Preparedness and Response, *Incident Response Framework Version 2.1*, 61; U.S. Department of Homeland Security: Federal Emergency Management Agency, *Pandemic Crisis Action Plan Version 2.0*, January 2018, 15-16.

During the HHS/ASPR/Critical Infrastructure Protection Program's formal coordination calls, CDC and HHS/ASPR/Critical Infrastructure Protection Division provided information to healthcare and public health sector partners regarding strategies to reduce demand, using engineering and administrative controls to reduce the need for personal protective equipment (e.g., N95 facemasks, gloves, and respirators). CDC and HHS/ASPR also encouraged the use of reusable products and extended limited reusability of personal protective equipment based on occupational exposure risks. As a result of the coordination and constant outreach with the healthcare and public health sector, private sector partners increased their knowledge of necessary workforce protection measures during an influenza pandemic.

However, messaging from HHS/ASPR's Critical Infrastructure Protection Division and other HHS' Operating Divisions to healthcare and public health private sector partners was inconsistent and inaccurate at times. Federal participants were unclear if there was a process to ensure that response guidance (e.g., vaccine and adjuvant handling, medical countermeasures availability, infection control) was vetted with the appropriate subject matter experts prior to dissemination to private sector partners. In particular, ASPR's Technical Resources, Assistance Center, and Information Exchange developed and disseminated a document to healthcare and public health private sector partners that contained incorrect information. In an actual incident, the lack of clear and accurate messaging may lead to incorrect response guidance and actions from healthcare and public health sector partners that negatively affect their workforce and other constituents.

Recommendations:

- HHS/ASPR's Critical Infrastructure Protection Division should establish a process to vet information prior to dissemination to private sector partners, without hindering the timely distribution of information.

4.4.2. Representatives of Emergency Support Function #14 – Long-Term Community Recovery successfully supported cross-sector coordination among infrastructure owners and operators, businesses and government partners.

The primary function of Emergency Support Function #14 is to align and support cross-sector operations among infrastructure owners and operators, businesses, and government partners to stabilize community lifelines as well as any impacted national critical functions.³¹ This new Emergency Support Function, coordinated by DHS' Cybersecurity and Infrastructure Security Agency, was created to provide unique

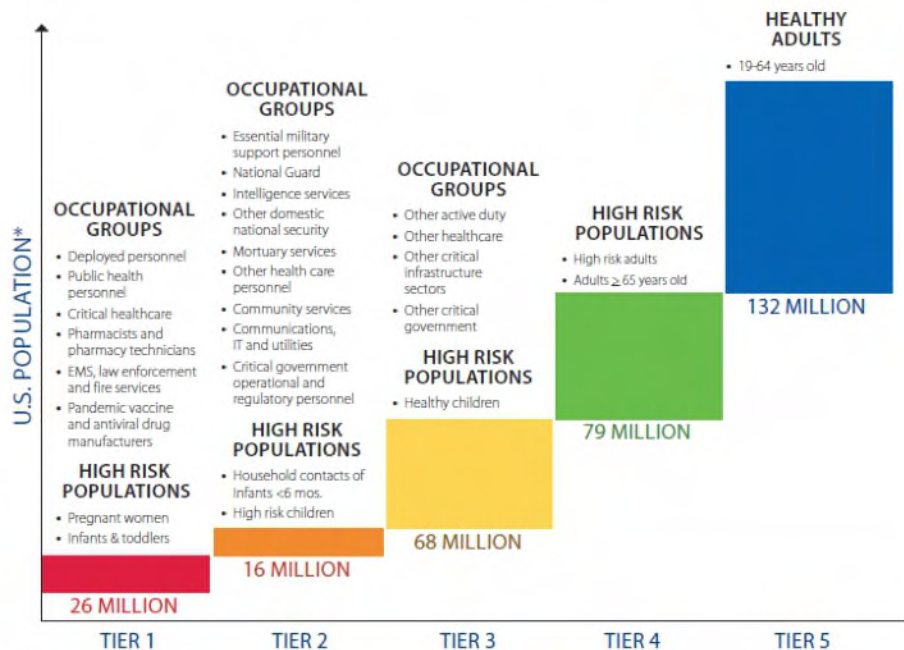
³¹ Federal Emergency Management Agency. Emergency Support Function #14 – Cross-Sector Business and Infrastructure Annex. May 2019.

services to enhance response operations, including a platform to engage the private sector in providing resources, a network of connections to additional partners, and analytical capabilities focused on interdependences. The exercise provided an opportunity for Emergency Support Function #14 partners to test their ability to provide such services during a nationwide pandemic influenza response.

Throughout the exercise, Emergency Support Function #14 representatives participated in daily coordination calls conducted by HHS/ASPR/Critical Infrastructure Protection Division. During one such call, the state of Arizona requested guidance regarding the use of refrigerated tractor trailers to transport the deceased. In response, Emergency Support Function #14 partners offered to support this request by coordinating with the Transportation Systems Sector. On another such call, a nonprofit medical center requested information about government regulations and flexibilities with respect to the use of expired respirators. In response, Emergency Support Function #14 representatives offered to educate partners on waivers that may be used to overcome challenges posed by restrictive regulations.

In addition to participating in HHS/ASPR/Critical Infrastructure Protection Division's coordination calls, Emergency Support Function #14 partners held a notional National Business Emergency Operations Center call to provide updates to and receive information from critical infrastructure partners. During the exercise, Emergency Support Function #14 partners also began to work with HHS—including the ASPR/Critical Infrastructure Protection Division and CDC—to identify minimum staffing requirements across critical infrastructure sectors. Partners agreed to continue this work following the exercise to ensure that critical infrastructure operators are appropriately ranked within the federal government's tiered vaccination recommendations. **Figure 8** below shows the recommended target groups to receive the pandemic (matched) vaccine first.

