



**Association of State and  
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June 26, 2020

Lamar Alexander, Chairman  
Senate Committee on Health, Education, Labor and Pensions  
United States Senate

Dear Chairman Alexander,

On behalf of the Association of State and Territorial Health Officials (ASTHO), I want to thank you and your committee for your steadfast leadership in advancing our nation's state of readiness for the myriad of traditional and emerging health threats our nation faces every day, including pandemics. We also applaud you for your commitment to this effort as exemplified by the recent release of the ***Preparing for the Next Pandemic*** White Paper and appreciate the opportunity to engage and provide the following comments, proffered in the spirit of collaboration and with the mutual goal of strengthening our collective capacity and capabilities to protect the public's health.

ASTHO is a 501(c)(3) nonprofit membership association serving the chiefs of state and territorial health agencies and the more than 100,000 public health staff that work in those agencies. Our mission, from which our organizational strategy flows, is to support, equip, and advocate for state and territorial health officials in their work of advancing the public's health and well-being. ASTHO tracks, evaluates, and advises members on the impact and formation of policy—public or private—pertaining to health that may affect state or territorial health agencies' administration and provides guidance and technical assistance to its members on improving the nation's health.

We respectfully submit for your consideration two sets of comments, the first being general reflections on the series of recommendations contained in the White Paper, and the second being somewhat detailed answers to key questions posed that are most relevant to the mission space of our members. Additionally, we defer to the comments provided by two of ASTHO's affiliates, the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE), given their expertise in clinical testing and disease surveillance, respectively; and the comments submitted by the Stakeholder Forum on Antimicrobial Resistance (S-FAR), of which ASTHO is a signatory, on the importance of addressing antimicrobial resistance as a key component of our nation's pandemic preparedness.



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**COVID-19 Lessons Learned So Far and Initial Recommendations**

In general, ASTHO finds the five recommendation tracts and the 20 specific sub-recommendations in the White Paper to be comprehensive, well informed by the experiences and lessons learned during past and current public health emergencies, and in line with issues requiring priority attention as we not only prepare for the next pandemic, but also work to sustain and make more impactful the current response to the COVID-19 pandemic.

To add to the body of knowledge summarized in the Summary of 'Past Federal Governmental Efforts to Prepare for a Pandemic' section of the White Paper, attached you will find our June 2010 report *titled, "Assessing Policy Barrier to Effective Public Health Response in the H1N1 Influenza Pandemic."* This report contains a robust set of recommendations, many of which align with experiences during the current COVID-19 response and were discussed in the White Paper. Also, in the 'Reviewing Legislation and Funding' section under *State Readiness*, the National Health Security Preparedness Index ([www.nhspi.org](http://www.nhspi.org)) is also a resource to consider, along with the Trust for America's Health *Ready or Not* report, which demonstrates consistent gains in preparedness made over time, but also remaining gaps, such as in community planning and engagement and healthcare delivery, as shown in last year's report.

Additional observations and thoughts include:

- In addition to the issues and recommendations contained in the White Paper, it is recommended that the following three areas be incorporated:
  - *Foundational Funding:* Throughout the White Paper, a detailed summary is provided on various funding mechanisms made available through routine and emergency avenues to support public health preparedness and response, including declines in funding to the two core federal programs, the CDC Public Health Emergency Preparedness Cooperative Agreement, and the ASPR Hospital Preparedness Program Cooperative Agreement.

ASTHO strongly believes that the White Paper should also cover the issue of public health infrastructure needs and highlight, via a recommendation, the need for sufficient and sustainable core funding for foundational all-hazards public health capacity and capability. In addition, ASTHO strongly supports the establishment of a mandatory public health infrastructure fund which would provide predictable, sustained, and increased investments for state, territorial, and local health departments.



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For additional details regarding discretionary funding recommendations, please refer to ASTHO's [FY21 Governmental Public Health Appropriations Book](#), which compiles top federal funding priorities and recommendations for nonprofit public health associations in FY20.

- *Public Health Workforce Resilience:* Part of America's cadre of frontline responders combating COVID-19 is our public health workforce. While they are often unsung heroes, they are now the target of unwarranted public criticism and personal threats for just doing their jobs in trying to save lives. This, coupled with the enormous unprecedented stress, strain, and 24/7 demands of COVID-19 response over the last three to four months have made them battle worn. A June 17, 2020 [opinion piece](#) discusses this in greater detail and articulates how these behaviors actually pose three major threats to public health. Given the gravity of this unfortunate situation, it is recommended that the issue of public health workforce resilience be addressed in the White Paper.
  
- *Personal Responsibility:* Notwithstanding state and local requirements, there must also be a comprehensive national campaign to inform and influence members of the public and compel voluntary adherence to [everyday steps to prevent COVID-19](#) as recommended by the CDC. As an example, on June 23, 2020 ASTHO released this statement: [State and Territorial Health Officials to the American Public: COVID is Not Over](#). The importance of gaining the public's trust and fostering a national, maybe even patriotic, movement of this type that can withstand campaigns of mis- and disinformation is paramount to the success in our war against COVID-19 and, as such, also warrants issue status in the White Paper with suitable recommendations.
  
- Express mention of, and attention paid to insular jurisdictions is warranted. The territories and freely associated states not only share similar threats of that of the states and localities, but also often are at elevated risk for natural disasters and infectious disease introduction attributed to global travel, and have unique and formidable preparedness and response challenges, particularly with infrastructure and workforce, and have needs as a result of geography, demographics, and culture (e.g., extremely remote islands and villages with limited public health services and healthcare capabilities). Additionally, critical funding for these jurisdictions through Medicaid are governed differently, and by statute, causing their systems to not be as resilient or able to recover as well from public health emergencies as states.



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- As part of the recommendations on tests, treatments, and vaccines, a priority focus on the constant threat of drug shortages, including finished product, active pharmaceutical ingredients, and the vulnerabilities associated with the reliance on offshore production should be captured in the White Paper. Consideration should be given to advancing the recommendations contained in the 2019 FDA [report](#), “Drug Shortages: Root Causes and Potential Solutions” and the [National Biodefense Strategy and Implementation Plan](#).
- The discussion on Issue 2.1 appropriately raises the concern over health disparities and the disproportionate impact on minority populations. This is an extremely important legacy matter that must be aggressively and systematically addressed, including social/societal stigmatization. While this is crosscutting and integral to many of the White Paper’s recommendations, a specific health equity-focused recommendation should also be included, rather than being subsumed in a recommendation framed as ‘ensuring timely communications.’
- Regarding Recommendations 3.3 and 3.5, which would require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished at both the federal and state level, it must be acknowledged that while this is a sound preparedness objective, it is also expensive to achieve. In addition to the procurement costs for the cache of materiel, there are also recurring maintenance costs, such as for storage space rental, inventory control, and security. Concomitant increases in sustained federal funding to states and territories, such as through the CDC Public Health Emergency Preparedness Cooperative Agreement, will be needed in order to realize the potential of this recommendation.

Additionally, ASTHO has historically advocated for including state and territorial health agencies in issues related to the strategic national stockpile (SNS). State and territorial public health is a critical member of the medical countermeasures (MCM) enterprise with primary responsibility for the “last mile” of distribution to communities. ASTHO strongly supports an addition of a formal mechanism to solicit and consider input from state, territorial, local, tribal, and public health officials, as well as recommends that the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) routinely solicit and incorporate state and local feedback regarding medical countermeasures to ensure that critical decisions affecting dispensing operations take into account local planning concerns. A process for obtaining input from state and local public health departments is included in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, which states that



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the “PHEMCE shall solicit and consider input from state, local, tribal, and territorial public health departments or officials as appropriate.” This provision has not yet been operationalized.

- Regarding Recommendation 3.4, ASTHO wholeheartedly supports the posture that the federal government, states, and private sector work more effectively together, especially as it pertains to vaccine allocation, distribution, and administration, including advance planning and coordination, as demonstrated during the H1N1 pandemic back in 2009-2010. ASTHO is concerned that this may not be the case currently under Operation Warp Speed where there is an apparent absence of consideration for the direct involvement and utilization on our nation’s public health system and existing private sector networks and key legacy programs that have the responsibility, foundational infrastructure, and experience in administering medical countermeasures such as vaccine to the general public. It remains unclear as to whether the role of the Department of Defense under Operation Warp Speed will be a complementary but separate, or a replacement system of vaccine delivery to that currently provided or coordinated by state and local health departments in partnership with private providers. Clarity, transparency, and collaboration must be prominent in this process. This issue is explored further in the Questions section of this letter below.

While the existing public health preparedness and response and immunization program infrastructure in the United States provides a solid foundation for a COVID-19 national vaccination campaign, gaps in capacity and capability across public health and health care systems, due in large part to the magnitude of this effort, must be addressed to ensure that our nation is prepared to engage in a timely, comprehensive, and equitable vaccination campaign. Infrastructure investments must be made now to further strengthen, enhance, and scale up the ability of public health primary care physicians, pharmacists, and other health care providers in the community who currently provide immunization to meet demand for a future COVID-19 vaccine. For your reference and for additional details, also attached you will find a June 1, 2020 letter sent to Congressional leadership containing a series of planning considerations and resource needs we would like to share with your committee for ongoing consideration.

- Recommendation 4.3 goes to the heart of outbreak suppression. The nation’s public health system must be revitalized and sufficiently enhanced in a sustainable way to aggressively investigate cases and conduct contact tracing in order to effectively quell further spread of COVID-19. In April, ASTHO collaborated with the JHU Center for Health Security to release [A National Plan to Enable Comprehensive COVID-19 Case Finding and Contact Tracing in the US](#). The report calls for a robust and comprehensive system to identify all COVID-19 cases and trace all close contacts of each identified case and outlines a vision—complete





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with resources and specific action steps—to accomplish this goal. In order to trace all contacts, safely isolate the sick, and quarantine those exposed, we estimate that our public health workforce needs to add approximately 100,000 (paid or volunteer) contact tracers to assist with this large-scale effort. This workforce could be strategically deployed to areas of greatest need and managed through state and local public health agencies that are on the front lines of COVID-19 response. To do this, we also estimate that Congress will need to appropriate approximately \$7.6 billion in emergency funding to state and territorial health departments. ASTHO recommends that these mission-critical resource needs be specifically referenced in the White Paper.

- Regarding recommendation 4.4, ASTHO shares the Committee’s viewpoint that significant improvements have been made in the way HHS/CDC is administering and awarding COVID-19 emergency supplemental funding to states and territories, through both established legacy funding mechanisms such as the Epidemiology and Laboratory Capacity Cooperative Agreement as well as specially designed mechanisms like the fairly new CDC Public Health Crisis Response Cooperative Agreement process. CDC should be commended for this effort, and the imperative to continue to further refine this process for greater expedience and simplicity, without compromising accountability, should be reinforced. That said, it must also be emphasized that when a major emergency breaks in a jurisdiction, the resources in place made available through the CDC Public Health Emergency Preparedness (PHEP) and ASPR Hospital Preparedness Program (HPP) can and should easily and seamlessly transition from a pre-event preparedness planning mode to a real-time response posture, given the demands of the crisis. This pivot should be promoted by federal agencies and any administrative barriers to this should be identified and removed to the fullest extent possible.
- Recommendation 5.2 appropriately highlights the importance and value of exercising plans. We suggest that this point be expanded to also include conducting of timely, transparent, and inclusive periodic COVID-19 in-progress reviews and an after-action report and improvement plan.

### Specific Questions Addressed

#### **Tests, Treatments, and Vaccines-Accelerate Research and Development**

ASTHO and its members stand ready and available to further illuminate any responses covered below and are able to bring together a set of experts who can provide visibility to operations on the ground, as well as an understanding of what will support and potentially interrupt their ability to prepare for and respond to public health emergencies.

#### **How can the federal, state, and private sector work together to distribute and administer treatments and vaccines more effectively?**

*A robust public-private partnership will become crucial as the nation looks*



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*A robust public-private partnership will become crucial as the nation looks towards safe and effective vaccines and treatments to prompt COVID-19 recovery. At first glance, countermeasures appear to be a simple process: a manufacturer develops a treatment or vaccine and healthcare providers give it to their patients. However, the system is much more complex. At every step, federal, state, and private sectors must work together to enhance and sustain a system that ensures safe and effective vaccines and treatments are available and accessible to the public.*

*Public and private sectors will have to work together to educate networks of providers to ensure they have the necessary information to help their patients make informed decisions regarding treatment and vaccine. New providers can enhance access but should be built upon the well-functioning system that has served the country for decades. For example, state health agencies are skilled in recruiting and educating networks of eligible vaccine providers to improve access and administer injections. Additionally, communication and coordination between public and private sectors will be vital to ensure the vaccine and treatment is properly allocated, distributed, and administered to priority groups. This collaboration should be inclusive of vulnerable populations to help assure health equity in the emergency response and equitable distribution of limited resources.*

*The country has a system in place that ensures delivery of vaccinations and treatments every day. Distribution should go through existing infrastructure, such as the Vaccine for Children program, which is a highly efficient and effective program that provides vaccines to more than 50% of the nation's children and enrolls more than 90% of the nation's pediatricians. Vaccines are distributed directly to providers through a centralized ordering system and a national distributor managed by the CDC. This system was effectively expanded to enroll adult providers during the 2009 H1N1 pandemic vaccination campaign. We encourage government and private sectors to build upon this existing system for COVID-19 vaccination.*

**Stockpiles, Distribution, and Surges – Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution**

**How can the Strategic National Stockpile be better managed and how can Congress increase oversight and accountability?**

*ASTHO supports national coordination of public health and health system preparedness efforts and promote collaboration among federal and state health agencies and non-governmental entities. The Strategic National Stockpile (SNS) needs consistent management and sustained funding. With the move of the SNS to ASPR approximately a year and a half ago,*



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*about processes and clarity of roles, responsibilities, and division of labor between ASPR and CDC. Strengthening public health preparedness capabilities and readiness at the state, territorial and local (S/L/T) levels is a critical component of the broader national public health emergency preparedness and response framework. Dedicated staff, at all levels, are crucial in maintaining a jurisdiction's ability to meet operational requirements and performance metrics for distribution of medical supplies, equipment, and pharmaceuticals and to coordinate the planning and logistics of the SNS. Federal staff play a pertinent role in preparing state, territorial, and local (S/T/L) agencies to respond effectively during an emergency when SNS assets are deployed. This planning and preparation is accomplished through extensive training, technical assistance, guidance on receiving and effectively using products from the stockpile, and support during developing and exercising preparedness plans. To maintain consistency in planning and evaluation efforts and integration with CDC's Public Health Emergency Preparedness (PHEP) program, Medical Countermeasures (MCM) specialists or subject matter experts should remain within CDC to provide technical assistance to S/T/L health departments. Operational and administrative control of the SNS at the state, territorial, and local level should remain within public health agencies, specifically within public health preparedness or other units that manage the Public Health Emergency Preparedness (PHEP) program.*

*The medical countermeasures (MCM) program was developed through public health preparedness funding, using public health staff and resources, and built into legislatively mandated jurisdictional emergency management processes and the partnerships of public health agencies with state and local emergency management and other governmental entities is imperative for effective response.*

**How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?**

*As briefly mentioned in the previous section, states and hospitals need a reliable sustained source of funding to maintain a stockpile in their jurisdiction. The SNS is an extremely valuable, comprehensive program that will require specific considerations for continued sustainment. A sustained source of funding would account for acquisition of materiel, and also include sufficient comprehensive resources for storage, security, climate control, inventory management, and replenishment.*

**What steps should be taken to ensure that health care providers and first responders have the supplies they need, such as personal protective equipment?**

*While resources to acquire and maintain sufficient stockpiles of supplies*





*remains the most crucial step, clear understanding of the role of the various levels of governments and expectations of who can and will provide what equipment is vital. This is an opportunity for leveraging public and private partnerships and ensuring that assessments of various levels of threats and risk are communicated throughout the healthcare system.*

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**As states and hospitals establish or build their own stockpiles, how will they know what supplies to stockpile?**

*Decisions about what to stockpile should be evidence-based on current practice and informed by documented burn and replenishment rates of critical supplies and a material threat analysis of pathogens of concern and recommended protective measures. Funding for stockpile supplies should be flexible enough to ensure the greatest utility of all materiel (i.e., use of expired products for exercising, use of soon-to-expire antibiotics for other public health purposes). A broad array of threats should be considered, since, as we know, public health emergencies are not limited to infectious diseases, but also acts of terrorism, weather-related events, as well as accidental, man-made events.*

**Could states and hospital systems establish their own vendor managed inventory programs with manufacturers and distributors?**

*While some jurisdictions have and will continue to establish vendor-managed inventory programs, it does not have universal applicability. Although emergencies begin and end in local jurisdictions, responses to pandemics such as COVID-19 are national in scope and the federal government must have the willingness and capability to support jurisdictions beyond their limitations. While states willingly support each other's responses through mutual aid during local or regional responses, a national response requires a national system as states will focus on their own needs.*

**Should the federal government or states contribute to such hospital stockpiles?**

*During a severe response such as COVID-19, the most seriously ill patients will receive their care in established acute care hospitals. These hospitals will have a responsibility to care for all patients who present to their facilities, ensuring that proper materiel to provide that care is on hand, and should not be overly dependent on a state's ability fill that void. This expectation of governmental public health may become even more challenging for states with economic downturn in the aftermath of the COVID-19 response where many will experience significant revenue shortfalls. The healthcare sector should work to expand its stockpiling options at the facility, system, and coalition levels going way beyond the "just in time" paradigm.*



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**Public Health Capabilities – Improve State and Local Capacity to Respond**  
**What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?**

*The focus should not be on change but rather enhancement of the current public health infrastructure, including providing sound federal programmatic support, sustained funding, and demonstration of leadership confidence of and reliance in the state, territorial, and local partnerships.*

**What changes can be made to Public Health Emergency Preparedness and Hospital Preparedness Program to help states prepare and respond more quickly?**