Figure 8. The federal government’s tiered vaccine recommendations for Tiers 1 and 2³²



* Based on 2015 U.S. population of 321 million people. <https://factfinder.census.gov/bkmmk/table/1.0/en/PEP/2015/PEPAGESEX>

Recommendations:

- Emergency Support Function #14 partners should continue to work with HHS—including HHS/ASPR’s Critical Infrastructure Protection Division and CDC—to identify minimum staffing requirements across all critical infrastructure sectors.

5. Situational Assessment

5.1. Federal Interagency Information-Sharing and Reporting

5.1.1. Federal interagency partners conducted a productive crisis action planning session to develop key leader decisions, critical information requirements, and essential elements of information for a pandemic influenza response.

In preparation for the exercise, HHS/ASPR’s Information Management Division conducted a series of meetings with CDC and DHS/FEMA partners to develop an information collection plan and national senior leader brief template tailored to an influenza pandemic response. The exercise provided a valuable opportunity for these partners to test the draft information collection plan and template. Exercise participants held a meeting to develop a list of key leader decisions on topics including but not limited

³² This graphic is derived from: <https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf>

to national declarations, operational coordination, public information and warning, Defense Production Act activation, law enforcement and security, waivers and exemptions, and continuity of operations. For each key leader decision, the group identified associated critical information requirements and essential elements of information. Following the exercise, HHS and DHS/FEMA leadership commended exercise participants for making significant progress in determining how the federal government will collect, analyze, and report local, state, federal, and private sector information during an influenza pandemic response.

5.1.2. HHS and DHS/FEMA’s use of disparate information management systems (i.e. SharePoint and WebEOC) hampered their ability to establish and maintain a national common operating picture.

During the exercise, HHS used its SharePoint-based Emergency Management Portal to share information and manage requests for information, while DHS/FEMA used its own information management system—Web Emergency Operations Center—to do the same. Because these systems do not interact with one another, information must be manually transposed between the two systems. When the Emergency Support Function #8 desk at the National Response Coordination Center received a request for information via the Web Emergency Operations Center, the Emergency Support Function #8 desk representatives had to manually enter the information into the HHS Emergency Management Portal, monitor the HHS Emergency Management Portal for a response, and then manually enter the response into the Web Emergency Operations Center. This process was labor intensive and slowed their ability to address and close requests for information. Furthermore, HHS’ personnel outside the National Response Coordination Center did not have access to the Web Emergency Operations Center and therefore could not assist the Emergency Support Function #8 desk in managing requests for information. To address this issue, exercise participants identified the need to grant Web Emergency Operations Center access and provide training on the system to select HHS personnel within the Incident Management Team and/or Incident Support Team to allow them to assist in managing requests for information. Exercise participants also suggested deploying a DHS/FEMA representative to the Secretary’s Operations Center to manage Web Emergency Operations Center inputs into the Emergency Management Portal; however, this was not implemented during the exercise.

In addition to identifying short-term options for managing the disparate systems, exercise participants also recommended that HHS and DHS/FEMA explore potential long-term information technology solutions to enable automated information sharing. Participants noted that automation would increase the timeliness of information sharing and allow both HHS and DHS/FEMA to more efficiently address and close requests for information.

Recommendations:

- HHS and DHS/FEMA should explore information technology solutions to allow for automated information-sharing and improve the efficiency of managing requests for information. Until such a solution is identified, HHS should identify Incident Management Team or Incident Support Team personnel to receive Web Emergency Operations Center access and training to prepare these personnel to support management of requests for information.

5.1.3. Both HHS and DHS/FEMA submitted senior leader briefs to the White House National Security Council during the exercise, which caused confusion regarding the official source of senior leader briefs.

During Senior Official Exercise 18-5, deputies agreed that HHS would coordinate with DHS/FEMA to develop senior leadership materials during a pandemic response to ensure a whole-of-government perspective. Later, during the Crimson Contagion Federal Interagency Seminar, senior federal officials affirmed that HHS, as the lead federal agency, would be responsible for developing a whole-of-government senior leader brief to provide the National Security Council with information on response activities and impacts of the pandemic, including information on second- and third-order effects.³³

In preparation for the Crimson Contagion 2019 Functional Exercise, HHS/ASPR's Information Management Division conducted a series of meetings with CDC and DHS/FEMA to develop an information collection plan and national senior leader brief template. On the first day of the exercise, HHS submitted a national senior leader brief to the National Security Council using this template. On the second day of the exercise, DHS/FEMA also submitted a senior leader brief to the National Security Council in its normal template, using its normal distribution list for disaster responses, but with some different information from HHS' senior leader brief.³⁴ As a result, senior officials were confused as to what information they should use to inform their decision-making and which agency was responsible for developing the whole-of-government senior leader brief during a pandemic response. To avoid such confusion in the future, HHS and DHS/FEMA identified the need to better coordinate and consolidate their information management activities to develop only one, national senior leader brief for the National Security Council, which may also involve DHS/FEMA making adjustments to or refining its pre-established distribution lists that are normally used during emergency responses.

³³ U.S. Department of Health and Human Services. Crimson Contagion 2019 Federal Interagency Seminar Day 1 Summary Report.

³⁴ In a real-world influenza pandemic response, the frequency with which senior leader briefs are developed may be only once a week or every 72 hours.