*The focus of response to a pandemic should be the same as in any other emergency incident—by using long developed and thoroughly tested response plans, systems, management structures, processes, procedures, and protocols. These traditional components of response work well when used for the purposes for which they were created and should be regularly evaluated and refined. Working outside of these systems or working at cross-purposes to them impedes efficient response, creates duplication, and wastes funding that has long been awarded to develop and maintain these capabilities (e.g., state MCM response plans for acquisition, allocation, distribution, and dispensing of medical countermeasures). The Hospital Preparedness Program still needs to clarify the role of healthcare coalitions in emergency response. Coalitions have been the primary focus of the HPP for several years but were not able to clearly define their role in the COVID-19 response. It is imperative that the public health system at all levels of government have consistent, predictable, and enough funding to hire, train, and retain the experts and staff necessary to plan, drill, and execute these programs. Without resources and the talented staff to implement the programs, they are simply pieces of paper in a binder, on the shelf.*

**How can the federal government ensure all states are adequately prepared without infringing on states' rights and recognizing states have primary responsibility for response?**

*The goal of federal emergency preparedness efforts should be to help build and support a national system for both local and nationwide responses. It is necessary for each state/territory to have capabilities to conduct requisite preparedness activities (e.g., planning, exercises, drills) and develop capabilities for the same elements of an emergency response (e.g., sheltering, mass distribution of medical countermeasures, disease surveillance and laboratory analysis, risk communications, etc.). States can prioritize the types of responses for which they prepare for and the amount of resources directed to preparedness and response activities. The federal government should explore options for ongoing utilization of the Defense Production Act to enhance the production of PPE and testing supplies as*



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*soon as possible to meet future, longer term needs experienced by the states and territories. Challenges associated with our supply chain are important to acknowledge and creating alternative strategies following an “all hands on deck” approach is necessary to ensure a strong national response, which is critical in order to save American lives. There is one critical role that only the federal government can take on, and that is the declaration of a public health emergency and that through the Stafford Act. These declarations unleash flexibilities and powers for states to respond in a nimble and supported way that otherwise is not possible. Finally, one clear lesson learned from this pandemic is the importance of having clear guidance from the federal government along with a communications strategy early on in the pandemic. None of these suggestions infringe on states’ rights and will serve to advance state and territorial preparedness.*

**Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency**

**Is the Assistant Secretary for Preparedness and Response the right position to coordinate a whole-of-government response to a pandemic?**

*Previous responses to emergencies have demonstrated that although the ASPR is well positioned to lead the HHS response, the leadership of a national response requires a position more highly placed within the Administration, such as the Office of the Vice President. During the Ebola response we had a “Czar,” and now during COVID-19 we have a “Coordinator, both ad-hoc positions.” Establishing a permanent position charged with this responsibility will carry with it an ability for that person/office to train and prepare with the federal interagency and state and local partners and be at the ready to lead early on in the response, which will be advantageous.*

**What is the appropriate role for HHS and how can FEMA be better integrated into a nationwide pandemic response?**

*HHS plays a significant role as the Emergency Support Function #8 lead and principal provider of medical/clinical subject matter expertise. FEMA’s role in an emergency is as the lead agency for the strategies, tactics, and logistics of the conduct of a response. Deployment of resources, multiplier of personnel, and coordination of an organized federal response will always be among the expertise of FEMA and can be conducted harmoniously with the technical expertise of HHS such as was done through the unified command of the National Response Coordination Center.*

**What is the right balance between specific and limited statutory authority and more flexibility for federal preparedness and response programs?**

*In a pandemic response, additional flexibilities are needed for state and*



*robust response effort. Oversight is important and valuable, however in the midst of a pandemic it can hamstring health departments, create administrative burden, and take staff away from the immediate crisis.*

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**Have well-intended requirements and directives created too much bureaucracy and slowed federal response?**

*As often noted in after-action reports of previous major emergency responses, the lack of a well-thought-out and executed communications plan between the federal government and its state/local counterparts and multiple federal agency requests for similar data again surfaced as an area needing improvement.*

**How can federal departments and agencies more effectively work together to respond to public health emergencies?**

*As we prepare for the next pandemic or other major public health emergency, having clear definitions of and delineation of roles and responsibilities, lines of authority, and communications pathways of federal agencies, including the White House; playing to the strengths and fully and appropriately engaging key USG staff and operating divisions with areas of expertise in decision-making; and leveraging ongoing partnerships with the states and territories are three areas worthy of mention.*

In closing, ASTHO again thanks the Committee for the opportunity to comment on ***Preparing for the Next Pandemic*** White Paper and its consideration of our recommendations. Should you have any questions, please feel free to contact Carolyn Mullen, senior vice president for government affairs and public relations ([cmullen@astho.org](mailto:cmullen@astho.org)), or James Blumenstock, chief program officer, health security ([jblumenstock@astho.org](mailto:jblumenstock@astho.org)).

Sincerely,

Michael R. Fraser, PhD, MS, CAE, FCPP  
Chief Executive Officer, ASTHO

Attachments



ASSESSING POLICY BARRIERS  
TO  
EFFECTIVE PUBLIC HEALTH RESPONSE  
IN THE  
H1N1 INFLUENZA PANDEMIC

PROJECT REPORT  
TO THE  
CENTERS FOR DISEASE CONTROL AND PREVENTION

June 2010

Association of State and Territorial Health Officials



## Acknowledgements

ASTHO thanks the state and territorial health officials and state and territorial health agency staff for their assistance in providing data and insights for this report. State and territorial health agency personnel have given freely of their time to contribute to this and many other evaluations of the public health system's response to the 2009 H1N1 pandemic influenza outbreak.

This report was made possible through funding from the Centers for Disease Control and Prevention (CDC) Cooperative Agreement to Improve the Nation's Public Health Infrastructure with State Public Health Agencies. ASTHO would like to thank project managers Jean O'Connor, JD, DrPH, Deputy Planning and Evaluation Officer, and Amy Feuss, JD, Public Health Analyst, with the CDC Office of Public Health Preparedness and Response. The contents of this report are solely the responsibility of ASTHO and do not necessarily represent the official views of the CDC.

This project was conducted under the technical direction and oversight for ASTHO by James Blumenstock, MA, Chief, Public Health Practice, and Charlotte Hyams Porter, MPH, Senior Director, Public Health Preparedness. ASTHO staff members Anna DeBlois Buchanan, MPH, Senior Director, Immunization and Infectious Disease, and Caroline Barnhill, MPH, Director, Emerging Diseases, also contributed to the project.

The report was written for ASTHO by Patricia I. Elliott, JD MPH, President, Logan Circle Policy Group LLC | 202-683-4114 | info@Logan.CirclePolicyGroup.com | www.LoganCirclePolicyGroup.com.



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Appendix 2: State Meetings Summary Report

*ASTHO H1N1 Policy Barriers Project State Meetings: Summary and Analysis*

Appendix 3: Survey Report

*ASTHO Survey of State Health Agencies on H1N1 Response Policy and Legal Issues: Summary and Analysis*

Appendix 4: Environmental Scan Report

*Environmental Scan of H1N1 Reviews and After-Action Reports: Identifying Policy and Legal Issues*

# Executive Summary

A novel influenza virus emerged in April 2009 and by June 2009 had created such widespread concern over its potential to cause global illness and death that the World Health Organization (WHO) declared an influenza pandemic. The novel H1N1 pandemic prompted a massive and coordinated response from the U.S. public health system, which provided the first opportunity to implement state and federal pandemic influenza plans in a real-world setting. While the nation's combined response efforts were commendable, all involved also acknowledged that the policies and plans did not fully anticipate or address the specific events and circumstances which unfolded during the H1N1 outbreak.

## Project Background and Description

The Centers for Disease Control and Prevention (CDC) funded the Association of State and Territorial Health Officials (ASTHO) to conduct a special project, *Assessing Policy Barriers to Effective Public Health Response to the H1N1 Influenza Pandemic*, to systematically identify and assess key policy barriers encountered during the H1N1 response. For the purposes of the project, ASTHO defined a "policy barrier" as a plan, course of action, principle or procedure adopted by a governmental entity which impeded or impaired an agency's/jurisdiction's ability to more effectively respond to the H1N1 public health emergency. A policy barrier could be of a legal (e.g., a federal or state statute, regulation, or other legal authority) or non-legal (e.g., federal or state administrative order, agency guidance) nature, and of national, regional or intrastate scope. The goal of the project was to advance continued strengthening and overall improvement in the national public health system's collective capabilities to effectively respond to future pandemics and other emerging threats by addressing the barriers encountered during the H1N1 response.

The H1N1 Policy Barriers Project differed from typical after-action reviews (AARs), which look at both areas of success and areas for improvement, by focusing almost exclusively on policy and legal barriers. As such, the project did not actively seek out information about successful elements of the H1N1 response, which were many. This information was, however, included in the project to the extent states provided it.

There were four elements to the ASTHO H1N1 Policy Barriers Project: (1) an environmental scan; (2) a state survey; (3) state H1N1 response review meetings; and (4) the project advisory panel meeting. ASTHO specified the following eight categories for use by the states in classifying the barriers: (A) ICS, Command and Control, and Authority; (B) Surveillance, Epidemiology, and Laboratory Services; (C) Medical Care and Countermeasures; (D) National Vaccination Campaign; (E) Workforce, Capacity, and Infrastructure; (F) Federal/State/Local Coordination; (G) Communications; and (H) Other. The same list of categories was used in all project activities (scan, survey, meetings, and advisory panel) to provide a common framework in which to compile and analyze the large amounts of data gathered during the project.

- **Environmental Scan**

The environmental scan compiled and analyzed prior observations about the policy and legal issues that arose during H1N1 response efforts. Data for the scan was drawn from the numerous in-progress reviews (IPRs), AARs, and other evaluations of the H1N1 response and recent general pandemic preparedness reviews conducted in 2009 and early 2010. State AARs, which are in the process of

being developed, were *not* included in the environmental scan. Priority was given to IPRs, AARs, and other evaluations by agencies and organizations involved in preparing for and responding to the outbreak.

- **H1N1 Policy Barriers State Survey**

ASTHO deployed a survey to state and territorial health officers, senior deputies, agency-assigned public health lawyers, directors of public health preparedness, and immunization managers inquiring about policy barriers they encountered in their H1N1 response activities. Respondents were asked to identify and discuss the top five policy or legal barriers they encountered during the H1N1 response. Respondents were asked to categorize their responses into one of the above eight categories specified by ASTHO.

- **State H1N1 Response Review Meetings**

ASTHO invited five states to conduct H1N1 response review meetings to identify and discuss key policy barriers. Participating states agreed to hold the review meeting and submit a written report to ASTHO. These response review meetings were not intended to be a substitute for participating states' H1N1 AARs. All states are in the process of completing full AARs and other evaluations in the aftermath of H1N1.

- **Project Advisory Panel Meeting**

ASTHO held a meeting of the H1N1 Policy Barriers Project Advisory Panel to review data compiled from the first three elements, identify top priorities for action, and make recommendations for mitigating the priority barriers.

## **Project Report**

This report is a synthesis of the many observations, comments and professional opinions on policy barriers encountered which have been shared by contributing state and territorial public health officials; it is not being represented as a consensus of the practice community. It was prepared in the spirit of collaboration and with the expectation that it will significantly contribute to the body of knowledge on the nation's public health response to the 2009-10 H1N1 Pandemic and will help elucidate key policy barriers and considerations warranting attention in order to improve our collective state of readiness for the next pandemic or other major public health event.

ASTHO combined information about the hundreds of policy barriers identified through the survey, state response review meetings and the environmental scan, and compiled them into this report, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic: Project Report to the Centers for Disease Control and Prevention* (the "Policy Barriers Project Report"). The *Policy Barriers Project Report* includes the top policy barriers identified by the Advisory Panel, discusses other key issues that emerged from the project, and provides detailed information about all the identified barriers, mitigation strategies, and suggestion recommendations from state participants. The most frequently identified issues in each of the categories are briefly listed below.

- **ICS, Command and Control, and Authority**

H1N1 response command and incident command systems (ICS); federal and state emergency declarations; statutory and regulatory waivers, Public Readiness and Emergency Preparedness Act (PREP) Act questions and general liability concern; and school closure and other community mitigation strategies.

- **Surveillance, Epidemiology, and Laboratory Services**  
Surveillance, data collection and analysis; reporting estimated cases, deaths and hospitalizations; and laboratory services capacity.
- **Medical Care and Countermeasures**  
Medical care and countermeasures allocation, prioritization and guidance; stockpiles, inventory management and supply chains; administration and dispensing sites/practices; tracking, coverage and adverse events reporting; recovery, destruction and disposal; N95 and personal protective equipment (PPE) guidance; emergency use authorizations; and medical equipment tracking.
- **National Vaccination Campaign**  
Vaccine availability, formulation, allocation, prioritization and guidance; ordering, delivery, and distribution; administering and dispensing; tracking, coverage, recalls, and adverse events reporting; and recovery, destruction and disposal.
- **Workforce, Capacity, and Infrastructure**  
Public health workforce surge capacity; health care and medical surge capacity; volunteer surge capacity; worker protection and employment; and workforce mandates.
- **Federal/State/Local Coordination**  
Coordination within and among federal, state and local agencies; Public Health Emergency Response (PHER) grants; flexing federal funding; state systems and operations; and pandemic influenza planning.
- **Communication**  
Messaging coordination and capacity; H1N1/vaccination ad campaigns and messaging; public and media outreach; communication with health care providers and other stakeholders; and outreach to minority communities and special/vulnerable populations.

### Priority Policy Barriers for Action

The Advisory Panel identified the following policy barriers for priority action. The *Policy Barriers Project Report* contains a detailed discussion of each of the barriers and identifies a series of recommendations to address them.

1. More consistent use of a unified command structure during the H1N1 outbreak would have benefited the response at all levels of government.
2. Delays in vaccine production and changing messages about its availability caused confusion for the public and damaged the credibility of governmental public health at all levels.
3. More consistency is needed nationally regarding surveillance strategies, data collection and analysis.
4. Federal stockpiling decisions affected state and local response activities and influenced the supply chain of key medical countermeasures.
5. Delays and conflicts in federal guidance on respiratory protection (N95) led to confusion, caused shortages in supplies, and delayed the release of state and local stockpiles.



6. Public Health Emergency Response (PHER) grants provided states with the resources necessary to mount H1N1 response activities but the format and requirements for managing the grants were, to some extent, burdensome and time consuming.
7. The H1N1 response strained public health laboratory capacity at the federal and state levels.
8. Flexing the public health workforce was a challenge especially given restrictions on federally-funded positions at the state and local levels.
9. Federal, state and local health agencies need to use new and more effective strategies to reach special and vulnerable populations and minority communities.

## Other Key Issues

- **“New” and “Old” Issues**

Through discussions with the Advisory Panel and after reviewing the various project elements (survey, meetings, scan) it became evident that the national H1N1 response efforts highlighted challenges that emerged from the unique circumstances of the H1N1 outbreak (“new” issues), as well as revealed issues that seem to recur frequently in public health emergencies (“old” issues). Examples of the issues emerging during the H1N1 outbreak included the dynamics of the N95 guidance, school closure guidance, and PREP Act questions. Examples of the recurring issues included the ability to flex and surge public health workers, concerns about laboratory capacity, and liability fears by staff and volunteers. The characterization of issues as “old” or “new” is not intended to diminish the importance of an item; it is simply to demonstrate that unanticipated issues/barriers will arise with each public health emergency and that work remains to be done on other issues/barriers.

- **Relationships among Barriers**

Comments received from the Advisory Panel and the input of states throughout the project emphasized the relationships and connections among barriers. In any response, a decision made about one issue will cause both intended and unintended consequences in other areas. The *Policy Barriers Project Report* highlights the following three examples: (1) command, coordination and communication; (2) legal authorities and liability concerns; and (3) public health capacity and funding.

- **Structural Issues**

States’ responses and other sources reviewed for the H1N1 Policy Barriers Project revealed ongoing structural challenges that are affecting the nation’s capacity to respond to emergencies, as well as to engage in daily public health and health care activities. The three structural challenges identified in the report are: (1) public health workforce and infrastructure capacity; (2) health care system capacity; and (3) supply chain issues.

- **Pending Issues**

The *Policy Barriers Project Report* also highlights several outstanding public health preparedness issues that did not feature prominently during the H1N1 response, but which likely would have been more significant had the H1N1 virus been more virulent. States identified the following issues as items still needing more attention by federal, state and local governments: (1) alternative/crisis standards of care; (2) alternate care sites; (3) quarantine/isolation and travel restrictions; and (4) refining pandemic plans.

# Introduction

A novel influenza virus emerged in April 2009 and by June 2009 had created such widespread concern over its potential to cause global illness and death that the World Health Organization (WHO) declared an influenza pandemic. The novel H1N1 pandemic prompted a massive and coordinated response from the U.S. public health system. It provided the first opportunity for the public health system to implement the national response strategy and the states' pandemic influenza operational plans in a real-world setting. While the nation's combined response efforts were commendable, all involved also acknowledged that the policies and plans did not fully anticipate or address the specific events and circumstances which unfolded during the H1N1 outbreak.

The Centers for Disease Control and Prevention (CDC) funded the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officers (NACCHO) to conduct a special project, *Assessing Policy Barriers to Effective Public Health Response to the H1N1 Influenza Pandemic*, to systematically identify and assess key policy barriers—both legal and non-legal—encountered during the H1N1 response and offer a course of action to address these barriers. The goal of the project was to advance continued strengthening and overall improvement in the national public health system's collective capabilities to effectively respond to future pandemics and other emerging threats by addressing the barriers encountered during the H1N1 response.

The H1N1 Policy Barriers Project differed from typical after-action reviews (AARs), which look at both areas of success and areas for improvement, by focusing almost exclusively on policy and legal barriers. As such, the project did not actively seek out information about successful elements of the H1N1 response, which were many. However, the report captures information about H1N1 response successes to the extent that states' provided that information.

It is also important to note that the H1N1 Policy Barriers Project was not intended to be a substitute for states' and territories' H1N1 AARs nor was the timing such to capture and consider the states' and territories' AAR findings for possible inclusion in this report. All jurisdictions are in the process of completing full AARs and other evaluations in the aftermath of H1N1.

## Project Elements

There were four elements to ASTHO's H1N1 Policy Barriers Project:

- Environmental scan of in-progress reviews, after-action reviews, and other evaluations of H1N1 response activities;
- Survey of state and territorial health officials and key agency staff;
- H1N1 response review meetings conducted in five selected states; and
- H1N1 Policy Barriers Project Advisory Panel meeting to review findings from the first three elements, identify top priorities for action, and make recommendations for mitigating the priority barriers.

Using all of these elements, ASTHO created a composite picture of the barriers identified, their impacts, and states' suggestions for mitigating the barriers' effects with the goal of improving the outcomes of

future public health responses. ASTHO retained Logan Circle Policy Group LLC to assist with each phase of the project, write reports analyzing each of the project elements, and write a comprehensive final project report for ASTHO that compiled and analyzed the data and recommendations from each phase.

This report is a synthesis of the many observations, comments and professional opinions on policy barriers encountered which were shared by contributing state and territorial public health officials; it is not being represented as a consensus of the practice community. It was prepared in the spirit of collaboration and with the expectation that it will significantly contribute to the body of knowledge on the nation's public health response to the 2009-10 H1N1 Pandemic and will help elucidate key policy barriers and considerations warranting attention into order to improve our collective state of readiness for the next pandemic or other major public health event.

### **Defining “Policy Barrier”**

For the purposes of the project, ASTHO defined a “policy barrier” as a plan, course of action, principle or procedure adopted by a governmental entity which impeded or impaired an agency's/jurisdiction's ability to more effectively respond to the H1N1 public health emergency. Barriers described through this project warrant remedial consideration since they will most likely recur in a future emergency. A policy barrier can be of a legal (e.g., a federal or state statute, regulation, or other legal authority) or non-legal (e.g., federal or state administrative order, agency guidance) nature, and of national, regional or intrastate scope. While important, it was not the primary intent of this project to capture issues of concern dealing with the operational, logistical, and administrative elements of the response; such issues were considered to the extent they revealed underlying policy and legal barriers.

To assist the states and territories in identifying potential policy and legal barriers, ASTHO created a list of policy barrier categories. The list provided was neither exhaustive nor was it intended to lead or narrow participants' identification of barriers; it was intended to prompt thought and stimulate recall of important issues that arose during H1N1 response activities. (See Table 1 below for the complete categories list.)

The same list of categories was used in all project activities (scan, survey, meetings, advisory panel) to provide a common framework in which to compile and analyze the large amounts of data gathered about the public health system's response to H1N1.

**TABLE 1**

**ASTHO H1N1 Policy Barriers Project Potential Policy Barrier Categories**

**ICS, Command and Control, and Authority**

- H1N1 Response Command
- Emergency Declarations
- School Dismissal/Closure and Community Mitigation Measures
- Quarantine/Isolation/Travel Restrictions
- National Guidance/Standards
- Liability Protections
- PREP Act (General)

**Surveillance, Epidemiology, and Laboratory Services**

- Laboratory Services
- Epidemiology
- Surveillance Data Collection/Analysis
- Reporting of Estimated Cases, Deaths and Hospitalizations
- Surveillance Guidance/Policies
- Surveillance, Epidemiology, and Laboratory Services (General)

**Medical Care and Countermeasures**

- Identification/Formulation
- Manufacture
- Stockpiling and Distribution
- Commercial Supply Chain Visibility
- Countermeasure Response and Administration (CRA) System
- Delivery/Administering
- Emergency Use Authorization
- PPE/Infection Control Procedures and/or Requirements (including N95 Respiratory Protection)
- Adverse Events Reporting
- EMTALA and HIPAA
- HAVBED Reporting
- Countermeasures Injury Compensation
- Medical Care and Countermeasures Guidance/Policies
- Medical Care and Countermeasures General

**Workforce, Capacity, and Infrastructure**

- Flexing Existing Staff
- Surge Capacity (e.g., public health, health care, pharmacy)
- Volunteers
- Workforce Mandates (e.g., vaccination)
- Workforce/ Capacity/Infrastructure (General)

**National Vaccination Campaign**

- Formulation and Manufacture
- Allocation Approaches
- Stockpiling and Distribution
- Delivery/Administering
- Reporting of doses administered (vaccine and/or antivirals); Tracking for recall of pediatric second dose vaccination
- Liability Protection
- Vaccination Authority (e.g., efforts to expand the pool of vaccinators by including dentists or a broader age range for pharmacist vaccination)
- Inventory Management
- Reimbursement for Services (including CMS Medicaid and CHIP)
- Adverse Events Reporting
- Coverage Determination and Reporting
- Vaccination Guidance/Policies
- Vaccination (General)

**Federal/State/Local Coordination**

- Categorical Grant/Cooperative Agreement Flexibility
- Common Operating Picture/Platform
- Public Health and Health Care Sector Interaction
- Stakeholder Engagement
- PHER Grants
- Technical Assistance
- Stafford Act Applicability and Provisions
- Coordination (General)

**Communication**

- Media relations and ad campaign efforts
- Public outreach
- Stakeholders
- Policy Makers
- FOIA Requests and Disposition
- Communication (General)

**Other**

- Issues not arising under other thematic areas
- Unintended Consequences/Conflicts (areas in which a law/policy to address one issue had unintended consequences/conflicts in another area).

# I. Project Elements and Methodology

Section I briefly describe each element of the ASTHO H1N1 Policy Barriers Project. These elements are: (A) state agency staff survey; (B) state H1N1 response review meetings; (C) environmental scan; and (D) H1N1 Policy Barriers Project Advisory Review Panel meeting.

## I.A State Survey

ASTHO deployed a survey on April 2, 2010 to state and territorial health officers, senior deputies, agency-assigned public health lawyers, directors of public health preparedness, and immunization managers inquiring about policy barriers they encountered in their H1N1 response activities. ASTHO did not require states to consolidate all responses from a state into a single response. This allowed for quicker completion of the survey, as well as a more robust range of views. Respondents were asked for, but not required to provide, their name, agency, and state affiliation. The views represented in the survey responses are those of the individual respondents; they do not necessarily reflect the official views of the states and territories.

Respondents were asked to identify and discuss the top five (5) policy or legal barriers they encountered during the H1N1 response. Respondents were instructed that the first item listed should represent their highest priority for attention; the second should be the next highest priority, and so on, through the five barriers identified. For each of the policy barriers identified, respondents were asked to provide the following information:

- A clear and succinct description/definition of each barrier and the legal and non-legal aspects of the barrier;
- How the barrier impacted/impeded the public health response and its consequences;
- What remedies or “work-arounds” were pursued and were they effective; and
- Recommendations for corrective action(s) to remove the barrier.

The survey instrument included a pull-down menu for respondents to assign their answers to one of eight (8) categories:

- ICS, Command and Control, and Authority
- Surveillance , Epidemiology, and Laboratory Services
- Medical Care and Countermeasures
- National Vaccination Campaign
- Workforce, Capacity, and Infrastructure
- Federal/State/Local Coordination
- Communications
- Other



ASTHO received completed surveys from 58 respondents, representing 26 states and 1 territory. Eighteen (18) respondents did not identify their state affiliation. A number of states submitted multiple responses. The survey respondents identified a total of 218 policy barriers. Some respondents listed less than five barriers, while a few identified more than five barriers.

The full text of the *ASTHO Survey of State Health Agencies on H1N1 Response Policy and Legal Issues: Summary and Analysis* is contained in Appendix 3.

## **I.B. State H1N1 Review Meetings**

Five states participated in the H1N1 response reviews: Arizona, Colorado, New York, North Carolina, and Wisconsin. ASTHO invited these states to participate in the project based on their geographic distribution and range of experiences with H1N1. Participating states agreed to hold a review meeting and submit a written report to ASTHO. The states received a small stipend from ASTHO to cover meeting costs.

It is important to note that the ASTHO H1N1 Policy Barriers Project reviews were not intended to be a comprehensive after-action review in which both successes and failures are evaluated. The focus of this project was to identify policy and legal barriers encountered in the H1N1 response with the goal of removing or alleviating them in future public health emergency response activities. As such, participating states were not required to include information about successful elements of the H1N1 response, which were many. To the extent that states' provided information about H1N1 response successes, however, this information was included. Finally, the states' reports for the ASTHO H1N1 Policy Barriers Project should not be considered to be the states' H1N1 after-action reports required under other federal grants/cooperative agreements. The states will be releasing these separately at a later date.

ASTHO provided the states with the following guidance regarding the content and format of their meetings. The guidance was provided to assure sufficient structure to yield a desired level of consistency and uniformity among the participating states, while allowing the states latitude in designing an approach and methodology to meet their individual needs and circumstances.

*Planning and Scheduling Guidance:* Several key elements were to be considered:

- Reviews were to be conducted by April 30, 2010.
- Reviews were to be a day-long event or a reasonable portion thereof, in order to fully discuss and deliberate the issues.
- An in-person event was preferred to the extent practicable, but ASTHO recognized that might not have been feasible. As such, teleconferences, videoconferences, and/or webinars were suitable alternatives.
- Reviews could be a free-standing event or part of larger previously planned H1N1 after-action reviews.
- Invited participants were to be of sufficient position to have a working knowledge of and exposure to the policies that were operational during the H1N1 response.
- Invited participants were to represent a broad range of stakeholder interests including local public health and tribal entities; cross-sector agencies such as education, law enforcement, and emergency management; political leadership at a state and local level; health care providers; community and faith-based organizations; and the general public.

*Documenting Policy Barriers:* Participating states were provided with the list of categories (as seen in Table 1 above) to facilitate the reviews and assist in documenting their findings. ASTHO requested that, for each policy barrier identified, states collect the following information:

- A clear and succinct description/definition of each barrier and the legal and non-legal aspects of the barrier;
- How the barrier impacted/impeded the public health response and its consequences;
- What remedies or “work-arounds” were pursued and an assessment of their effectiveness; and
- Recommendations for corrective action(s) to remove the barrier.

ASTHO did not expect the states to generate comprehensive lists of every federal and state, legal and non-legal barrier they encountered. ASTHO sought the states’ perspectives on what they identified as the three most significant barriers encountered warranting immediate action in each of the following categories:

- ICS, Command and Control, and Authority
- Surveillance , Epidemiology, and Laboratory Services
- Medical Care and Countermeasures
- National Vaccination Campaign
- Workforce, Capacity, and Infrastructure
- Federal/State/Local Coordination
- Communications
- Other

While not a requirement of their project with ASTHO, each participating state was encouraged to also create a more detailed written record of the H1N1 barriers review proceedings for the state’s future reference.

Each of the five states provided ASTHO with a written report of the issues/barriers identified in their respective meetings. The participating states identified a total of 110 issues/barriers. The data from these reports has been compiled and analyzed into a summary report, *ASTHO H1N1 Policy Barriers Project State Meetings: Summary and Analysis*, which is included in Appendix 2 of this document.

## **I.C Environmental Scan**

The environmental scan component of the ASTHO H1N1 Policy Barriers Project was designed to identify, compile and analyze previous observations made about the policy and legal issues that arose during the public health system’s H1N1 response efforts. Data for the scan was drawn from the numerous prior in-progress reviews (IPRs), after-action reviews (AARs), and other evaluations of H1N1 response and recent general pandemic preparedness reviews conducted in 2009 and early 2010. State AARs, which are in the process of being developed, were *not* included in the environmental scan. Documents available as of May 1, 2010, were considered in this scan.

The scan reviewed approximately 30 published or distributed sources identified by ASTHO, which included IPRs, AAR, other H1N1 evaluations, reports and articles, and recent pandemic preparedness

assessments. The environmental scan was not intended to be a comprehensive review or a literature review of all materials evaluating H1N1 response efforts. Priority was given to IPRs, AARs, and other evaluations by agencies and organizations involved in preparing for and responding to the outbreak. As such, the scan focused primarily on federal, state and local governmental, non-governmental organization, and academic center resources. Elements from these sources were organized according to the list of categories identified previously in Table 1.

Data from the scan was combined with the survey and state H1N1 response review meeting findings to develop the consolidated group of barriers discussed in Section III, “Compilation of Barriers Identified” of this report.

The full text of the *Environmental Scan of H1N1 Reviews and After-Action Reports: Identifying Policy and Legal Issues* report is contained in Appendix 4.

## **I.D Advisory Review Panel Meeting**

The final element of the ASTHO H1N1 barriers project was to convene an advisory panel of selected state and territorial health agency staff to discuss the barriers identified in the project, designate priority barriers for action, and make recommendations for addressing the priority barriers.

The advisory review panel met in ASTHO’s offices on May 25, 2010. The approximately 25 participants included representatives from nine state health agencies (including the five states that held H1N1 response review meetings) and CDC, as well as staff from ASTHO, NACCHO, and ASTHO’s consultant, Logan Circle Policy Group. The meeting agenda and attendees list are contained in Appendix 1.

The priorities and recommendations generated from the H1N1 Policy Barriers Advisory Review Panel meeting are contained in Section II, “Overview of Barriers and Priorities for Action” of this report.

## II. Overview of Barriers and Priorities for Action

Section II section provides a brief overview of the major policy barriers identified through the ASTHO H1N1 Policy Barriers Project. More importantly, this section identifies the priority policy barriers that the project's Advisory Review Panel determined should be addressed immediately to enhance the public health systems' response for future events.

### II.A Overview of Policy Barriers

ASTHO received input from state and territorial health agencies about hundreds of H1N1 policy barriers through the various mechanisms of the H1N1 Policy Barriers Project. The identified barriers, mitigation strategies and suggested recommendations are compiled in detail in Section III "Compilation of Policy Barriers." Section II.A highlights the major policy barriers identified in the each of the following seven categories, which categories were used throughout the project: (A) ICS, Command and Control, and Authority; (B) Surveillance, Epidemiology, and Laboratory Services; (C) Medical Care and Countermeasures; (D) National Vaccination Campaign; (E) Workforce, Capacity, and Infrastructure; (F) Federal/State/Local Coordination; and (G) Communications. The items in this section are *not* presented in any priority order.

#### ICS, Command and Control, and Authority

States found that more consistent use of a unified command structure during the H1N1 outbreak would have benefited the response at all levels of government. Inconsistent use of a formal incident command system (ICS) by some states was tied to the absence of state emergency declarations in some instances. Participants in the Policy Barriers Project noted that federal and state officials need to provide more information to the public and stakeholders about the processes and implications of various emergency declarations (e.g., Stafford Act, Public Readiness and Emergency Preparedness Act, state emergency laws).

Federal and state emergency declarations trigger a range of emergency response powers, liability protections, as well as waive various statutory and regulatory requirements. States identified several issues related to emergency powers and waivers. Specifically, federal and state legal counsel need to understand the scope of statutory and regulatory waivers allowed under current federal and state emergency declarations and evaluate other areas in which waivers could be used to enhance future response efforts. Additional guidance and outreach is also needed about the application and implications of the Public Readiness and Emergency Preparedness (PREP) Act. Finally, states noted ongoing concerns held by public and private sector participants and volunteers about their potential legal liabilities during the H1N1 response.

States also frequently identified barriers related to school closure and other community mitigation measures. Changes in school closure guidance and triggers for implementing closure caused confusion, were at odds with how communities were experiencing the outbreak, and created gaps in services to children. Other community mitigation strategies to control the spread of H1N1 needed greater attention during the response.

## **Surveillance, Epidemiology, and Laboratory Services**

States frequently identified the need for more consistency nationally regarding surveillance strategies, data collection and analysis. States also noted that inconsistent case reporting methods nationally led to differing case counts, conflicting messaging, and challenges dealing with the media and public about reported cases. States found it challenging to balance the need to provide case information while preserving individuals' privacy, especially when discussing the outbreak at the local level.

States uniformly identified strained public health laboratory capacities at the federal and state levels as a significant issue during H1N1. Timing limitations imposed on state laboratory-related expenditures in the Public Health Emergency Response (PHER) grant further hindered laboratory capacity during the H1N1 response. State and federal public health laboratories need sustained federal funding.

## **Medical Care and Countermeasures**

States identified a range of policy barriers related to medical care and countermeasures. Overall, states found that gaps in information and federal and state approval processes for guidance on medical care and countermeasures impacted the timely distribution and utility of these guidances during the H1N1 response.

States had difficulty assessing the status and location of supplies of medical countermeasures because of limits on the states' ability to access information about private supply chains. Regarding the federal Strategic National Stockpile (SNS), states found that the lack of closer federal-state consultations about the types of SNS assets distributed to states hindered the effectiveness of those assets during the response. States also identified ongoing questions about the ownership status of surplus medical countermeasures distributed from the SNS, which left states unable to deploy and use these materials quickly. Delays and conflicts in federal guidance on respiratory protection (N95s) led to confusion, caused shortages in supplies, and delayed their release of state and local stockpiles.

States expressed several concerns about administering countermeasures, including uncertainties about dispensing countermeasures to federal employee populations, fees for dispensing countermeasures, and the use of federal stockpile antivirals for prophylaxis. States also noted that data elements and systems necessary to assess the use and potential adverse effects of federal countermeasures stockpiles must be better defined, especially for determining if countermeasures are being equitably distributed to vulnerable populations. States expressed concerns over confusion and impending costs for recovering and disposing of expired and surplus countermeasures.

Regarding emergency use authorizations (EUAs), states encountered health care providers who were uncertain about the safety and legality of using EUA products and were therefore resistant to offer them to patients. States also expressed concerns that information supplied to patients with EUA products may not ensure that informed consent is obtained.

Finally, states noted that alterations in the process, scope and frequency of reporting for the National Hospital Available Beds for Emergencies and Disasters (HA<sub>v</sub>BED) by the U.S. Department of Health and Human Services (HHS) caused frustration and confusion among states, hospitals and vendors. HHS's request for direct reports from hospitals disregarded established reporting systems going from hospitals through the states to HHS.