Recommendations:

- HHS should coordinate with DHS/FEMA to develop a single, national senior leader brief for the National Security Council using the newly developed template and to define the process by which each agency provides input to the creation of the senior leader brief. HHS should be responsible for providing this senior leader brief to the National Security Council, as agreed upon during Senior Official Exercise 18-5 and the Crimson Contagion Federal Interagency Seminar.
- The White House National Security Council should consider conducting Senior Official Exercises with federal interagency partners to discuss the processes, including the process to produce a national senior leader brief, which should be implemented when DHS/FEMA is not the lead federal agency in an incident response.

5.1.4. Response partners lack clarity on CDC's data use and sharing policies.

The exercise revealed that HHS/ASPR, other HHS Operating Divisions and Staff Divisions, and federal interagency partners have limited knowledge of CDC's data use and sharing policies. This lack of clarity gave rise to two key issues during the exercise. First, partners made unapproved modifications to CDC's data and improperly disseminated sensitive information. Second, HHS/ASPR and other partners expressed concern that CDC's restrictions on data sharing prevented them from performing critical analysis to create derivative products for senior leaders, such as layered maps or reports. To address these issues, participants identified the need to clarify data sharing restrictions, both within and outside of HHS.

Recommendations:

- CDC should socialize current data use and sharing policies and restrictions, and consider establishing a review process for derivative analysis that uses CDC data.

5.2 State-Federal Information Sharing

5.2.1. Federal partners did not provide state, local, tribal, and territorial public health and medical and emergency management partners with a standard template to report information across the full spectrum of community lifelines.

During the exercise planning process, federal planners indicated that state, local, tribal, and territorial participants should expect to receive questions from federal departments and agencies about the status of critical infrastructure within each of the seven community lifelines, along with other informational requirements. However, during the exercise, most

state, local, tribal, and territorial partners received very few, if any, requests for information related to critical infrastructure outside of the health and medical lifeline. Because the reporting process was not exercised as planned, states remained unable to anticipate future community lifelines reporting requirements and plan accordingly to provide them.

To gather public health and medical information during the exercise, the Secretary's Operations Center Information Management Section disseminated a Mission Generation Field Report template to Regional Emergency Coordinators. The template contained fields for information related to public and environmental health, healthcare facilities, shelter operations, patient movement, and human services, as well as a field for miscellaneous issues. Some states were also asked to provide information (e.g., real-time accounting of ventilators in use) that they do not track, were unaware they would be asked to provide, and would find difficult to track due to the transient nature of the information. State, local, tribal, and territorial participants suggested that federal partners coordinate to develop a single template that addresses all lifelines and captures all information needed to develop the national senior leader brief.

Recommendations:

- HHS should coordinate with federal interagency partners to determine state, local, tribal, and territorial reporting requirements for each community lifeline during a pandemic influenza response. Federal interagency partners should then inform all relevant state partners what information will be requested and how the information should be reported. When state partners receive this guidance, they should develop or update plans to be able to satisfy these information collection and reporting requirements.
- HHS should explore options for developing a web-based reporting template that Regional Emergency Coordinators and other approved field personnel could complete using their mobile devices or computers.
- HHS/ASPR should ensure that the Mission Generation Report aligns with other, HHS OPDIV/STAFFDIV reporting requirements.

5.2.2. HHS regional staff lack clear guidance on the distribution of federal information management products to state and local partners.

During the exercise, the Secretary's Operations Center Information Management Section worked with CDC and federal interagency response partners to generate a variety of valuable products to support situational awareness, including maps of influenza-like illness levels and confirmed H7N9 cases by state, graphs depicting the projected

epidemic curve, and lists of federal facilities near areas with high rates of absenteeism. These products were made available to HHS responders via the Emergency Management Portal. Regional Emergency Coordinators noted that many of the products contained information pertinent to state, local, tribal, and territorial partners; however, it was unclear to them which, if any, products had been cleared for release to their state and local partners. It was also unclear to Regional Emergency Coordinators when updated or new products would be available and where those products would be stored on the Emergency Management Portal. To address these issues, the Regional Emergency Coordinators identified the need for HHS to develop a clear process for distribution of new and updated information management products to state, local, tribal, and territorial partners.

Recommendations:

- HHS should develop protocols for distribution of information management products to state, local, tribal, and territorial partners during a pandemic influenza response. These protocols should include instructions for HHS Regional Emergency Coordinators to access products approved for dissemination, and clear marking for products approved and not approved for further dissemination.

5.2.3. CDC's State Health Official and Regional Emergency Coordinator calls provided state health officials with valuable insight into pandemic response activities at the national, regional, and state levels; however, the amount and types of information shared, as well as the existing limited mechanisms to share information did not align with state expectations.

CDC's State Coordination Task Force conducted two State Health Official and Regional Emergency Coordinator calls during the exercise to facilitate information-sharing among CDC, state, local, tribal, and territorial public health agencies, and public health partners. State and local partners found these calls to be well structured and informative. Each call began with an update from the Federal Health Coordinating Officer, who provided an overview of the federal coordinating structure and response priorities. CDC then provided an update on the current epidemiological situation, medical countermeasures supply, community mitigation, and public information. Following these updates, CDC invited state partners to provide updates and ask questions about the response. State partners appreciated the opportunity to hear about challenges faced by other states and the actions they were taking to address those challenges. However, participants noted that time constraints may not allow for such discussion during a real-world pandemic affecting all 50 states. In light of this concern, participants identified the need for CDC to consider what changes, if any, may be necessary to the call structure, duration, and/or frequency during a nationwide influenza pandemic.

Beyond CDC's State Health Official and Regional Emergency Coordinator calls, the public information officer calls, and HHS/ASPR's Critical Infrastructure Protection Division calls (private sector calls), some states received no information from federal entities about the national-level pandemic response. States noted that national-level information, when provided, was helpful to guide their response operations; however, the amount, types, and frequency of information shared was insufficient. For example, states were looking for nationally aggregated data on the course of the pandemic including updated case counts, intensive care unit admissions, hospitalizations, fatalities, lab testing results, and any new concerning trends. They also wanted to know the impact of the pandemic on nearby states. Additionally, information was primarily shared only through phone calls, and not through documents (e.g., Situation Report), which made validating the information heard challenging.

Based on previous experience, such as the Ebola outbreak and H1N1 pandemic, states anticipated more of a "push" of information from their federal partners.³⁵ In another example, states should not have had to ask for the updated guidance on recommended personal protective equipment from CDC. Rather, when CDC created the new guidance, they should have "pushed" it to the state. This is because states would have no way of knowing new guidance was available to ask for, if not informed about it. Instead, they would have continued to use the standard guidance and protocols for a high-risk respiratory disease.

Recommendations:

- CDC should consider reviewing the current structure, frequency, and content of State Health Official and Regional Emergency Coordinator calls during a nationwide influenza pandemic to enhance the utility of these calls for state partners.
- CDC should clearly define and communicate how states will receive information from them during a pandemic influenza response.

5.2.4. Inconsistent use of terminology regarding vaccine types and stockpiles caused confusion among response partners at all levels of government.

Throughout the exercise, participants used multiple terms to refer to the same vaccine type. To refer to the 2017 H7N9 and 2013 H7N9 vaccine held in HHS' pre-pandemic influenza vaccine stockpile, participants interchangeably used the terms "pre-pandemic vaccine", "stockpiled vaccine", and "priming dose". To refer to the 2019 H7N9 vaccine

³⁵ This is partially a result of exercise artificiality, as CDC did not use all of its systems to collect or disseminate information as it normally would in a pandemic influenza response.

that manufacturers were notionally developing during the exercise, participants used the terms “2019 H7N9 vaccine”, “pandemic vaccine,” and “matched vaccine.” The multitude of terms caused confusion, particularly among the many response personnel unfamiliar with influenza and vaccine types. Similarly, exercise participants often used the term “stockpile” without specifying whether they were referring to the Strategic National Stockpile, another federal stockpile, or a state stockpile.

Recommendations:

- HHS should promote the use of common terminology for vaccine types and stockpiles. To do so, HHS should work with federal and state, local, tribal, and territorial partners to ensure that current and future plans use common terms.
 - HHS should hold a seminar to clarify what is in the Strategic National Stockpile for an influenza pandemic response and the vaccine distribution program.
- During a pandemic influenza outbreak, HHS should distribute information with a lexicon for commonly misunderstood terms.

6. Resources

6.1. Scarcity

6.1.1. The current medical countermeasure supply chain and production capacity cannot meet the demands imposed by countries during a global influenza pandemic.

The U.S. lacks the ability to produce or source some of the raw materials necessary to produce vaccine in sufficient quantities to respond to the domestic requirements of a severe influenza pandemic. Further compounding this challenge, global manufacturing capacity will also be unable to meet domestic demand for medical countermeasures, including personal protective equipment and ancillary supplies (i.e., syringes), and it is anticipated that countries will keep their own stockpiled supplies for their own citizens. The U.S. also lacks domestic manufacturing capacity for the production of sufficient quantities of personal protective equipment, needles, and syringes. Domestic supplies of on-hand stock of antiviral medications, needles, syringes, N95 respirators, ventilators, and other ancillary medical supplies are limited and difficult to restock, because they are often manufactured overseas.

Recommendations:

- Promote growth of the domestic medical countermeasure industrial base with a



focus on bolstering input supply chain development (raw materials) and enhancing rapid manufacturing capacity.

- Increase the pool of funds available to rapidly secure manufacturing capabilities for a matched vaccine as soon as, or prior to, when a novel influenza strain is identified in the U.S.
- Increase the level of readily available funding for procurement of scarce medical countermeasures such as vaccines, personal protective equipment, needles and syringes, diagnostic resources, and antiviral medications.
- Develop a prioritization strategy for the distribution and allocation of scarce resources nationwide.
- Develop a global map of pandemic supply manufacturers and a report for Congress that details existing supply chain shortages, as well as HHS' gaps and anticipated needs to successfully respond to an influenza pandemic with high morbidity.

6.1.2. Federal exercise participants were not clear on the applicability or use of Title I, Priorities and Allocations Authority, of the Defense Production Act to mitigate medical countermeasure and ancillary supply shortages during an influenza pandemic response.

Title I of the Defense Production Act authorizes the federal government to ensure timely availability of critical materials, equipment, and services produced in the private market in the interest of national defense.³⁶ It directs the head of six federal departments, including HHS, to issue final rules that establish standards and procedures to promote national defense. It also allows the President to allocate or control the general distribution of materials, services, and facilities. However, the definition of national defense does not explicitly include health care resources, thereby highlighting the uncertainty of using the Defense Production Act to produce much needed medical countermeasures and matched vaccines in response to an influenza pandemic.³⁷

As articulated during the “snap” Domestic Resilience Group meeting, participants were unclear as to how the Defense Production Act could be used to compel or influence the private sector industry to acquire or produce critical resources. Specifically, participants

³⁶ Congressional Research Service. “The Defense Production Act of 1950: History, Authorities, and Considerations for Congress, <https://fas.org/sqp/crs/natsec/R43767.pdf>.