## **National Vaccination Campaign**

States acknowledged the tremendous efforts of the federal government to develop the H1N1 vaccine in a short time, especially given the nation's current vaccine production technology. Because the H1N1 vaccine figured so prominently in the response, states identified a number of significant issues arising from the national vaccination campaign. States uniformly concluded that delays in vaccine production and changing messages about its availability caused confusion for the public and damaged the credibility of governmental public health at all levels. Initial vaccine delays resulted in the postponement of vaccination clinics and the inability to capitalize on public demand for the vaccine. States also acknowledged that differing strategies used by states and localities for vaccinating priority groups and the general public caused some confusion.

Regarding vaccine ordering and distribution, states observed that vaccine ordering systems were too complex and did not provide useful ways to manage ordering and delivery information. Requirements for ordering vaccines in 100 dose-count minimums necessitated that states engage in additional distribution activities and further delayed delivery of vaccines to providers and localities. Some states indicated that requiring centralized state distribution systems for H1N1 vaccines ran counter to some states' existing immunization systems causing confusion and delay with providers and localities.

School-based vaccination clinics, though an effective strategy to reach target populations, were limited by decentralized legal/policy authorities among education and health officials at the local level. States reported employing various strategies to expand the pool of eligible vaccinators, but state statutory limitations and a generalized fear of liability persisted among potential vaccinators. States also found that payment and reimbursement issues and systems for H1N1 vaccine administrations costs were slow to be addressed and must be improved.

States encountered problems tracking H1N1 vaccines administered if the state did not require mandatory reporting of vaccinations through state immunization registries. States also reported ongoing questions and limitations on receiving reports of vaccinations administered in school-based clinics. Overall, states concluded that better systems are needed for tracking vaccine uptake, coverage, recall and adverse events. Finally, states expressed confusion and concerns over the impending costs of recovering and disposing of expired H1N1 vaccine.

## **Workforce, Capacity, and Infrastructure**

Flexing the public health workforce was a challenge, especially as repeated rounds of budget cuts and hiring freezes have shrunk standing capacity in state health agencies. States acknowledged that PHER grants were vital in allowing states to enhance their public health surge capacity. States observed that surge capacity in the health care sector remains limited and could be quickly overwhelmed during a prolonged pandemic event. While volunteers provided important surge capacity during the H1N1 response, they were not appropriate for all public health positions in a response. States also encountered issues dealing with volunteers' continuing fears about their potential legal liabilities for participating in H1N1 response activities.

States noted several issues pertaining to employer policies and work place protections. States observed that public health recommendations were not universally supported by employers' sick/administrative leave policies. Workers, who feared losing their wages or jobs, may not have complied with public health recommendations to stay home when sick. States also encountered ongoing questions and concerns about mandating vaccination for health care and other workers.

## Federal/State/Local Coordination

States found that coordination between and among federal, state, and local governmental entities was, at times, inconsistent over the course of the H1N1 response. Some linked poor coordination with the lack of a clear unified command structure through which to work on a combined federal, state and local response.

PHER grants provided states with the resources necessary to mount H1N1 response activities, but requirements for managing the grants were cumbersome and time-consuming. Federal grant and cooperative agreement requirements generally did not allow the states' enough flexibility to surge personnel and resources in mounting H1N1 response activities. Some state governmental policies and procedures, as well as the internal operations of state agencies, tended to delay the rapid deployment of funds and personnel designated for pandemic response activities.

States frequently noted that as the less virulent nature of H1N1 became apparent, response plans based on worst-case scenarios were not appropriate for this outbreak. Prior pandemic influenza planning has been geared toward a worst-case scenario but must become more flexible and scalable to allow for pandemics of less virulent influenza viruses.

## Communication

States noted that federal, state and local governments need to achieve and maintain more consistent communications practices and messaging during emergency responses. Inconsistent and slow federal messaging and ad campaigns complicated state and local efforts to communicate about H1N1 response activities. Delayed federal decision-making and inconsistent messaging about the severity of the H1N1 outbreak created significant public and media outreach demands on the states.

States also observed that federal, state and local agencies did not consistently and efficiently communicate with stakeholders, especially health care providers. Governments at all levels needed to develop and use more effective strategies to reach minority communities and special and vulnerable populations during the H1N1 outbreak.

## II.B Policy Barriers Requiring Priority Action

This section lists in order the priority barriers identified for action by the ASTHO H1N1 Policy Barriers Project Advisory Review Panel. For each of the following nine priority items, the policy barrier is identified and discussed and recommendations for addressing the barrier are suggested.

### **1. More consistent use of a unified command structure during the H1N1 outbreak would have benefited the response at all levels of government.**

Federal, state and local governments did not consistently operate under a unified command structure or an incident command system (ICS) during the H1N1 outbreak. The lack of coordinated command structures led to problems with communication and coordination, and ultimately hindered the collective governmental response to H1N1. All levels of government need to adopt and consistently use common operating protocols and terminology across all levels of government during an emergency response.

At the federal level, it was unclear during the H1N1 response if federal agencies were operating under a unified command structure. This gave rise to a perception among states of fragmented federal decision making, inconsistent messaging, and the issuing of conflicting guidance. States also received input and

requests from multiple federal agencies, which caused confusion for state and local governments and required duplication of efforts to satisfy inquiries and manage the confused public.

States' use of unified command structures or ICS varied as well. States identified whether or not a state emergency was declared as a factor contributing to the inconsistent use of command structures. States encountered difficulties with staffing ICS roles due to the prolonged H1N1 response and lack of staffing depth in key positions.

At the local level, the states saw that local governments use' of a unified command during the H1N1 response was mixed. Advisory Panel participants remarked that some local governments used unified command more consistently than did some of their state counterparts; localities in these states were concerned with the apparent lack of an ICS/unified command at the state level.

## Recommendations

### Overall

- A careful review should be conducted to evaluate how implementing a clear UCS/ICS structure could have improved the H1N1 response at all levels.
- Reinforce the importance that all levels of government routinely train and exercise UCS/ICS plans as per the National Incident Management System (NIMS).
- Federal, state and local governments should explore options for alternative unified command structures (UCS)/ICS to be implemented during prolonged emergencies such as a pandemic. This may be especially necessary for state and local governments in which lack of staffing depth may hinder full implementation of UCS/ICS plans.
- The states and the federal government should explore using vehicles such as grants and cooperative agreements as mechanisms to reinforce the expected use of UCS/ICS during a response.
- Federal programmatic funding should cover the time that state and local personnel who are supported by federal grants are deployed to the UCS/ICS and response activities during a declared national emergency.

### Policy Barriers Requiring Priority Action

1. More consistent use of a unified command structure during the H1N1 outbreak would have benefited the response at all levels of government.
2. Delays in vaccine production and changing messages about its availability caused confusion for the public and damaged the credibility of governmental public health at all levels.
3. More consistency is needed nationally regarding surveillance strategies, data collection and analysis.
4. Federal stockpiling decisions affected state and local response activities and influenced the supply chain of key medical countermeasures.
5. Delays and conflicts in federal guidance on respiratory protection (N95) led to confusion, caused shortages in supplies, and delayed the release of state and local stockpiles.
6. Public Health Emergency Response (PHER) grants provided states with the resources necessary to mount H1N1 response activities but the format and requirements for managing the grants were time consuming and somewhat cumbersome.
7. The H1N1 response strained public health laboratory capacity at the federal and state levels.
8. Flexing the public health workforce was a challenge especially given restrictions on federally-funded positions at the state and local levels.
9. Federal, state and local health agencies need to use new and more effective strategies to reach special and

### *Federal*

- Define clear roles for each federal agency involved in the response, clearly communicate these roles to all federal, state, and local government partners, and respect these roles during an event.
- Coordinate planning and messaging from the federal government to different populations served by different federal, state and local agencies.
- Build a transparent, coordinated process for identifying information that federal agencies want states and localities to monitor and coordinate to avoid confusing, conflicting messages from multiple federal agencies.
- Ensure that there are robust procedures for informing and preparing new federal staff at all levels on current emergency response plans, available critical resources, and protocols for working with state and local governments during an emergency.

### *State and Local*

- State and local governments must consistently train health agency staff on the use of UCS/ICS and regularly practice use of these response structures through exercises.
- States and localities should develop policies that allow for activation of a joint incident command early in an event even if other parts of the state's emergency management response are not activated.
- If UCS/ICS is used, all levels of the state health agency should comply with the response structure and process requests through specified channels.
- There must be laboratory and epidemiology staff within the response structure to provide insights into attack rates and monitor laboratory testing capacity and results. This is especially true when there is an outbreak of a novel virus, as in the case of the H1N1 outbreak.

## **2. Delays in vaccine production and changing messages about its availability caused confusion for the public and damaged the credibility of governmental public health at all levels.**

States recognized that the federal government did an admirable job in quickly isolating the H1N1 virus, developing and testing vaccine, and getting it into large-scale production. States also understood that the federal government was limited in its ability to affect vaccine production capabilities, especially given the nation's current vaccine production technology. For better or worse, vaccine issues became the definitive aspect of the H1N1 response. States concluded that dealing with slow and variable vaccine delivery from manufacturers and the shifting messages about vaccine availability overshadowed all of their other response activities, which were many.

Advisory Panel participants identified public messaging about the vaccine as highlighting the central challenge for governments at all levels during the H1N1 response—balancing the desire to rapidly provide information to the public with the need to ensure the information is accurate. Federal efforts to demonstrate a quick public health response to H1N1 resulted in accelerating the estimated arrival date for vaccine, which raised the public's expectations about its availability. When the vaccine production did not meet the announced availability date, this was seen as a delay by the public. Small and uneven initial delivery of vaccine further exacerbated perceptions of delay and governmental mismanagement.

Initial vaccine delays resulted in the postponement or cancellation of state and local H1N1 vaccination clinics. More significantly, vaccine delays caused governments to fail in capitalizing on the public's interest in vaccination when demand was at its highest. States perceived that the overall handling of

vaccine issues hurt the credibility of governmental public health with providers and the public. Advisory Panel participants also concluded that federal vaccine messaging difficulties related back to the lack of clear a UCS/ICS at federal level.

### **Recommendations**

- One federal entity should be in charge of communicating vaccine supply information.
- The federal government should be cautious in making projections rather than causing unrealistic expectations from optimistic estimates.
- The federal government should postpone public communications about vaccine availability until sufficient supplies are available to engage in meaningful vaccination activity. Vaccine distribution on the mid-October target would have eliminated many of the problems experienced with the October 1 release announcement.
- Federal, state and local agencies need to improve their ability to plan, organize, and communicate when production and delivery of the essential piece of the response strategy (i.e., sufficient vaccine) is outside of governmental control.
- The federal government should have a greater role in monitoring the development and production of vaccine, especially when manufacturers are creating vaccine to combat a novel virus like H1N1.
- The U.S. needs to approve vaccine manufacturing technology improvements to more quickly produce vaccines. Until technology fixes are addressed, federal agencies need to improve their communication strategies and present realistic representations of vaccine availability to the public.
- Sufficient supplies of vaccine should be ready for distribution when a national vaccination campaign effort is launched.
- Vaccination should not be the only focus of pandemic response activities. It is equally important to stress personal infection control measures (e.g., hand washing) and community mitigation measures, too.
- Anti-vaccination messages should be expected and messages countering anti-vaccination sentiments should be proactively developed and deployed.

### **3. More consistency is needed nationally regarding surveillance strategies, data collection and analysis.**

Advisory Panel participants uniformly affirmed that surveillance data is the foundation of the public health system and upon which public health emergency response decision-making is based. States commented on disparities in the types and amounts of data collected at different levels of government and among jurisdictions. These disparities made it more difficult to make good decisions during the H1N1 response and to give meaningful reports of the outbreak's spread and patterns.

### **Recommendations**

- Federal, state and local governments should conduct a joint evaluation of epidemiologic and surveillance systems used during the H1N1 response to determine what worked well and what should be improved. As part of this process, it should be determined what data elements were necessary and eliminate that were not useful in order to streamline data acquisition and analysis during a public health emergency.

- Priorities for surveillance during a public health emergency need to be clarified. Top priorities for surveillance should be determining the severity of illness and identifying risk factors for infection because these data drive decision-making during a response.
- Develop national standards for the use and reporting of data from syndromic surveillance systems.
- Federal, state, and local governments and stakeholders should move toward greater nationwide consistency in the reporting of data.

#### **4. Federal stockpiling decisions affected state and local response activities and influenced the supply chain of key medical countermeasures.**

Advisory Panel participants acknowledged that federal, state and local governments may have different views on the purposes and strategies for using Strategic National Stockpile (SNS) assets. Some states revealed challenges in trying to forward deploy SNS assets in preparation for H1N1 rather than waiting until the state was in a response posture. States voiced concerns that state and local needs and plans for using the stockpile did not align with perceived federal ideas about managing SNS inventory.

Other states observed that there was a perception among some stakeholders during the H1N1 response that the federal government purchased mass quantities of medical supplies for the SNS, which caused a supply shortage leading to prolonged delays for health care facilities to obtain their standard supply of medical care items (i.e., sanitizer, surgical masks, N95 masks, bandages, syringes, etc.). States agreed that they need better information during emergencies about the status of medical countermeasures in private supply chains serving their jurisdictions in order to make decisions about the need for and targeting of SNS assets.

#### **Recommendations**

- Federal, state and local governments should evaluate the ways in which SNS assets were used during the H1N1 outbreak, as well as the ways in which states wanted to use SNS assets but were unable to do so because of policies or other response conditions.
- Policies and procedures for states' in requesting SNS assets should be evaluated and revised. The federal government needs to: (1) clearly define the data it needs from states when they request additional materials from the stockpile; (2) identify the timeline for receipt of order and response to the state; (3) maintain better communications with the states during the process to avoid duplication and to reduce the time between request and response; and, (4) make tools (such as a dashboard) available to SNS coordinators for managing stockpile assets.
- Establish a federal-level system for monitoring stock levels and locations of key medical countermeasures (e.g., antivirals, antibiotics, masks, etc.) in private supply chains during a declared national emergency. This information should be available to state and/or local health officials on at least regional level so public health leaders can be advised of supply chain capacity and make more informed decisions about deploying state/federal stockpiles.
- To the extent possible, the federal government should purchase material for the SNS in advance of an emergency. Large scale federal purchases in the midst of a public health emergency can severely limit the national supply chain for all purchasers. Private sector just-in-time manufacturing practices can further exacerbate shortages of medical countermeasures during national public health emergencies.

## **5. Delays and conflicts in federal guidance on respiratory protection (N95) led to confusion, caused shortages in supplies, and delayed the release of state and local stockpiles.**

There were conflicting opinions as to the level of personal protective equipment (PPE) required for health care workers (i.e., N95 respirators or surgical mask) during the H1N1 response. States cited a range of potential guidances from the CDC, the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), the Institute of Medicine (IOM), state health and occupational agencies, and even some from local health agencies. Some states issued their own guidance addressing the N95 respirator issue while other states followed CDC guidance or were not comfortable issuing their own recommendations.

The range of guidances and their accompanying conflicts and inconsistencies left health care and other affected organizations wondering which one(s) to follow. States observed that conflicts among CDC, OSHA and state health and occupational directives/guidances on N95 respirators raised particular concerns among health care facilities about potential enforcement and other liabilities.

The requirement to use N95 respirators for H1N1 resulted in supply shortages and required extra time and resources by health care facilities, especially those using N95s supplied from the SNS. States experienced significant challenges with the N95 supply chain throughout the pandemic response. State and local health agencies did not know what brands of N95 were in the stockpile and what mix of sizes and brands would be delivered to them for use by facilities in their jurisdictions. Often the N95s from the SNS did not match the brands regularly used by the receiving health care facilities, thereby necessitating additional fit testing activities by recipients.

### **Recommendations**

#### *Overall*

- Federal agencies should coordinate in advance of an event to create timely decision-making protocols and identify realistic rules that will be instituted in an emergency situation, whether it is a mild communicable disease or something more severe.
- Federal, state and local governments need to clarify respiratory protection policies early. Governments should proactively consult with various stakeholders using PPE regarding policies on use and supply issues.
- Once respiratory protection policies have been agreed on, governments should work with suppliers to ensure that necessary supplies of PPE are available to implement the guidance.

#### *Scientific Evidence for N95 Guidance*

- The federal government should re-examine the need for and most appropriate use of N95 respirators for H1N1 cases.
- Infection control measures and recommendations about H1N1 from organizations such as the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Association for Professionals in Infection Control and Epidemiology (APIC) should be carefully considered. Once it was discovered that the H1N1 virus was transmitted similarly to seasonal influenza, infection control recommendations should have been adjusted to match those of seasonal influenza.
- HHS and CDC should implement a more streamlined process to evaluate and respond to these types of technical issues during an outbreak event.

- Federal guidelines should be adjusted as new information and evidence becomes available.

#### *N95 Implementation Issues*

- Assuming that the scientific evidence continues to show that surgical masks are effective against transmission of influenza, new guidance should recommend their use, given that N95s are significantly more expensive.
- CDC should issue policies, such as the N95 respirator guidance, earlier and take into account not only the available science, but also realistically consider the full range of practical/management implications involved in the process of providing health care for large numbers of individuals.
- CDC should create a list of activities for which N95 respirators should be reserved, define criteria for states to use in determining and declaring a N95 shortage, and develop aids to assist in planning and estimating N95 respirators needed considering different priorities and situations.

#### *N95/PPE Supply Issues*

- State and local public health officials need better and timelier information about the supply chain for N95s/PPE.
- CDC and the states need to define what is meant by a “shortage” of N95/PPE and its use as a trigger for releasing stockpiles and implementing protocols to deal with shortage conditions.
- Federal and state governments need to cooperate in proactively identifying the types of N95 and other PPE used by health care facilities. The CDC should survey the states to determine N95/PPE brands preferred by health care facilities in the states and stock these brands in federal stockpiles. Alternatively, the federal government should stock the SNS with various brands and sizes of N95/PPE so that correct supplies can be shipped to health care facilities and minimize the need for them to re-fit test employees to the SNS assets.
- The federal government should consider purchasing FDA-approved respirators for the stockpile without an expiration date so they would not need to be released under an emergency use authorization.
- There should be a central repository of N95s which is replenished for future events. Federal contracts with N95 and PPE manufacturers generally should be strengthened to prepare for supply chain disruptions during future public health emergencies.

#### *Federal Guidance and Enforcement Questions*

- Definitive guidance from OSHA is necessary to resolve the current N95 issue and to address PPE issues that will arise in future public health emergencies.
- The CDC’s National Center for Immunization and Respiratory Diseases (NCIRD) should work with NIOSH and OSHA to clarify and resolve how CDC recommendations interact with OSHA safety requirements. OSHA should clarify how it will handle hospitals and other institutions that follow their states’ worker protection recommendations if those recommendations conflict with CDC recommendations.
- States and health care facilities need a definitive understanding from the federal government about the status of CDC guidance as either non-compulsory (i.e., recommended action) or mandatory (i.e., required action) during an event, particularly when the agency’s guidance conflicts with other federal agencies’ guidances, policies or regulations.



- All federal agencies involved with determining PPE should coordinate and agree about guidances issued. It is especially necessary to include agencies with regulatory and/or enforcement authority (e.g., OSHA, EPA).

**6. Public Health Emergency Response (PHER) grants provided states with the resources necessary to mount H1N1 response activities but the format and requirements for managing the grants were time consuming and somewhat cumbersome.**

States readily acknowledged that the Public Health Emergency Response (PHER) grants provided states with the resources necessary to quickly mount H1N1 response activities, especially given the ongoing budgetary constraints of states and territories across the nation. States further agreed that prior federal investments in state and local public health and pandemic influenza preparedness established a vital foundation for a national response and identified pandemic planning as a national priority.

With the H1N1 response, states found that CDC's the cooperative agreement format used to deliver the PHER funds was challenging to manage while simultaneously responding to H1N1 outbreak. States found the need to submit multiple applications for the various phases of the grant and await CDC approvals to be time consuming and a hindrance to the states' ability to respond appropriately to the event. The delivery of PHER monies in phases—with changing limitations on the use of funds in different phases—made it difficult for states to plan and manage their response activities. States observed that the PHER grants also highlighted the limitations of some states' procurement and personnel systems/policies in their inability quickly utilize the funds. Advisory Panel participants agreed that states were able to successfully manage PHER application processes and direct multiple grant streams all while responding to H1N1 only because of their prior experiences handling Public Health Emergency Preparedness (PHEP) and Hospital Preparedness Program (HPP) grants and related cooperative agreements.

States voiced significant ongoing concerns about the possibility that carryover will not be permitted for the PHER grants, thereby requiring states to use the funds by July 31, 2010. Health departments are still in the process of responding to H1N1. Recovery efforts and improvement plans will be taking place long after July 31, 2010. States believe this potential limitation on the use of PHER funds makes it very difficult to be good stewards of public funds should states need to expend the remaining funds before July 31, 2010.

**Recommendations**

- PHER funds should be eligible for carryover the way PHEP funds are.
- The application process needs to be simplified in the future. Funds should be awarded in one phase with more flexibility on their allowable uses in order to permit states' to use funds to cover their unique response efforts. Awarding the funds in one phase would also streamline the purchasing and contracting processes at both the state and local levels.
- Even if grant funds will be delivered in phases, the federal government should identify the total amount of funding to be provided to a state over the life of the grant. This will allow states to better plan for using the funds.
- Identify more appropriate mechanisms for funding future response activities. The cooperative agreement process is better designed for funding long-term enhancement activities, not emergency response operations.

- CDC should work with states to formulate templates for "emergency" funding applications that still have elements of accountability, but do not take weeks to complete and can be quickly approved by CDC and its Procurement and Grants Office (PGO).
- If application processes are required, reconsider using similar processes to those CDC used during the post 9/11 PHEP supplemental awards and pandemic influenza supplement in 2006. Specifically, use the methodology of releasing 20 percent of the funds, with authorization for use of the additional 80 percent based on a comprehensive application submission.

## **7. The H1N1 response strained public health laboratory capacity at the federal and state levels.**

Public health laboratory testing capacity was a concern at the state and federal levels during the H1N1 response. For some states, laboratories were unable to keep pace with processing specimens which had a negative impact on surveillance activities, slowed states' ability to correctly identify and describe the extent of the disease, and limited states' support to local health departments. States also voiced concern over the capacity of the CDC laboratories to keep pace with the demands placed on it by H1N1.

State procurement and contracting processes conflicted with the timeframes established by federal cooperative agreements, thereby delaying the purchasing of laboratory equipment and supplies, and hiring of laboratory and epidemiology personnel. PHER funds could not be expended for laboratory expenses after Phase 1 of the grant. States reported that most of the Phase 1 laboratory funds went to cover spring 2009 costs; thereafter, states were unable to hire needed laboratory staff and were limited as to the types and amounts of supplies they could buy with other phases of the PHER funds.

States also emphasized the need for sustained investments in laboratory capacity. Public health laboratories are a crucial component of the nation's public health surveillance system that needs ongoing federal support.

### **Recommendations**

#### *Addressing Stressed Capacity*

- To alleviate extreme demands placed on the CDC laboratory during a national public health emergency, explore pre-staging laboratory activities in more than one laboratory in the country.
- Develop better clinical guidelines and clinician education about which patients should be tested to reduce the burden on laboratories and target testing to public health needs.
- Consider making CDC laboratory test kits available to at least a subset of trusted private partners to increase laboratory surge capacity and overall sentinel surveillance capacity.
- Improve communication and cooperation with private laboratories. Both public and private laboratories are critical to a comprehensive understanding of the outbreak and a successful response.

#### *Sustaining Capacity*

- Provide more flexible funding guidelines to maximize and plan for workforce capacity issues as needed. Funding restrictions were a barrier to H1N1 response state public health laboratories. Although vaccination was a primary role for every state, laboratory testing and surveillance were critical to ongoing monitoring of H1N1 and funds should have been made readily available for these purposes.

- Secure sufficient and sustained federal funding to improve public health laboratory capacity to ensure more timely results and the ability to maintain a high level of testing as needed.
- More research is needed to produce national standards (e.g., case definition, which other elements should be reported) for syndromic surveillance. Funding is needed for states to implement those standards with laboratory capability.
- The federal government should fund and expand electronic reporting capabilities nationally.

## **8. Flexing the public health workforce was a challenge especially given restrictions on federally-funded positions at the state and local levels.**

States acknowledged that PHER funds helped tremendously in supplementing the states' staffing needs as the overall state public health force was already greatly reduced at the beginning of the H1N1 outbreak. Even with PHER funds, however, states noted that because of the states' fiscal crises, there was reluctance on the part of state personnel agencies to hire staff, even for a limited term. States responded by using temporary employees, but they required intensive training by staff already taxed with response activities.

Some states observed that they did not have sufficient staff capacity to sustain activation of emergency operations centers (EOCs) for long periods of time. States had to pull staff from other public health agency programs beyond preparedness and immunization programs to staff the EOC. As a result, many other public health programs had to put their regular activities and responsibilities on hold or on reduced staffing levels.

States faced continuing challenges in flexing and surging capacity using staff that is funded under other federal grants/cooperative agreements in areas not immediately involved with the H1N1 response. While there was limited ability to flex federal funding, Advisory Panel participants observed that states faced obstacles in trying to adequately staff H1N1 response activities while maintaining activities on other federally funded projects and meeting state-matching requirements on those grants. States also recognized that the lack of sustained funding to support the overall public health infrastructure would have severely limited the nation's capacity to respond to H1N1 absent supplemental federal funding.

### **Recommendations**

- The federal funding process should allow federal agencies to advance a portion of emergency grant funds to state and local governments so they can initiate response activities immediately. Having to await the full application and review process delayed initial response activities.
- HHS and CDC should allow for staff in positions that are funded by any HHS or CDC program to assist in a public health emergency response as long as they are needed or while there is a federal emergency declaration in place.
- Federal grants and cooperative agreement requirements and processes need to be more flexible during public health emergencies.
- State health agencies should identify and routinely train and exercise more staff for various EOC/ICS positions. These staff should be provided with ongoing opportunities to remain engaged in state public health preparedness activities. This will improve states' preparedness to respond to public health emergencies, but will require funding beyond what can be accomplished using current federal base preparedness funding.

- Federal, state and local governments need to rebuild the public health infrastructure during non-emergency times so that there is adequate staffing to rely on during a pandemic or other emergency event.
- Federal and state public health officials should work to ensure that public health preparedness is recognized as a key component of the nation's homeland security strategy, and is treated on par with federal and state funding for other national security response capabilities.

## **9. Federal, state and local health agencies need to use new and more effective strategies to reach special and vulnerable populations and minority communities.**

States noted that state and local public health agencies were challenged in engaging members of special and vulnerable populations and other members of the public in vaccination efforts, particularly those in minority populations. Some observed that federal vaccine messaging to minority communities was conducted as a routine public health outreach campaign; however, more proactive measures were needed to identify potential areas of resistance and to construct messages to overcome areas of resistance. States commented that African-American and, to a lesser degree, Hispanic residents, expressed negative feelings or beliefs about the safety of the H1N1 vaccine. States learned that feelings of fear, anger and distrust about H1N1 vaccine among these communities also stemmed from a lack of confidence in state and federal governments generally. The inability to effectively reach minority and vulnerable populations resulted in decreased vaccination rates, delays in seeking vaccination, spread of misinformation, and ultimately disparate percentages of hospitalizations and deaths in minority patients with H1N1 compared to non-minorities. Advisory Panel participants agreed that governmental public health agencies need to engage in more successful partnerships with minority communities and develop more effective outreach tools for everyday use and during emergencies.

### **Recommendations**

- Federal, state and local governments need to partner with stakeholders in minority communities and groups representing special and vulnerable populations to develop new and re-imagined outreach strategies to these populations. Priority should be given to identifying and addressing reasons for negative beliefs about the H1N1 vaccine and vaccination in general.
- Follow well-established and proven risk communication strategies prior to launching public information and health education outreach campaigns for minority communities and special/vulnerable populations.
- Federal, state, and local governments need to understand and address the sources of governmental mistrust held by various members of the public.
- Governmental public health agencies must begin now to build more effective partnerships with minority communities for collaboration on ongoing outreach, as well as during emergencies.
- The federal government should take the lead in routinely translating pandemic materials into multiple languages.

## **II.C Analysis of Barriers and Other Issues**

The ASTHO H1N1 Policy Barriers Project identified significant policy barriers on a range of topics. Through discussions with the Advisory Review Panel and the various project elements (survey, meetings,

scan) it became evident that the national H1N1 response efforts highlighted challenges that emerged from the unique circumstances of the H1N1 outbreak, as well as revealed issues that seem to recur frequently in public health emergencies. The project also identified barriers that relate to underlying structural issues and outstanding public health preparedness issues that did not feature prominently during the H1N1 response, but which likely would have been more significant had the H1N1 virus been more virulent.

### Issues “New” and “Old”

The H1N1 outbreak featured “new” policy and legal issues—items that arose due to the circumstances of the H1N1 outbreak and response and that featured prominently in the states’ responses to the H1N1 the Policy Barriers Project. Examples of these issues include the dynamics of the N95 guidance, school closure guidance, and PREP Act questions. The H1N1 outbreak similarly highlighted “old” policy and legal issues—items that federal, state, and local public health officials have frequently identified dealing

**TABLE 2: KEY AND RECURRING ISSUES**

	Key Issues in the H1N1 Outbreak	Recurring Issues in Public Health Emergencies
<b>Policy</b>	<ul style="list-style-type: none"> <li>• PHER Grants</li> <li>• H1N1 Vaccine – Availability Messaging, Allocation Systems,</li> <li>• PPE – N95 – Guidance/Enforcement Issues</li> <li>• Pandemic Plans – Scalability; Relation to WHO Pandemic Stages</li> <li>• School Closure – Guidance; Impact on Other Services</li> <li>• Antiviral/Vaccine – Recovery/Disposal</li> <li>• Surveillance/Case Reporting – Federal v. State</li> <li>• Medical Supplies-HAvBED Direct Report to ASPR</li> <li>• Intergovernmental Coordination – No ICS</li> <li>• Employer/Employee Compliance with Guidance</li> </ul>	<ul style="list-style-type: none"> <li>• Flexing Personnel and Funding</li> <li>• Public Health Surge and Infrastructure</li> <li>• Health Care Surge Capacity</li> <li>• Vaccine – Allocation; Distribution; Production Capacity</li> <li>• Laboratory/Epidemiology – Capacity; Electronic Surveillance Systems</li> <li>• State Procurement/Personnel Systems</li> <li>• Communication – Messaging Coordination; Outreach to Public and Stakeholders</li> <li>• Outreach to Special and Vulnerable Populations</li> <li>• Workforce Vaccination Mandate - Health Care Workers</li> </ul>
<b>Legal</b>	<ul style="list-style-type: none"> <li>• Emergency Declaration – PREP Act</li> <li>• Response with/without State Emergency Declaration</li> <li>• PREP Act – Scope/Liability Coverage</li> <li>• School/Public Health Issues – Scope of Authority</li> <li>• Vaccination – Expanding Authority to Vaccinate</li> </ul>	<ul style="list-style-type: none"> <li>• Emergency Declarations – Scope/Implications</li> <li>• Volunteer Liability Concerns</li> <li>• Statutory/Regulatory Waivers</li> <li>• Coordination among Public Health Attorneys</li> <li>• Coordination of Legal and Policy Solutions/Personnel</li> </ul>

with in other public health emergency response activities. Examples of these items include the ability to flex and surge public health workers, concerns about laboratory capacity, and liability fears by staff and volunteers. Table 2 highlights some of the key H1N1 and recurring public health emergency issues.

It is important to note that Table 2 certainly does not provide a comprehensive listing of all the H1N1 and recurring issues/barriers. More importantly, the characterization of issues as “old” or “new” is not intended to diminish the importance of an item. It is simply to demonstrate that unanticipated issues/barriers will arise with each public health emergency and that work remains to be done on other issues/barriers. The key issues identified for the H1N1 outbreak may occur again in future events. With

the recurring issues, governmental public health agencies need to anticipate that these types of issues are likely to arise with each response and work proactively between emergency events to alleviate these barriers if possible, or at least prepare strategies to address these challenges when they arise in future events.

## **Relationships among Barriers**

Comments received from the Advisory Review Panel and the input of states throughout the project emphasized the relationships and connections among barriers. In any response, a decision made about one issue will cause both intended and unintended consequences in other areas. Several areas demonstrating these interactions are discussed below.

### *Command, Coordination and Communication*

Advisory Panel participants found that the inconsistent use of some type of unified command structure by federal, state, and local governments was not only a central barrier to the H1N1 response, but also gave rise to other coordination and communication barriers. Participants cited several examples drawn from the compilation of identified barriers. (See Section III.) States indicated that more coordinated and consistent federal decision making could have reduced the barriers identified with communications about the availability of H1N1 vaccine. Better coordination regarding communication of vaccination priority groups and explaining differences in federal/state/local targeting of vaccine priority groups and the general population was needed at all levels of government. Panel participants further noted that the challenges governmental public health agencies encountered with vaccination among minority populations stemmed, in part, from poor communications and coordination. Delays in vaccine availability, which states believed hurt government's credibility during the H1N1 response, only further exacerbated long-standing mistrust in government held by some in minority communities.

States indicated that H1N1 clearly demonstrated the importance and impact of federal guidance on public health emergency response efforts. Advisory Panel participants highlighted issues with several federal guidances—N95, school closure, and pediatric antiviral formulations—as being emblematic of the challenges state and local governments faced when federal guidances were delayed and/or conflicted with other guidance or current laws/policies. Participants observed that some of the problems associated with these guidances could have been avoided, or lessened, had there been more effective coordination among federal agencies and better communication among federal, state, and local health agencies.

Panel participants noted that command issues were affected in part by emergency declarations. Since emergency declarations at the federal and state levels trigger a range of enhanced authorities, liability protections, and statutory/regulatory waivers, these declarations impacted the H1N1 response. States commented that both public and private sector actors were at times uncertain about the implications of operating under an emergency declaration. It was also noted that not all states issued emergency declarations. Given the less virulent nature of the H1N1 virus, the outbreak did not qualify as a 'significant' public health emergency under some states' emergency laws, therefore, a state emergency could not be declared. One state indicated that it could not institute a state emergency unless there was a federal Stafford Act declaration; because the federal declaration was made under the National Emergencies Act, that state could not fully institute its emergency response activities.

The practical and legal implications of operating without a state emergency declaration varied among the states. One state noted that it was still able to offer statutory and regulatory flexibility to health care facilities dealing with H1N1 response pressures under existing state health care licensing laws despite the absence of state emergency declaration. Another state noted that the absence of a state emergency declaration meant that emergency command structure led by the state's emergency management agency

was not activated. However, this permitted the state health agency to remain the lead agency on the outbreak response, which was seen a preferable given that it was a public health emergency. Other states could not institute an ICS or EOC without a state emergency declaration. All of these issues demonstrated the command, coordination and communication challenges governments encountered related to emergency declarations. Advisory Panel participants discussed the need for governments to explore alternative command strategies that would permit a robust response to public health emergencies that may not be classified as emergencies under state laws.

#### *Legal Authorities and Liability Concerns*

States providing information to the H1N1 Policy Barriers Project frequently indicated that governmental personnel, stakeholders like health care providers, and volunteers were uncertain about the legal authorities and immunities granted under various federal and state emergency laws. There has been a proliferation of new emergency laws in the ensuing years since the September 11, 2001 World Trade Center attacks, which have helped to more clearly define governmental and public health authorities during emergencies and provide liability protections for a variety of actors necessary to mounting a robust response. With so many relatively new and untested emergency laws, states reported that both public and private sector personnel still have questions about the operations of these laws and how they interact. States most frequently identified questions about the PREP Act and its operation, coverage, and relationship with other federal and state laws. States also observed recurring challenges with understanding and communicating the requirements and processes for waivers under the federal Emergency Medical Treatment and Active Labor Act (EMTALA) and Section 1135 of the Social Security Act.