³⁷ Titles III and VII of the Defense Production Act may be applicable in an influenza pandemic response, but they were not discussed during the exercise.

were unclear if the Health Resources Priority and Allocation System under the Defense Production Act could be used in response to a non-Stafford Act incident. Ultimately, participants did not determine how, or if, the Defense Production Act could be used to enforce or encourage the development and manufacture of vaccines or medical countermeasures and ancillary supplies domestically.

Recommendations:

- Clarify the possible uses of the Defense Production Act so that the U.S. can compel private sector industry to domestically manufacture vaccines, medical countermeasures, and ancillary supplies for use during an influenza pandemic.
 - Examine the applicability of Title III and Title VII of the Defense Production Act as well as Executive Order 13603 to address supply chain and material shortages during an influenza pandemic response. Examination should include conversations with domestic industry partners in order to identify specific gaps and possible solutions.
 - DHS/FEMA should consider providing a publicly accessible educational briefing on the Defense Production Act and its possible uses in different kinds of incidents.

6.2. Resource Requests, Distribution, and Allocation

6.2.1. States experienced multiple challenges requesting resources from the federal government due to a lack of standardized, well-understood, and properly executed resource request processes.

During the exercise, states experienced multiple issues when requesting resources from federal Emergency Support Function #8 partners. First, the resource request process between state and local jurisdictions and federal agencies for anti-viral medications, personal protective equipment, ventilators, and other medical supplies was not standardized. Without a standard request form, jurisdictions submitted essay-style requests for resources, which led to confusion about what resources were being requested and delayed the resource fulfillment.

Second, at least one state planned to employ their full allocation of ventilators and priming doses, and accordingly submitted requests to HHS/ASPR. However, HHS/ASPR declined to fulfill these requests on the basis of its own evaluation of the conditions in the state. The state was not prepared to address denial of its requests because of its understanding that states are responsible for identifying their own requirements via their own

assessment process (not a federal assessment process), as well as its understanding that the requested resources had already been allocated and made available to them.

Third, requests submitted to federal partners often went without acknowledgement. In the absence of confirmation of receipt of requests for information or requests for resources, jurisdictions re-submitted documents. The additional duplicate requests further encumbered the process, gave rise to version control issues, and did not account for partial approvals or denials. This situation was complicated by the fact that the Division of the Strategic National Stockpile did not use their system of record to acknowledge or deploy resources.

Fourth, resource request and allocation tracking was not transparent to the range of state, local, tribal, and territorial and federal response partners. CDC controlled allocations of the pre-pandemic vaccine priming dose while HHS/ASPR's Division of Strategic National Stockpile controlled Strategic National Stockpile assets and HHS/ASPR's Resource Coordination Branch controlled all other potential assets. These resources are all tracked via different processes in different systems, which poses a challenge to developing a comprehensive resource common operating picture.

Fifth, state participants were unsure if they should submit resource requests (along with requests for information and response data) to HHS/ASPR (specifically, the Regional Emergency Coordinators), to CDC, or to both.

Sixth, states were unsure whether only those requests for resources that could be filled with Strategic National Stockpile resources should be submitted to HHS/ASPR while other requests for resources should be submitted to CDC (e.g., for priming dose vaccine for resourcing through the National Pre-Pandemic Influenza Vaccine Stockpile).

Recommendations:

- HHS should clearly define the process for requesting federal assets (e.g., Strategic National Stockpile) and develop a corresponding resource request and allocation information management system that can be widely accessed by state, local, tribal, and territorial and federal response partners.
- HHS/ASPR's Division of the Strategic National Stockpile should consider developing a resource request form or adopt DHS/FEMA's 213RR form to streamline data requirements for resource requests.
- HHS should socialize its resource request, allocation, and tracking processes and system with state, local, tribal, and territorial partners via training and additional exercises between state and federal response partners.

- HHS should conduct exercises with state partners in which states use their real-world tracking tools, as required by grant guidance.

6.2.2. The majority of participating states indicated that they were unclear on pre-pandemic vaccine and the Strategic National Stockpile asset distribution in response to an influenza pandemic.

Several states did not possess a clear understanding of how Vaccines for Children supply chains would be used to distribute pre-pandemic vaccine priming doses. State participants were concerned that the currently registered Vaccines for Children providers may not sufficiently represent the target patient populations.³⁸

In addition, states were concerned that without funding provided under a major disaster declaration, they would not have the resources to distribute Strategic National Stockpile assets from initial reception points to areas across that state.

Recommendations:

- HHS should consider providing an updated fact sheet with information regarding (1) the distribution of pre-pandemic vaccine through the Vaccines for Children and (2) receipt, distribution, and use of federally stockpiled medical countermeasures to all CDC and HHS/ASPR federal grant recipients, (3) and differences between the influenza vaccine and other vaccines.
 - HHS should also clarify the distribution of vaccine for federal employees working in states across the country.

6.2.3. States questioned the rationale behind federal decisions to decline resource requests.

Using outbreak data and epidemiological forecasts, one of the participating states identified the need for its full allocation of ventilators from the Strategic National Stockpile and vaccine doses from the pre-pandemic influenza vaccine stockpile. Based on the epidemiologic curve, its healthcare capacity, and its medium disease burden profile status, the state anticipated a sharp increase in influenza cases and sought to: 1) pre-position ventilators in facilities with the capacity to operate the equipment and adequately care for higher level acuity patients; and 2) vaccinate priority groups with the priming dose vaccine as quickly as possible. To execute these actions, the state required and planned

³⁸ This may be due to the fact that (1) states are unaware that they are expected to enroll additional pandemic vaccine providers into the Vaccines for Children program in order to vaccinate their entire state population and (2) misinformation in state grant guidance on how the influenza vaccine would be handled.

to employ its full allocation of ventilators and priming doses and accordingly submitted requests to HHS/ASPR. HHS/ASPR declined to fulfill these requests on the basis of its own evaluation of the conditions in the state. The state was not prepared to address denial of its requests because the state believed it was responsible for identifying its own requirements via its own assessment process (not a federal assessment process). Additionally, the state held the understanding that the requested resources had already been allocated to them.