States also noted significant perennial concerns on the part of public and private sector employees and volunteers about potential liability for their roles in H1N1 response activities. Although there are increasingly more robust federal and state legal protections for responders and volunteers, persistent liability concerns emerge during each new response and hinder efforts to quickly deploy surge personnel and volunteers. Liability concerns were cited in activities such as H1N1 vaccination clinics and the use of EUA products by health care providers. Other states noted efforts by some private health care providers to be included under a grant of state governmental immunity for administering H1N1 vaccinations—an expansion of state governmental immunity that gives pause to state legal counsel. Concerns about liability continue to overshadow public health preparedness and response activities. Project participants indicated that governments at all levels must redouble their efforts to educate all parties about available legal protections.

#### *Public Health Capacity and Funding*

Advisory Panel participants reiterated a sentiment held by all states: federal PHER grants provided vital funding to supplement public health workforce capacity, especially in key areas such as surveillance and immunization, during the H1N1 outbreak. Continuing budget crises in the majority of states has resulted in further diminution of state and local public health capacity. Federal funding for public health preparedness and emergency response activities will continue to be a priority.

### **Structural Issues**

States' responses and other sources reviewed for the H1N1 Policy Barriers Project revealed ongoing structural challenges that are affecting the nation's capacity to respond to emergencies, as well as to engage in daily public health and health care activities.

### *Public Health Workforce and Infrastructure Capacity*

States uniformly acknowledged that lack of adequate and sustained funding to support public health infrastructure resulted in limited capacity to respond to H1N1 absent supplemental funding through the PHER grants. As a result of shrinking federal and state dollars, state and local health departments have cut back on core public health capacity, leaving them without the staff and resources required to mount a quick and coordinated response to an event such as H1N1. Advisory Panel participants observed, however, that short-term, supplemental dollars are not an adequate alternative to thoughtful, consistent funding geared toward building core capacity and ensuring the availability of a trained workforce and adequate laboratory surge capacity.

### *Health Care System Capacity*

States indicated that the surge capacity of some health care systems (i.e., providers, hospitals, emergency departments, other health care facilities) was taxed during the H1N1 outbreak. Many observed that had the H1N1 outbreak been worse, health care operations would have been unable to keep pace with the demand for care. Like the public health sector, daily health care operations in many communities are operating on thin margins due to economic pressures. As a result, medical surge capacity is limited in many jurisdictions, presenting a challenge to mounting a community-wide response. The HHS HPP grants have provided some capacity enhancements, but states and hospitals agree that the funding levels to date have been insufficient to truly boost public health/health care medical surge capacity.

### *Supply Chain Issues*

Throughout the H1N1 Policy Barriers Project, participating states detailed ongoing frustrations about their inability to more precisely identify the amounts and location of various countermeasures (e.g., vaccines, antivirals) and medical supplies in both public and private supply chains during the H1N1 outbreak. States appreciate that such information, especially in regards to private supplies, is sensitive data. Advisory Panel participants observed that having more reliable and timely access to this information during emergencies would better allow public health officials to monitor supplies available to health care providers/facilities in their jurisdiction and coordinate the use of federal SNS assets. Participating states also expressed concerns about the ability of current just-in-time supply chains to handle a nationwide pandemic more severe than the H1N1 outbreak.

## **Pending Issues**

Given the mild virulence of the H1N1 virus, the recent pandemic was not as severe as many were expecting should there have been an H5N1 pandemic, for instance. As a result, some facets of nation's collective response did not come into play, but certainly would have if the H1N1 pandemic had been more severe. States identified the following issues as items still needing more attention by federal, state and local governments.

### *Alternative/Crisis Standards of Care*

The public health and health care communities in all states have had ongoing discussions in recent years about the operational, legal and ethical considerations involved in providing medical care during emergencies. While different terms have been used to describe the concept (e.g., alternative, alternate, crisis, disaster or emergency standards of care), the concern is how should care decisions be made during an emergency when there may be inadequate staffing or supplies to provide the level of care that would be expected in a given community under 'normal' conditions. During the H1N1 response, some states characterized the initial limited availability of certain formulations of H1N1 vaccine as potentially setting up a circumstance in which altered standards of care should be activated. While states have initiated conversations about the topic in their jurisdictions, and many have developed robust strategies for



addressing alternative/crisis standards of care, the H1N1 outbreak provided states with salient examples with which to renew and update their dialogues about standards of care in emergencies.

#### *Alternate Care Sites*

Some state meeting participants identified a few barriers related to providing medical care at alternative sites to traditional hospital settings. While the use of alternate care sites did not feature prominently during the H1N1 response, the barriers that were identified about this issue during the recent pandemic are instructive. One state noted that staffing was the biggest barrier to alternate care site planning because hospitals did not want to divert their staff to off-site facilities. Another state noted that community health centers (CHCs) were limited in their ability to offer support to hospitals/clinics experiencing patient surge because CHCs cannot legally work outside their scope of practice (which are defined by assigned zip codes and populations) due to legal and insurance constraints. These issues demonstrate some of the operational, policy and legal barriers constraining use of alternate care sites. Governments at all levels should evaluate their experiences during H1N1 and the lessons learned regarding alternate care site planning and policy.

#### *Quarantine/Isolation and Travel Restrictions*

Issues relating to quarantine, isolation, and travel restrictions did not feature prominently in the feedback from states for the H1N1 Policy Barriers Project. This was in part because of the mild nature of the H1N1 virus and that the disease emerged so quickly in the U.S. that travel restrictions would have been ineffective. Quarantine and isolation measures were primarily achieved through voluntary means and school closures. Again, the H1N1 outbreak provided public and private sector entities with the opportunity to implement and evaluate the effectiveness of various response strategies under less severe conditions. States frequently identified concerns with individuals' willingness and/or ability to voluntarily exclude themselves from work or school for prolonged periods of time. Employment-based sick/administrative leave policies may not be conducive to allowing persons to voluntarily isolate/quarantine themselves. Persons without paid sick leave may not have the economic ability to remain home when they are sick. Parents whose children's schools have been closed due to an outbreak may not be able to leave work to stay home. All of these demonstrated the practical challenges that accompanied the public health measures and recommendations instituted to combat H1N1. These challenges must now be evaluated to determine how future pandemic response efforts will address them.

#### *Refining Pandemic Plans*

Advisory Panel participants and other states uniformly agreed that the H1N1 outbreak demonstrated the need for governments at all levels to reevaluate their pandemic response plans to make them more scalable to address outbreaks of varying degrees of severity. It was observed that U.S. pandemic planning to date has focused on worst-case scenarios like those envisioned should an H5N1 pandemic emerge. While this was a prudent approach to take for initial nationwide pandemic planning, these plans should now be refined to add more flexible and scalable elements. States also raised questions about whether U.S. is going to modify the *HHS Pandemic Influenza Plan* to reflect the 2009 World Health Organization (WHO) pandemic phases. Federal, state and local governments should closely coordinate in discussions about how these elements will be addressed in pandemic plans at all levels.



availability, prioritization, and allocation) that reflects the frequent interdependencies among these issues as discussed by the states.

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<b>Issue Type:</b>	Characterization as a policy issue or a legal issue (i.e., a policy issue that has legal implications). Where both elements apply, the primary characterization appears first (e.g., Legal; Policy)
<b>Level:</b>	Characterization as a state or federal issue. Where it applies to both levels, the primary characterization appears first (e.g., State; Federal).
<b>Discussion:</b>	Explication of the barrier and its various impacts on the H1N1 response.  The information is quoted directly from the original source material (i.e., survey response, state meeting summary, IPR, AAR, etc.).
<b>Mitigation Strategies Employed:</b>	Listing of the solutions or “work-arounds” various states employed to address or overcome the barrier.  The information is quoted directly from the original source material (i.e., survey response, state meeting summary, IPR, AAR, etc.).
<b>Recommendations Suggested:</b>	Listing of the various recommendations suggested by states to remove or improve the barrier. These do not represent the overall project recommendations.  The information is quoted directly from the original source material (i.e., survey response, state meeting summary, IPR, AAR, etc.).
<b>[Sources:</b>	Survey:                      Meetings:                      Environmental Scan:                      ]

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## III.A ICS, Command and Control, and Authority

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### **Summary of Barriers Identified**

The primary barriers identified related to ICS, command and control, and authority issues were (numbering does *not* reflect a priority order for the barriers):

- A.1 H1N1 Response Command**—All levels of governments could have made better use of the Incident Command System (ICS) than was done during the H1N1 outbreak.
- A.2 Emergency Declarations**—Federal and state attorneys need to better understand and explain the implications of emergency declarations made under various statutory authorities.
- A.3 Emergency Declarations**—Federal and state officials need to provide more information about the process and implications of emergency declarations to the public and stakeholders.
- A.4 Statutory and Regulatory Waivers**—Federal and state legal counsel need to understand the scope of statutory/regulatory waivers allowed under current federal/state emergency declarations and evaluate other areas in which waivers could be used to enhance future response efforts.
- A.5 PREP Act**—Additional guidance and outreach is needed about the application and implications of the Public Readiness and Emergency Preparedness (PREP) Act.
- A.6 General Liability Concerns**—Participants in the H1N1 response expressed fears about their potential legal liabilities during the response.
- A.7 School and Daycare Closure**—Changes in school closure guidance and triggers for implementing closure caused confusion, were at odds with how communities were experiencing the outbreak, and created gaps in services to children.
- A.8 Community Mitigation Measures**—Other community mitigation strategies to control the spread of H1N1 needed greater attention.

### **Selected Successes/Mitigations Identified**

#### *ICS, Command and Control, and Authority Generally*

- “The federal government provided states with recommendations for responding to the H1N1 pandemic; these recommendations were developed as tools for the state to follow.”
- “Although the state recognizes the federal government’s efforts in this regard, states had to develop guidance and policies specific to state conditions and authorities.”

- “Pre-existing legislation related to emergency powers for the state health director and liability protection for providers and businesses assisting with a disaster were utilized and allowed for efficient and effective use of resources.”
- “The leadership and direction established by the Governor’s Office, as well as the development of a state H1N1 task force were successful in the command and control process.”

#### *Use of ICS/Unified Command Structure*

- “Excellent cooperation and collaboration between the local unified command and local mental health management agencies, local education agencies, local emergency management agencies, emergency medical services, hospitals, community partners, and the state’s public health coordinating center facilitated synchronized communication and response during the event.”
- “Coordination between state and local authorities, decision to use a state emergency management team to facilitate distribution of medicine and supplies and competent staff were resources that worked well during the event.”
- To address the perceived lack of unified federal command, one state health agency “delegated staff liaisons to all other state agencies and held regular meetings to assure that response activities among the various agencies were well coordinated.”

#### *Emergency Declarations*

- “Emergency declarations were critical in this process and PREP Act guidance from U.S. Department of Health and Human Services was readily available, as well as timely and understandable.”
- States explained through the media “why the emergency declarations were being made, what they meant and why they were important in an attempt to lower public concern and anxiety and to maintain public confidence in local, state and federal government leadership.”

#### *PREP Act*

- “State agency counsel worked with the CDC Public Health Law Program and Office of General Counsel staff to get subsequent PREP Act declarations clarified so that all vaccinators authorized by state law would be covered.”

#### *General Liability Concerns*

- “Educated volunteers regarding the protections under the PREP Act to resolve concerns related to H1N1.”
- “The state distributed summaries of the liability protections available under federal and state laws to local health agencies, providers and volunteers to help quell their liability fears.”

#### *Waivers*

- “The state health agency informed healthcare partners of the existing state licensing flexibilities in absence of a state emergency declaration.”

#### *School Closure*

- “State and local public health departments coordinated with the state health agency to develop state-specific recommendations for school closure.”
- “Schools worked closely with local health departments through daily communications regarding recommendations to close or remain open.”

- “Local health departments built upon relationships already developed with schools through earlier identification of POD sites or regular meetings, and by providing timely, accurate information about 2009 H1N1.”
- “Over the summer, many local public health departments were able to work with their school districts and colleges to implement policies and procedures for capturing ILI-related illness and surveillance data; unfortunately, not all school districts throughout the state were cooperative.”
- “School surveillance activities will be continued in the state due to the success of H1N1 ILI school-based surveillance.”
- One state health agency noted that it “established very strong relationships with education officials and had already been working on the school closure issue through a multidisciplinary school safety committee.”
- “Through close communication and coordination, health and education officials were able to avoid major problems and effectively work through the few issues that did arise.”
- Another state reported that, “once the epidemiology of the epidemic was better clarified, the eventual federal policy of not closing schools in most instances was more readily accepted.”

*Community Mitigation Generally*

- “The issuance of Quarantine and Isolation orders, as well as communication from state leadership was also key contributions in the early phases of the event.”

**Barriers/Recommendations Identified Detail**

**H1N1 Response Command**

<b>Issue:</b>	<b><u>A.1</u> All levels of governments could have made better use of the Incident Command Structure (ICS) than was done during the H1N1 outbreak.</b>
<b>Issue Type:</b>	Policy
<b>Level:</b>	Federal; State
<b>Discussion:</b>	Federal, state and local governments did not make consistent and/or full use of ICS during the H1N1 outbreak.

*Federal- Level Issues*

At the federal level, there was a lack of coordination and clear Incident Command and Control at the federal level. The White House, the U.S. Department of Homeland Security (and its agencies) and the U.S. Department of Health and Human Services (and its agencies) created confusion about who ultimately was in charge of the U.S. response to H1N1 by not clearly and definitely implementing and announcing an Incident Command Structure. The various responding federal agencies had different lead spokespersons presenting sometimes differing messages. Additionally, federal agencies sometimes made overlapping requests to states using conflicting information-sharing distribution lists and protocols. DHS and HHS had their own (often conflicting) pandemic influenza plans.

### *State-Level Issues*

At the state level, respondents discussed inconsistent use of ICS or some other unified command structure during the H1N1 response. In some states, an ICS or emergency operations center (EOC) was not formally instituted because there was not a state emergency declaration for H1N1. Other states reported using modified ICS/unified command structures to compensate for challenges staffing and ICS/EOC during the prolonged H1N1 outbreak. Agencies' policies regarding staff participation in the ICS needed to be implemented to that ensure response activities were appropriately and adequately staffed. Failure and/or delay to implement ICS postponed the mobilization of staff necessary to perform operational and support roles.

In one state that had implemented ICS, "many people did not follow ICS." As a result, the state's immunization program staff received a "constant flow of numerous and redundant assignments and requests for information." This dynamic taxed the capacity of program staff and distracted from important outbreak response activities.

One survey respondent observed that "states that did not have a laboratory voice present in their ICS to counter public perceptions about the ready availability of and need for H1N1 confirmatory testing risked being swamped with samples from the 'worried well'."

One state observed that ICS was used more reliably by local health departments in the state than it was at the state level: "Local health departments use ICS now, not only because it is federally mandated, but also because the system works. ICS is not a training issue, but a culture issue; it must be used for daily response, not just during large-scale outbreaks."

### **Mitigation Strategies Employed:**

- One state reported using CQI [continuous quality improvement] tools to "better define the process, roles and responsibilities in developing and maintaining the ICS and COOP [continuity of operations] list."
- To address the perceived lack of unified federal command, one state health agency "delegated staff liaisons to all other state agencies and held regular meetings to assure that response activities among the various agencies were well coordinated."

### **Recommendations Suggested:**

#### *Federal-Level Issues*

Regarding the federal ICS response, "a careful review should be conducted to evaluate how implementing a clear ICS structure could have improved response at all levels." Specific recommendations are to:

- "Ensure federal agencies adhere to national incident management standards and collectively make appropriate policy decisions when guidance crosses into more than one federal agency."
- "Coordinate planning and messaging to different populations served by

different agencies.”

- “Build in a clear process for information to be monitored and coordinated to avoid confusing, conflicting messages.”
- “Develop robust procedures for informing and preparing new administrations and their key staff (at all levels) on current emergency response plans and available critical resources.”
- “CDC needs to use ICS and make formal ICS positions and Incident Action Plans (IAPs) available to states for review.”

#### *State-Level Issues*

Regarding state ICS response, “agencies must implement procedures for maintenance of ICS and COOP lists in order to maintain their ICS capacity and visibility.” Other suggestions included:

- “If the ICS is used, all levels of the state health agency—including upper management—need to respect the ICS structure and process requests through ICS channels.”
- “There must be laboratory and epidemiology staff within the ICS structure to provide insights into attack rates and monitor laboratory testing capacity and results. This is especially true when there is an outbreak of a novel virus, as in the case of the H1N1 outbreak.”
- “State health agency needs to implement ICS in a more formal way.”
- “State should enhance programs such as WebEOC such that it is usable at the state and local level. Develop policies for its use.”
- “More robust electronic communication conduit(s) to streamline communications outside of public health and communicate incident management.”
- “States should develop policies that allow for activation of a joint incident command (JIC) early in the event, even if other parts of the state’s emergency management response are not activated.”
- “Need to implement an established ICS for events that cross internal and external agencies (crossing county lines), staffing policies on the number of hours/shifts command staff can safely work during crisis before mandatory replacement is authorized, and initiating more ICS practice and exercises.”
- “State/local governments should develop comprehensive policies for all state/local agencies for training and implementation of ICS.”

[Sources: Survey: X Meetings: X Environmental Scan: ]



## Emergency Declarations

**Issue:** **A.2** **Federal and state attorneys need to better understand and explain the implications of emergency declarations made under various statutory authorities.**

**Issue Type:** Legal

**Level:** Federal; State

**Discussion:** *Federal Issues*

Federal legal counsel need to clarify the implications of the various types of federal emergency declarations and what resources flow from the various declarations. The issuance of an H1N1 emergency declaration under the National Emergency Act as opposed to the Stafford Act required clarification as to the differences between the two types of emergencies, as well as how these declarations differ from the Secretary of HHS's determination of a public health emergency.