Similarly, during the State Health Officer and Regional Emergency Coordinator calls, CDC stated that there were sufficient quantities of antiviral medications in the market place and they would therefore not recommend releasing additional quantities of antiviral medication allocations to state and local jurisdictions. Although the exercise was designed with a central focus on non-pharmaceutical interventions and the production of vaccine for a novel influenza strain, the decision to forgo adjudication of state and locals' requests for what they understood as pre-allocated quantities of antiviral medications drove confusion about how these requests would be addressed in a real world incident.³⁹ Very few states or jurisdictions maintain an U.S. Food and Drug Administration-compliant, on-hand pharmaceutical capability and by day 48, felt that they would likely encounter retail pharmacy shortages. One jurisdiction anticipated exhaustion of its anti-viral medication supply and sought private sector input to determine costs for product replenishment; the generic version of the products would have cost just under \$42M.

Recommendations:

- HHS/ASPR should consider publishing a strategy to adjudicate state requests for resources during an influenza pandemic.

7. Public Information and Risk Communications

7.1. Public Information-Sharing and Risk Communications

7.1.1. CDC used multiple information-sharing channels to successfully provide the public and responders with information about the influenza pandemic response, as well as guidance on safe work practices, and personal protective equipment for first responders.

According to the *Pandemic Crisis Action Plan Version 2.0* (January 2018) and CDC's *Pandemic Influenza Appendix to the Biological Incident Annex of the CDC All-Hazards Plan*, CDC is tasked with providing guidance on the use and distribution of medical

³⁹ This is due in part to an exercise artificiality, as MedFinder was not updated during exercise conduct to show the latest levels of antivirals.

countermeasures, on protective measures for first responders and public health providers, and for disseminating key public health and safety messages to the public.⁴⁰

During the exercise, CDC provided technical and workforce safety guidance to state, federal, and private sector participants through a number of national-level coordination calls, including the CDC State Health Officer and Regional Emergency Coordinator call, National Incident Coordination Conference Line call, State Incident Coordination Conference Line call, the CDC State Epidemiology call, Emergency Support Function #8 Public Health and Medical Services call, the HHS/ASPR's Critical Infrastructure Protection Division call, and the National Pandemic Influenza Situation Update video teleconference call. State, federal, and healthcare and public health private sector partners found the information provided by CDC and their state counterparts to be informative and helpful. CDC provided key response information including the timeline for distribution of the pre-pandemic priming dose vaccine, the estimated timeline for the well-matched vaccine, and the lack of availability of federal teams to cover the response due to disease transmission.

7.1.2. The implementation of school closures among some participating states highlighted the many cascading impacts to communities; and the variation in timing of school closures caused confusion among exercise participants.

During the exercise, CDC recommended that states delay school openings for six weeks, a follow-up to the initial (pre-exercise) recommendation that states delay the opening of schools for two weeks if the disease is present in the area. Many local jurisdictions and school districts have the authority to decide to close schools (or keep schools open). This distributed approach to school closure decisions caused confusion centered on discrepancies between schools that remained open and those that closed.

In addition, while school delays and dismissals may be necessary over the course of the pandemic response, state participants identified any continued school delays and dismissals as having serious cascading impacts that require a concerted public messaging campaign and government coordination. Multiple states realized that dismissing schools is much more complex than they previously appreciated. In the State of Illinois alone, the human services impact and financial impact rose to a key concern. The Chicago Department of Public Health roughly estimated that the economic cost of school closures for the City of Chicago, which accounts for approximately 21 percent of the Illinois' population, would be approximately \$40 million per week. This finding

⁴⁰ U.S. Department of Homeland Security: Federal Emergency Management Agency, *Emergency Support Function #15 – External Affairs Annex*, June 2016, accessed September 30, 2019, https://www.fema.gov/media-library-data/1470148861791-ef933ffb72424da5925348b4695b4a00/ESF_15_External_Affairs_20160705_508.pdf.

prompted the state to request a Stafford Act declaration; however, deriving the economic impact in real-time would be a huge task for state and locals (this also aligns with information in the 2017 Community Mitigation Guidelines to Prevent Pandemic Influenza). Regarding the human services impact, state participants considered the possibility that schools are often a child's only way to receive hot meals throughout the day. As a result, states were less likely to implement guidance from CDC without first receiving notifications that emergency funding through the Stafford Act was approved.

Recommendations:

- HHS should increase coordination with states on public messaging associated with school delays and dismissals during an influenza pandemic, including why there are variances in school closures or delays across the country.
- CDC should coordinate with states to develop appropriate school delay and dismissal guidance that takes into account the cascading impacts in economic and human service sectors.
- States should continue to examine and estimate the economic and other impacts of school closures to communities during an influenza pandemic. This should also include examination of economic recovery.
- The U.S. Department of Agriculture should communicate mechanisms for requesting food from its programs during times when schools are closed.
- Future influenza pandemic exercises should also include examination of the political aspects involved in managing pandemics.

7.1.3. The reasons for HHS' decision to halt seasonal influenza administration and distribution were unclear to state participants.