Even the specific wording of an emergency declaration can have significant implications. The President's declaration of emergency under the National Emergency Act addressed Section 1135 waivers and specifically named Medicare, Medicaid, the Children's Health Insurance Program (CHIP) and the Health Insurance Portability and Accountability Act (HIPAA) as programs specifically eligible for waiver under the Act. However, EMTALA was not named in the Presidential declaration, although it was specifically named in the Secretary's 1135 waiver granting CMS the authority to waive EMTALA penalties where indicated. The inconsistency between the wording of the two declarations left state agency counsel wondering if the omission in the Presidential declaration was intentional or an oversight.

*State Issues*

At the state level, some states' statutory requirements for declaring an emergency are very narrowly proscribed, such that state emergency declarations were not made for the H1N1 outbreak. Because many extraordinary response measures are tied to the declaration of an emergency, state agency counsel are concerned that restrictive statutory requirements for declaring an emergency could delay or hinder a robust public health response.

**Mitigation Strategies Employed:** None identified

**Recommendations Suggested:** *Federal Level*

- "Provide states with notifications regarding a pending Presidential Declaration to assist in incident action planning."
- "Need to resolve the missing reference to "EMTALA" in the President's

Declaration of National Emergency.”

- “The federal government needs to clarify the implications of alternative types of federal emergency declarations.”
- “Federal government should develop clear guidelines for the federal use of emergency declarations to include Stafford Act and non-Stafford Act declarations. Educate state and local agencies on the authorities of these declarations.”
- “Federal government should evaluate the similarities and differences between a Stafford Act declaration and the Public Health Emergency declaration with an eye toward benefitting the systems as a whole and avoid silos in funding and response.”
- “Further clarification of details for tracking expenses in order to accurately apply for reimbursement in a disaster declaration is needed.”
- “Develop and disseminate to state and local public health agencies a fact sheet that compares the implications of alternative federal emergency declarations, especially for the availability of financial and other resources they trigger.”

*State Level*

- “The state needs to implement more flexible disaster declarations to account for public health response.”
- “Change current policies to enable the state department of emergency management to activate the state EOC and free up additional state/local resources without the Governor declaring an official state of emergency.”

[Sources: Survey: Meetings: X Environmental Scan: X ]

**Issue:** **A.3 Federal and state officials need to provide more information about the process and implications of emergency declarations to the public and stakeholders.**

**Issue Type:** Legal; Policy

**Level:** Federal; State

**Discussion:** *Explain the Implications of Emergency Declarations*  
Federal and state officials need to demystify the emergency declaration process for the public, media and stakeholders. These audiences need to better understand the differences among various federal and state declarations, their purposes, and the effects of each (e.g., PREP Act, Stafford Act, state emergency declarations).

During the H1N1 outbreak, federal emergency declarations, which governmental personnel know serve as administrative triggers that allow the release of critical funding and other resources, were seen as confusing and potentially frightening to the public. When these declarations were announced during the pandemic, some respondents believed the declarations “made the situation sound much more severe and threatening than it actually was.” Some noted that “the emergency declarations were extremely hard to explain to the public, tended to heighten anxiety and fear, and put pressure on state governments to make the same declarations.” Still other states noted that “a presidential declaration prior to a state declaration resulted in a need for clarification of the declaration process for public health agencies and healthcare partners.”

*Implications of Operating with/without a State Emergency Declaration*

The real and perceived need for a state to issue an emergency declaration once a federal emergency declaration has been made depends on a state’s statutory and regulatory landscape. Some states have sufficient statutory and regulatory flexibility to allow for public health emergency response activities to occur even if there has not been a formal state declaration of emergency. One state noted, for example, that “the state health agency informed health care partners of the existing state licensing flexibilities in absence of a state declaration.” Another state noted that its statutory requirements for declaring an emergency are very narrowly proscribed, such that the H1N1 outbreak did not rise to a level meeting the requirements to issue a state emergency declaration.

In some states, it is the state’s emergency management agency that is the statutorily-defined lead agency on emergency response activities. In these instances, the state emergency management agency “cannot stand up the state EOC until the Governor declares a state emergency. Thus, “a better process for activating the state EOC without an emergency declaration” is needed.

Another state, which was operating under a state emergency declaration, remarked on the “lack of willingness of other state agencies to suspend rules (which the Governor’s declaration called for), which ultimately slowed response and wasted human resources.” It concluded that “if this had been a more severe pandemic, lack of administrative nimbleness could have been catastrophic.”

A state representative also noted that “several counties received pressure from their partners to declare a local disaster to free up additional resources.” However, “as the case mortality rate was not unlike that of seasonal influenza, state and local health departments did not see the need to formally declare a state/local disaster.”

Another state representative observed that: “Disaster declarations posed several state/local issues that made it apparent that public health emergencies should be classified differently. Public health emergencies tend

to emerge slowly and require a longer period of response. This is why it can be difficult to determine when to declare an emergency, establish ICS, etc. There needs to be a formal response that does not trigger the full disaster declaration, but addresses public health-specific issues.”

**Mitigation Strategies Employed:**

- States explained through the media “why the emergency declarations were being made, what they meant and why they were important in an attempt to lower public concern and anxiety and to maintain public confidence in local, state and federal government leadership.”

**Recommendations Suggested:**

*Federal Level*

- “Provide states with notifications regarding a pending presidential declaration to assist in incident action planning.”
- “Federal policies and laws need to be changed to allow for the release of assets under conditions or statements other than emergency declarations.”
- “Declarations of emergency should be reserved for true emergencies when the public must be made aware of the situation’s severity and be prepared to take prudent action.”

*State Level*

- “The state needs to implement more flexible disaster declarations to account for public health response.”
- “Change current policies to enable the state department of emergency management to activate the state EOC and free up additional state/local resources without the Governor declaring an official state of emergency.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

**Statutory and Regulatory Waivers**

**Issue:** **A.4** **Federal and state legal counsel need to understand the scope of statutory/regulatory waivers allowed under current federal/state emergency declarations and evaluate other areas in which waivers could be used to enhance future response efforts.**

**Issue Type:** Legal

**Level:** Federal; State

**Discussion:** At the federal level, clarification is needed as to the scope, process and implication of CMS waivers for Medicaid and EMTALA requirements during an emergency.

States' approaches to statutory/regulatory waivers vary according to their specific laws and approaches to managing emergency responses, as well as the structure of their public health systems (i.e., centralized, decentralized, etc.). Agencies must identify all of their states' laws/policies that should be waived during the response.

**Mitigation Strategies Employed:**

None identified

**Recommendations Suggested:**

*Federal Level*

- “CMS needs to adopt the use of a standard format for Medicaid waivers and that they are issued in a timely manner.”
- “All regional HHS/CMS offices develop pre-drafted orders authorizing such waivers.”

*State Level*

- “State agency counsel need to share information about states’ approaches to statutory/regulatory waivers.”
- “States’ counsels also need to examine alternative legal and policy approaches to expanding authority and improving response during public health emergencies.”

[Sources: Survey: Meetings: Environmental Scan: X ]

**Public Readiness and Emergency Preparedness (PREP) Act**

**Issue:** **A.5 Additional guidance and outreach is needed about the applications and implications of the Public Readiness and Emergency Preparedness (PREP) Act.**

**Issue Type:** Legal

**Level:** Federal

**Discussion:** State agencies and various stakeholders like health care providers and volunteers need more information and education about the PREP Act and its interplay with other emergency declarations; the contours of PREP Act coverage; and the extent of PREP Act liability coverage compared to other liability and compensation laws. More information is specifically needed about: (1) the relationship between PREP Act and state liability protections; (2) the extent of PREP Act liability coverage and scope of remedies available; and (3) the types of adverse incidents covered under the PREP Act.

Other specific PREP Act barriers identified by the states were:

- *The differences between activities covered under the PREP Act versus injuries covered under the Countermeasure Injury Compensation Program (CICP).* The PREP Act appears to protect for more losses than the CICP pays for. It is thus possible that there will be no relief for certain claimants. As one respondent noted, “because CICP program administration and the types of injuries covered have not been determined yet, states are faced with questions they cannot answer.”
- *The interplay of the PREP Act, EUAs and off-label uses.* Because the PREP Act does not cover off-label uses, CDC had to revise its recommendations for off-label use of H1N1 vaccines to extended populations (e.g., young children). A state respondent noted that “this omission in PREP Act coverage acted as a disincentive for providers to use valuable countermeasures when liability is not covered.”
- *The impact of PREP Act declaration language on those authorized to vaccinate.* “The language of the PREP Act declarations for antivirals and the vaccine varied, causing uncertainty whether state emergency declarations (which can expand the persons qualified to act) were necessary– or would be effective–to procure PREP Act protection. Drafting issues with the first vaccine PREP Act declaration led to a narrower group of “qualified persons” than the authority granted by the PREP Act itself would have allowed. As a result, persons authorized by state law, but not licensed, to administer vaccines were initially uncovered by the H1N1 vaccine declaration.”

**Mitigation Strategies Employed:**

*CICP issues:*

- “States have been directing inquiries to the CICP website, advising about the filing deadline, and acknowledging that CICP program administration practices are unknown.”

*Authorized vaccinators:*

- “State agency counsel worked with CDC Public Health Law Program and Office of General Counsel staff to get subsequent PREP Act declarations clarified so that all vaccinators authorized by state law would be covered.”

**Recommendations Suggested:**

*CICP Issues*

- “Address the discrepancies, if any, between the PREP Act and CICP and finalize the CICP administrative rules and injury table.”

*Off-label Use*

- “Amend the PREP Act to include liability coverage for off-label use.”

*Impact of PREP Act and Federal Laws Generally*

- “Implementation practices for emergency laws, rules, and acts should be

communicated to states from federal partners in weekly conference calls.”

- “Federal partners should outline in writing the impact federal laws/rules will have on states.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## General Liability Concerns

**Issue:** **A.6 Participants in the H1N1 response expressed fears about their potential legal liabilities during the response.**

**Issue Type:** Legal

**Level:** Federal; State

**Discussion:** Despite an increasingly robust collection of federal and state laws addressing immunity, liability limits, and compensation for various participants in governmental emergency preparation and/or response activities, state and local health agency staffs, private providers and volunteers continue to voice concerns over the possibility of liability arising from their involvement in emergency response activities.

- *Assuring volunteers about liability protections:* One state noted that “the lack of state liability protections initially hampered mobilization of volunteers to help coordinate and conduct mass vaccination activities.” Medical Reserve Corps leaders reported that “the lack of state provisions ensuring liability protections for health care and other volunteers inhibited recruitment and made some reluctant to volunteer initially to help with H1N1 response activities.” “Protections provided through the federal PREP Act resolved the issue for the H1N1 response, but underscored the importance of ensuring adequate liability protections for volunteers.”
- *Indemnification of private health care providers:* Another state noted that “private providers in that state sought indemnification that the state, as a sovereign, was not able to give.” “The hospital association and medical society asked the state department to provide indemnification in case they were sued for following triaging protocols recommended by a state/stakeholder group. State law limited the agency’s authority to provide the indemnification, plus there was concern over the ‘slippery slope’ of expanding that law (grant them ‘agent’ status) to cover those entities’ practices. While it remained a theoretical issue because the H1N1 outbreak was not severe enough, this potential barrier does expose the push-pull between public health needs and the need to limit the acts for which the state indemnifies.”

**Mitigation Strategies Employed:**

- “The state distributed summaries of the liability protections available under federal and state laws to local health agencies, providers and volunteers to help quell their liability fears.”
- “Educated volunteers regarding the protections under the PREP Act to resolve concerns related to H1N1.”
- “The state health agency sent an explanatory letter as to why they refused to cover the hospitals and doctors in the above example.”

**Recommendations Suggested:**

- “State agencies need to better reach and educate providers’ and local health agencies’ legal counsel so they can assure their clients of the protections in place.”
- “Renewed efforts are needed at the state and federal level to encourage states to enact comprehensive liability protections.”
- “Have HHS consider PREP Act coverage for a wider range of responses that would include the actions of private providers acting under specified parameters.”
- “Implementation practices for emergency laws, rules, and acts should be communicated to states from federal partners in weekly conference calls.”
- “Federal partners should outline in writing the impact federal laws/rules will have on states.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## School and Daycare Closure

**Issue:** **A.7 Changes in school closure guidance and triggers for implementing closure caused confusion, were at odds with how communities were experiencing the outbreak, and created gaps in services to children.**

**Issue Type:** Policy; Legal

**Level:** Federal; State

**Discussion:** *School Closure Guidance Issues*  
There was confusion due to changing federal guidance/policies regarding school and daycare closures, especially early in the event, when some states were in the mitigation phase while others were still in the containment phase. As one respondent observed, “the public found it confusing that schools closed for H1N1, while there were similar numbers of cases of seasonal flu each year and schools did not close.” “Tying school dismissal



policies to the WHO's pandemic phases became problematic when the pandemic did not develop as it potentially could have."

Another noted: "CDC was slow to adjust plans while state and local authorities resisted following the (then) current guidance. Fortunately, a last-minute reversal in federal guidance stopped the closures before they were to begin. However, the resulting confusion and lack of clear direction confounded state and local public health and school authorities and led to a loss of public confidence in the government's ability to provide clear and meaningful direction."

#### *Impacts of School Closures*

The full impact of implementing school and daycare closure policies must be assessed and planned for. Children enrolled in subsidized feeding programs (e.g., school breakfast, lunch and snack programs) were adversely affected by school closure. One state told of economic impacts: some schools had to close for financial reasons because parents were fearful of sending children to school in the fall, and school reimbursement is based on per capita attendance. Another state reported that it did not follow CDC school closure guidance because of the secondary effects doing so would have.

#### **Mitigation Strategies Employed:**

- One state health agency noted that it "established very strong relationships with education officials and had already been working on the school closure issue through a multidisciplinary school safety committee."
- "Through close communication and coordination, health and education officials were able to avoid major problems and effectively work through the few issues that did arise."
- Another state reported that, "once the epidemiology of the epidemic was better clarified, the eventual federal policy of not closing schools in most instances was more readily accepted."
- "Schools worked closely with local health departments regarding recommendations to close or remain open through daily communications."
- "Local health departments built upon relationships already developed with schools through earlier identification of POD sites or regular meetings, and by providing timely, accurate information about 2009 H1N1."

#### **Recommendations Suggested:**

##### *General Recommendations*

- "Improve communication between state health and education agencies."
- "Strengthen/promote more widely the state health agency message to "keep your child home if sick" and infection control measures for

parents.”

- “Recruit educator support of parental choices to keep child home, without requiring physician notes or other justification.”
- “Coordinate and provide guidance from state health and education agencies in a timelier manner.”
- “Work to provide consistent messages/communication between school districts within each county.”

#### *School Closure Guidance Issues*

- “Future federal school closure plans must be more nimble, guided by situational awareness, real-world input from state and local stakeholders, and be based on the best available scientific expertise.”
- “Changes in state school policies which would allow for more flexibility in school funding during epidemics and pandemics.”
- “Earlier and clearer school and daycare closure guidance from both the federal and state levels are needed.”
- “It would have been helpful to have options/alternatives to provide to states (maybe a model) versus taking extreme action by shutting down schools.”
- “School closure guidance needs to be reviewed and refined. There is a need to develop appropriate guidance to assist in both the community decision process and marketing strategies that: (1) identify the issues to consider; (2) recommend who should be involved in the discussions; (3) provide strong rationale why to keep schools open – “safe schools guidance;” and (4) provide recommendations for decision-making if closures are indicated.”
- “Messages need to include reasoning for closing schools and *not* closing schools (e.g., the best place for well children is at school; the best place for sick children is at home).”
- “Federal guidance should contain verbiage that states can develop alternate recommendations based on local conditions and authorities.”
- “Conduct additional federal multi-agency meetings prior to developing guidance.”
- “CDC school dismissal should address both preemptive and reactive dismissals (disease control measure versus operational/management issues) with better clarification and communication, as well as a clear understanding of the standards and trigger points for required control measures for state school/university closures.”

*Impacts of School Closures*

- “Work with partners to review all policies creating obstacles (e.g., school funding, meals issues). Consider: (1) developing alternative solutions to deliver nutrition in a different way when schools closed; and (2) seeking federal funds to continue even if schools are closed during a public health crisis.”
- “Federal, state and local governments should conduct forums for the development of consistent school closure policy and the continuation of services delivered through school administrations such as reduced cost meals and other social services.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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**Issue:** **A.8 Other community mitigation strategies to control the spread of H1N1 needed greater attention.**

**Issue Type:** Policy

**Level:** State

**Discussion:** States noted examples in which more could have been done to promote other community mitigation measures to limit/delay the spread of H1N1.

*Hospital Visitor Restriction Policies*

“Hospital visitor restrictions varied from hospital to hospital. Hospitals wanted policies to be consistent and have recommendations from the state; restrictions were hard to enforce without state guidance. Child welfare issues were also an issue at some hospitals as some parents left their children unattended in waiting rooms if they were not allowed to visit patients.”

*State Workforce Travel Restrictions*

One state noted that “policies on travel restrictions (specifically air travel) for state employees during emergency events were strongly recommended for setting an example for others.”

**Mitigation Strategies Employed:** None identified

**Recommendations Suggested:** *Hospital Visitor Restrictions*

- “Hospital visitor restrictions need to be more clearly communicated to the public as early as possible to ensure that children are left at home.”
- “Hospital visitor restrictions should be consistent statewide; guidelines should be provided by the state health agency during future outbreaks.”

*State Workforce Travel Restrictions*

- “Policies on travel restrictions (specifically air travel) for state/local employees during emergency events were strongly recommended setting an example for others.”
- “State and local governments should develop human resource policies that protect the workforce and allow for setting an example to others regarding health policy programs.”