At the start of the exercise, CDC provided guidance to states on delaying the administration and distribution of seasonal influenza vaccines. However, the guidance lacked clear context leading to confusion within several state public health communities.⁴¹ Some states noted that halting distribution and administration of the seasonal influenza vaccine so late in the year would likely result in inconsistent adherence to the federal-level guidance to provide the seasonal vaccine. By late July, many providers, facilities, and pharmacies in states would have already received their allotment of the seasonal influenza vaccine. In this situation, many healthcare and public health providers would

⁴¹ This may have been due to a limited understanding among participants of ground truth information developed prior to exercise conduct.

likely continue to administer the seasonal vaccines despite guidance from CDC. Considering this, states noted that messaging to the public about this would be critical. Specifically, it would be important for patients and the public to understand that the seasonal flu vaccine would not provide protection against the pandemic H7N9 strain. A significant outreach component would also be necessary to both the vaccine providers and the public to justify why these vaccines should not be administered and increase compliance with recommendations.

7.2. National-Level Coordination Calls

7.2.1. Despite initial technical issues, the National Incident Coordination Conference Line call enabled federal government response partners to coordinate on the development of public messages.

According to the *Emergency Support Function #15 – External Affairs Annex*, the National Incident Coordination Conference Line call should act as a standing conference line designated, maintained, and supported by the DHS Office of Public Affairs as the primary means for interagency incident communications information sharing during an incident requiring federal government coordination.⁴² During the exercise, HHS/ASPR and DHS coordinated the facilitation of the National Incident Coordination Conference Line call on August 13, 2019. Federal government participants considered the issues that their organizations could face as the pandemic worsened over the next month. Participants also discussed the public messaging implications of the pandemic and coordinated messaging approaches to the public, as well as their respective federal workforces.

7.2.2 State government public information officers found the State Incident Coordination Conference Line calls useful to create state-based public messaging.

According to the *Emergency Support Function #15 – External Affairs Annex*, the State Incident Coordination Conference Line call should act as a standing conference line designated, maintained, and supported by the DHS Office of Public Affairs as the primary means for federal-to-state incident communications and information sharing during an incident requiring such coordination.⁴³

⁴² U.S. Department of Homeland Security: Federal Emergency Management Agency, *Emergency Support Function #15 – External Affairs Annex*, June 2016, accessed September 30, 2019, https://www.fema.gov/media-library-data/1470148861791-ef933ffb72424da5925348b4695b4a00/ESF_15_External_Affairs_20160705_508.pdf.

⁴³ U.S. Department of Homeland Security: Federal Emergency Management Agency, *Emergency Support Function #15 – External Affairs Annex*, June 2016, accessed September 30, 2019,

During the exercise, states found the information provided by the federal government and their state counterparts to be useful in guiding their response operations.⁴⁴ Federal and state partners shared relevant and needed information (e.g., the timeline for distribution of the pre-pandemic priming dose vaccine, the estimated timeline for the matched vaccine). Additionally, states found the State Incident Coordination Conference Line useful to hear what other states were facing as a result of the pandemic. Broad, transparent coordination during the State Incident Coordination Conference Line calls provided states with ideas about actions they might want to pursue as the disease increases in their state.

https://www.fema.gov/media-library-data/1470148861791-ef933ffb72424da5925348b4695b4a00/ESF_15_External_Affairs_20160705_508.pdf.

⁴⁴ During the exercise, a number of state public information officers did not receive the call-in information for the State Incident Coordination Conference Line call, as neither HHS/ASPR nor CDC had the contact information for many of the state public information officers that handle public information in an influenza pandemic response. As a result, many states were not aware when the State Incident Coordination Conference Line calls would occur, the dial-in information, or the intended audience for the calls.

CONCLUSION

The Crimson Contagion 2019 Functional Exercise provided local, state, federal, nongovernment organizations and private sector partners an opportunity to practice implementing response actions, as well as engage in candid discussions about response, resource, and capability challenges during an influenza pandemic across all levels of government.

During the exercise, a significant topic of concern centered around the inadequacies of existing executive branch and statutory authorities to provide HHS with the requisite mechanisms to serve successfully as the lead federal agency in response to an influenza pandemic. Exercise participants highlighted the need to codify policies and procedures for HHS to lead, direct, and source funding in response to all kinds of public health emergencies.

In addition, further examination is needed to determine how federal interagency partners will coordinate with one another on a variety of pandemic influenza-specific response activities, including but not limited to information-sharing with the White House National Security Council, addressing shortages in medical countermeasure and ancillary supplies, bilateral state-federal request for information coordination nodes and processes, and the respective roles and responsibilities of HHS and DHS/FEMA in response to a complex and unique threat, with a nontraditional lead federal agency.

The exercise also demonstrated issues faced by participating states, including confusion regarding the purpose of and target audience for national conference calls, challenges requesting resources from the federal government due to a lack of standardized, well-understood, and properly executed resource request processes, and varying degrees of development and implementation of crisis standards of care, ranging from the absence of standards, to standards narrowly focused on the allocation of specific resources (e.g., ventilators), to relatively mature standards and standards-implementation approaches.

The exercise also revealed several strengths, including collaboration between the federal government and healthcare and public health private sector partners and the ability of federal interagency partners to conduct a productive crisis action planning session to develop key leadership decisions, critical information requirements, and essential elements of information to successfully gather information for and maintain situational awareness products.

Overall, the Crimson Contagion 2019 Functional Exercise provided a valuable opportunity for participants to learn about one another's capabilities and identify issues requiring further examination. Addressing these issues will enhance the ability of the



whole community to implement integrated response operations and mitigate an influenza pandemic's impacts in order to save American lives.

APPENDIX A: CRIMSON CONTAGION 2019 FUNCTIONAL EXERCISE PARTICIPATING ORGANIZATIONS

Federal Organizations
Executive Offices of the President
National Security Council
U.S. Department of Health and Human Services
Administration for Children and Families
Administration for Community Living
Centers for Disease Control and Prevention
Centers for Medicare and Medicaid Services
Food and Drug Administration
Health Resources and Services Administration
Indian Health Service
National Institutes of Health
Office of the Assistant Secretary for Administration
Office of the Assistant Secretary for Financial Resources
Office of the Assistant Secretary for Health
Office of the Assistant Secretary for Legislation
Office of the Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Public Affairs
Office of the General Counsel
Office of the National Coordinator for Health Information Technology
Substance Abuse and Mental Health Services Administration
U.S. Department of Agriculture
U.S. Department of Commerce
U.S. Department of Defense



Federal Organizations
Office of the Assistant Secretary of Defense for Homeland Defense and Global Security
Office of the Assistant Secretary of Defense for Health Affairs
Joint Staff J3 (Operations Directorate)
Joint Staff Surgeon
USNORTHERN COMMAND
Region 1 Defense Coordinating Element
Region 1 Joint Regional Medical Plans and Operations
U.S. Department of Energy
National Nuclear Security Administration
Office of Cybersecurity, Energy Security, and Emergency Response
Office of Environment, Health, Safety, and Security
U.S. Department of Homeland Security
Countering Weapons of Mass Destruction Office
Customs and Border Protection
Office of Operations Coordination
National Operations Center
Joint Incident Advisory Group
Operations Continuity Division
Federal Emergency Management Agency
National Response Coordination Center
National Business Operations Center
Region I
Region VI
Immigration and Customs Enforcement
Office of Public Affairs
Management Directorate
Transportation Security Administration



Federal Organizations
U.S. Coast Guard
U.S. Department of Housing and Urban Development
U.S. Department of Interior
U.S. Department of Justice
Federal Bureau of Investigation
U.S. Marshal Service
U.S. Department of Labor
Occupational Safety and Health Administration
U.S. Department of State
Office of Emergency Management
U.S. Department of Transportation
Federal Aviation Administration
U.S. Department of Treasury
U.S. Department of Veterans Affairs
Veterans Health Administration
Environmental Protection Agency
General Services Administration
Office of the Director of National Intelligence
Office of Personnel Management
Small Business Administration

State and Local Organizations
Commonwealth of Massachusetts
Massachusetts Department of Public Health
State of Connecticut
Connecticut Department of Public Health
Connecticut Department of Emergency Management and Homeland Security



State and Local Organizations	
State of New Hampshire	
	New Hampshire Department of Health and Human Services
	New Hampshire Department of Safety, Homeland Security and Emergency Management
State of New York	
	New York State Department of Health
Commonwealth of Pennsylvania	
	Pennsylvania Department of Health
	Pennsylvania Emergency Management Agency
	Allegheny County Health Department
	Erie County Health Department
State of South Carolina	
	South Carolina Department of Health and Environmental Control
	South Carolina Emergency Response Team
City of Chicago	
	Chicago Department of Public Health
	Chicago Office of Emergency Management and Communications
State of Illinois	
	Illinois Department of Public Health
	Illinois Emergency Management Agency
State of New Mexico	
	New Mexico Department of Health
	New Mexico Department of Homeland Security and Emergency Management
State of Nebraska	
	Nebraska Department of Health and Human Services
State of Colorado	
	Colorado Department of Public Health and Environment
State of Arizona	



State and Local Organizations
Arizona Department of Health Services
Arizona Department of Emergency and Military Affairs
State of Idaho
Idaho Department of Health and Welfare
Idaho Office of Emergency Management
Panhandle Health District
Idaho North Central Health District
Southwest District Health
Central District Health Department
South Central Public Health District
Southeastern Idaho Public Health District
East Idaho Public Health District

Tribal Nations and Pueblos
State of New Mexico
Sandia Pueblo
Navajo Nation
State of Arizona
Cocopah Indian Tribe
Colorado River Indian Tribes
Fort Mojave Indian Tribe
Gila River Indian Community
Hopi Tribe
Kaibab Band of Paiute Indians
Navajo Nation
Pascua Yaqui Tribe
Quechan Indian Tribe



Tribal Nations and Pueblos

Salt River Pima – Maricopa Indian Community
San Carlos Apache Nation
Tohono O’Odham Nation
White Mountain Apache Tribe

Nongovernmental and Private Sector Organizations

Aetna
Allegheny Health Network
Amador Health Center
American Hospital Association
American Red Cross
Association of Public Health Laboratories
Association of State and Territorial Health Officials
Carestream Health
Council of State and Territorial Epidemiologists
Ephraim McDowell/James B. Haggin Hospital
Giant Eagle Pharmacy
Grand Strand Health/HCA
Health Information Sharing and Analysis Center
Healthcare and Public Health Sector Coordinating Council
Healthcare Ready
International Safety Equipment Association
Juware
Kidney Community Emergency Response Program
Mayo Clinic
Moldex-Metric Inc.
National Alliance of State Pharmacy Associations



Nongovernmental and Private Sector Organizations
National Association of County and City Health Officials
National Community Pharmacists Association
National Indian Health Board
North Shore University Health System
Patients' Hospital
RBC Limited
San Mateo County Health – EMS Agency
Seqirus Inc., USA
Spectrum Health
TriStar Skyline Medical Center
University of Minnesota