[Sources:                      Survey:                      Meetings: X                      Environmental Scan:                      ]

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## III.B Surveillance, Epidemiology, and Laboratory Services

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### **Summary of Barriers Identified**

The primary barriers identified related to surveillance, epidemiology, and laboratory services issues were (numbering does *not* reflect a priority order for the barriers):

- B.1 Surveillance, Data Collection and Analysis**—There must be more consistency nationally regarding surveillance strategies, data collection and analysis.
- B.2 Reporting Estimated Cases, Deaths and Hospitalizations**—Inconsistent case reporting methods led to differing case counts, conflicting messaging, and concerns about privacy.
- B.3 Laboratory Services Capacity**—The H1N1 response strained the laboratory capacities at the federal and state level. States’ and laboratory capacities need sustained funding.

### **Selected Successes/Mitigations Identified**

#### *Surveillance Data Collection and Analysis*

- “Improvements were made to school absentee surveillance reporting systems and additional training/outreach to local health departments/schools, leading to a 240% increase in school participation rates.”
- “Local health departments worked to share school closures/absentee rates throughout counties no matter which surveillance system was used.”
- “The state’s epidemiology program provided weekly webinars, communications with hospital epidemiologists, and guidance on sample submissions in a timely manner.”
- “The use of existing state surveillance systems, as well as the easy transitions from one system to another, assisted with successful disease surveillance; the CDC’s Influenza-Like Illness Network (ILI NET), the state epidemiologic tracking and collecting system, hospital-based epidemiologists, state public health laboratory, and the state medical assets tracking system were among the top surveillance.”
- “A few states building on the CDC/APHL PHLIP [Public Health Laboratory Interoperability Project] pilot project were able to report electronically.”

#### *Reporting Cases*

- “Worked with reporting sources through the pandemic and eased some reporting requirements as local epidemiology warranted. It was difficult to balance partnership and reporting requirements.”

#### *Laboratory Capacity*

- “The state public health laboratory was successful in implementing a team approach to receive, process, test and report for H1N1 samples in a timely and efficient manner and provided the local health departments with regional surveillance reports.”
- “The state public health laboratory utilized additional staff resources to handle laboratory surge.”

- “Used epidemiology staff as a gatekeeper to prioritize testing samples to address the demands on public health laboratories.”
- “Where possible, purchased equipment through state contract vendor. Other equipment purchases are being attempted through departmental processes.”

## ***Barriers/Recommendations Identified Detail***

### **Surveillance, Data Collection and Analysis**

**Issue:** **B.1 There must be more consistency nationally regarding surveillance strategies, data collection and analysis.**

**Issue Type:** Policy

**Level:** Federal and State

**Discussion:** States identified the need for more consistency regarding surveillance strategies, data collection and analysis in several respects:

#### *Surveillance System Administration/Monitoring*

Dissemination of information between local, state and federal levels was seen as inconsistent. It was noted that “roles and responsibilities are not clear for each sector (i.e. local, state and federal) and the role of private testing for private providers must be clarified.” “Overall, a less labor intensive surveillance system needs to be established. Goals need to be determined and set as to how the surveillance system will be used. Questions about “who” will monitor and/or control the surveillance system needs to be determined, especially as more data sources are combined and data streams become more consistent and consolidated nationally.”

#### *Surveillance/Data Goals*

H1N1 surveillance goals and guidance need to be updated as the outbreak progresses (e.g., spring vs. fall 2009). Top priorities identified by states for surveillance were determining the severity of illness and risk factors for infection. “The current system does not capture or determine the severity of illness in real time. There is also the need to balance the tension between the immediacy of the situation versus the granularity of information. It will be a challenge to identify how best to refine surveillance systems to detect and capture the occurrences of considerable variability in disease, both geographically (e.g. neighborhood/community outbreaks) and within population groups (e.g. race/ethnicity).”

#### *Data Uniformity/Comparability*

Strong sentiment was expressed that there is a need for greater uniformity nationally among data collection and confirmatory laboratory testing procedures to strengthen H1N1 and overall response capacity. “State and federal health officials must determine how to reduce variability among surveillance systems to provide a clearer national picture.” A respondent

noted that the “lack of national standardized performance goals allowed extreme variation in confirmatory testing that was available for nationwide epidemiological comparison.” Further, “inconsistent utilization of confirmatory laboratory testing negatively impacted surveillance data comparisons between states.”

#### *Data Streams and Data Systems*

Data systems and protocols should build on and improve upon those used for seasonal influenza. “Alternate data sources and health information technology, such as syndromic surveillance and electronic health records systems, should be leveraged for better situational awareness.” Syndromic surveillance information proved useful; many jurisdictions used school absenteeism data to help enhance their understanding of influenza and support local decisions.

Several states noted that “the lack of electronic laboratory data transmission (ELR) capacity at state and local levels hindered case reporting and data aggregation.” “This proved to be a significant barrier for laboratory and epidemiology units to coordinate and consolidate numbers across the state and country.” One specifically observed that the “Public Health Information Network (PHIN) recommends that labs must accept electronic requests and deliver reports as part of PHIN certification.”

#### *Confirmatory Testing*

States reported that “it was confusing in the early stages of the H1N1 outbreak to have preliminary testing at the state, yet needing to wait for confirmatory testing by CDC.” One respondent observed that “shifting case definitions are probably unavoidable, especially early on, but causes problems for clinicians and the public.”

Policy guidance is needed to validate clinical/private laboratory assays. One state noted that: “State/county epidemiology units need to use laboratory test results from clinical labs (non public health) for case reporting. This responsibility needs to be clarified at the national level. Whose responsibility is it to do the validation? Lack of a policy or pre-existing plans for validating clinical laboratory assays was in place.”

Another state noted that: “According to the Clinical Laboratory Improvement Amendments (CLIA), it is not currently mandatory that patient addresses be included with all laboratory test requests. Labs may never receive this important information and often need to follow up on each case to obtain address information. Public health and reference labs must know the exact location of each case for community mitigation purposes—aggregate state-level case counts are not helpful in this regard.”

#### *Rapid Testing*

Information is also needed to inform health care providers about the role of rapid testing. It was observed that: “The lack of a reliable rapid H1N1 influenza test similar to one used for seasonal flu case management without comparable laboratory data leads to less than optimal decisions for the

patient. It also exposes others and leads to confusion among health care providers, and complicates influenza burden estimates. Many providers continued to over-rely on inaccurate quick tests because of their availability and belief it was “good enough”. Surveillance data may have been skewed by rapid test utilization and false negative tests could have delayed some appropriate patient care, which may have resulted in serious outcomes and even death. Transmission of disease could have been prolonged.”

#### *Surveillance in Schools and Universities*

Some states specifically commented on the challenges of conducting surveillance activities in educational settings, such as schools and universities. One state deployed an electronic school-based surveillance and reporting system to track school absenteeism. It was noted that “a number of local health departments did not utilize the system as it was perceived as being a significant burden on school nurses, who were short-staffed.” Thus “a lag in reporting occurred when all schools were not utilizing the system, and there was a perception that too many reporting systems existed.”

#### **Mitigation Strategies Employed:**

“A few states building on the CDC/APHL PHLIP pilot project were able to report electronically.”

#### **Recommendations Suggested:**

##### *Surveillance System Administration/Monitoring*

- “Conduct an evaluation of epidemiologic and surveillance systems used during the H1N1 response to determine what worked well and what could be improved. As part of this process, determine what data elements were necessary and useful and cull those which were not for the purpose of streamlining and simplifying data acquisition and analysis.”

##### *Surveillance/Data Goals*

- “Surveillance priorities need to be clarified. Top priorities for surveillance are: (1) determining the severity of illness; and, (2) the risk factors for infection because these data drive decision-making. There should be movement toward greater nationwide consistency in the reporting of data. Use of sentinel providers is an option for more timely, less labor intensive surveillance.”

##### *Data Uniformity/Comparability*

- “Re-examine ILINet for the purpose of creating greater standardization and consistency among states as it pertains to definition interpretation (e.g. “widespread, “regional”, etc) and reporting.”

##### *Data Streams and Data Systems*

- “Obtaining more locally oriented and granular disease surveillance data (as compared to statewide or national) to better target public health response and services, given local variability of influenza outbreaks.”
- “Revise surveillance systems to capture more specific data on at-risk and



vulnerable populations.”

- “Expand the PHLIP standards for ELR to all reporting entities.”

#### *Confirmatory Testing*

- “CLIA should be modified to mandate that patient addresses be included with all lab test requests.”

#### *Rapid Testing*

- “Develop a reliable rapid test for H1N1 as well as seasonal flu.”

#### *Surveillance in Schools and Universities*

- “Continue to develop ongoing relationships at the state and federal level between public health and educational institutions. CDC, HHS and U.S. Department of Education should be communicating on how to better partner for routine and emergency disease surveillance.”
- “Federal agencies should also better support their state/local counterparts in these efforts; U.S. Department of Education should loosen grant restrictions that interfere with collaboration with public health and that hinder reporting requirements.”
- “Use existing surveillance system, rather than a new one, especially during an event.”
- “Develop policies for access, data entry, integration of existing systems.”
- “Continue to use school-based surveillance/reporting systems for all communicable disease surveillance; strengthen partnership between local health departments and schools to improve system.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Reporting Estimated Cases, Deaths and Hospitalizations

**Issue:** **B.2 Inconsistent case reporting methods led to differing case counts, conflicting messaging, and concerns about privacy.**

**Issue Type:** Policy and Legal

**Level:** Federal and states.

**Discussion:** States identified a number of barriers related to reporting of cases, hospitalization and deaths.

#### *Consistency Among Case Counts*

States noted that the “two options for hospitalization and death reporting,

while intending to allow flexibility to states, ended up creating confusion about how to compare/contrast data.” “Unlike most disease reporting systems where there are standardized case definitions and methods for national data comparison, H1N1 surveillance was either by lab confirmed hospitalizations and deaths for a majority of state and/or by syndromic data as well in 14 states.” Some states were not able to compare the datasets; therefore, reports were based solely on the lab confirmed data submitted. It was observed that “those states using in-patient hospitalizations data acquired via syndromic surveillance lacked adequate historical data, making discussions with reporters or data-driven pandemic response challenging at best and inconsistent/misguided at worst.”

Regarding the use of confirmed case counts, a respondent remarked that “CDC did not follow a consistent procedure for surveillance of H1N1 at the national level,” which was “for confirmed case counts to be reported to CDC by states, after vetting of information by states.” It was observed, however that “CDC regularly reported (to the media and on its web site) data that included cases which it learned about through mechanisms that bypassed this consensus reporting procedure, resulting in reporting of inconsistent numbers of cases by CDC and states.” Others noted that states had to deal with significant media demands early in the outbreak to explain varying sources of data and differences in case counts.

Another state commented that: “Data from CDC did not allow for a coordinated mechanism for timely comparisons between large cities. Aggregate cumulative case counts were not an accurate measure of incidence because states stopped testing at different times and/or used different testing criteria. Aggregate data was confusing and changed perception of the pandemic’s severity.”

There needed to be additional outreach to hospitals and death certifiers regarding completeness and accuracy of H1N1-related death certificate filing. According to one respondent, “national death certificate data varied widely on H1N1, influenza, and pneumonia.”

Ultimately, some states believed that “case-based reporting is not practical or sustainable over the course of an outbreak, especially if it were more severe than H1N1 turned out to be.”

#### *Messaging about H1N1 Case and Death Reports*

States agreed that the use of data in media communications was a complicated issue. There was a need for “enhanced explanations of CDC case, hospitalization, and death estimates to the public.” One respondent characterized it as: “in some instances, the federal government got ahead of states/locals when reporting state/local cases before families and communities had been notified.” States recognized the need and importance of collecting and packaging data in useful ways to numerous audiences with differing needs, particularly the media.

### *Balancing Case Reporting and Privacy*

Questions and concerns arose about balancing the need to disclose H1N1 case information to state and local officials and the media to inform the public about H1N1 risks with federal and state privacy requirements. This issue arose in situations such as the disclosure of information through channels outside of public health (e.g., coroner's office); disclosure of names of schools or school districts with students with confirmed H1N1 to inform other parents of risks; and the release of published updates about cases (e.g., MMWR). Privacy issues were raised with regard to the federal Health Insurance Portability and Accountability Act (HIPAA) and the Family Educational Rights and Privacy Act (FERPA), as well as state privacy laws.

#### **Mitigation Strategies Employed:**

##### *Case Reporting*

- “Worked with reporting sources through the pandemic and eased some reporting requirements as local epidemiology warranted. It was difficult to balance partnership and reporting requirements.”

#### **Recommendations Suggested:**

##### *Case Reporting*

##### *Data types and systems:*

- “Use both lab-confirmed data and syndromic data (with clear definitions) in the future and provide appropriate funds so that work can be done and continue to find innovative ways to use syndromic and other nontraditional data sources.”
- “CDC should regularly use state-based case reporting systems to assure consistent counts between the states and the federal government.”
- “A national policy should be established using National Electronic Disease Surveillance System (NEDSS) to report incidence information and national notifiable diseases.”
- “Patient, lab, and hospital databases across the nation should report the same data in a compatible way, preferably by using Health Level Seven electronic data exchange.”

##### *Case reporting procedures/standards:*

- “Develop a collection and reporting standard operating procedure (SOP) for disease surveillance that is sustainable during a long-term response. The guidance must include exceptions for targeted populations of interest, such as pediatric deaths, pregnant women, and health care workers.”
- “CDC should: (1) provide case counts for each state using the same case definition and testing criteria; and (2) develop a sampling plan for larger cities and/or sentinel sites to do additional surveillance and reporting.”
- “It is recommended that a standardized way of reporting cases that can

be easily understandable and track-able throughout the event be developed and implemented, as well as earlier availability of mortality rates.”

- “Need a policy to determine and communicate when a novel disease is no longer novel.”
- “More research is needed to produce national standards (case definition and which other elements should be reported) for syndromic surveillance.”
- “CDC should clearly define the case message for the electronic health record.”

*Death reporting:*

- “Provide national educational tools and outreach to death certifiers on the importance of accurate and complete death reporting. Develop quality improvement projects involving certifiers so they know what additional questions/information would have been useful on a subset of the death certificates they certified.”
- “Acknowledge that mortality data is a critical component of pandemic preparedness and tracking.”
- “It was recommended the state develop an electronic death certificate system.”

*Identifying federal, state and local roles:*

- “Provide clear state health agency guidance for local health departments on trigger points for response to surveillance data and supplementary information on surveillance systems in a quick, easy to use format.”
- “Federal and state governments should develop policies that clarify roles of the multiple response agencies and their responsibilities for data collection and support functions.”
- “Federal and state governments should develop policy standards for data collection: what is to be collected, who collects it and who can use it. This data includes human health, school absenteeism and hospital capacity information.”
- “States should develop standards for local policy development regarding data collection.”

*Case/Death Reports Messaging*

- “States should have the ability to preview CDC’s media messages so states could be ready for media questions, when feasible.”
- “Common characteristics of success stories on this topic included

systematically identifying the most useful public information for the media, consistently placing it in context, and publicly releasing that information on a regular schedule and in a standard format.”

- “Ensure that state and local public health officials are notified of case fatalities before reports are made at the national level.”
- “When reporting data at the federal level, provide a disclaimer stating state and local data may be more accurate.”

#### *Disclosure and Privacy Issues*

- “Guidance is needed about the level of identifiable information and parties permitted to receive disclosures.”
- “Well-established communication security for patient confidentiality (conference call/video system) is needed.”
- “Further national discussion is needed concerning uniform criteria and standards in disclosure and privacy of case information provided by health departments to the public.”
- “The federal government should clarify regulations regarding patient privacy and provide education for PIOs and media staff.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Laboratory Services Capacity

**Issue:** **B.3 The H1N1 response strained the laboratory capacities at the federal and state level. States’ and laboratory capacities need sustained funding.**

**Issue Type:** Policy

**Level:** Federal and State

**Discussion:** *H1N1 Stressed Capacities*  
Laboratory testing capacity was a concern at the state and federal level. For some states, laboratories were unable to keep up to date with processing specimens. It was observed that “this had a negative impact on surveillance, slowed down states’ abilities to correctly identify and describe the extent of the disease in a timely manner, and rendered states unable to provide needed support to local health departments.”

One respondent noted that: “CDC’s backlog in the testing laboratory in the beginning of the epidemic caused delays in diagnosis and undue public concern. Some state public health laboratories were ready to perform the appropriate testing within hours of receiving the kits from CDC, but had to

wait over a week to receive authorization from CDC to use the kits.” Other states also noted that backups and delays at CDC’s laboratory hindered response activities. One jurisdiction without adequate public or private laboratory capacity “had to await testing results from CDC.”

Another state noted: “the lack of electronic test reporting capabilities contributed to delays in reporting and analyzing epidemiological data. The process of reporting data manually is exhaustive and time consuming. This issue led to delays in reporting real-time results and characterization of the H1N1 pandemic.”

*Sustained Investment in Capacities*

State procurement and contracting processes conflicted with timeframes established by federal cooperative agreements, thereby delaying the purchasing of laboratory equipment and supplies, and hiring of laboratory and epidemiology personnel.

**Mitigation Strategies Employed:**

- “Used epidemiology staff as a gatekeeper to prioritize testing samples to address the demands on public health laboratories.”
- “Where possible, purchased equipment through state contract vendor. Other equipment purchases are being attempted through departmental processes.”

**Recommendations Suggested:**

*Addressing Stressed Capacities*

- “Explore the use of pre-staging laboratory activities in more than one laboratory in the country.”
- “Consider making CDC laboratory test kits available to at least a subset of trusted private partners to increase laboratory surge capacity and overall sentinel surveillance capacity.”
- “Develop better clinical guidelines and clinician education on which patients to test to reduce the testing burden on laboratories and target testing to public health needs.”
- “Communication and cooperation with private laboratories is critical to a comprehensive understanding of the outbreak and a successful response.”

*Sustaining Capacity*

- “Secure sufficient and sustained funding to improve laboratory capacity to ensure more timely results and the ability to maintain a high level of testing, if necessary; this is especially critical in the territories.”
- “The federal government should fund and expand electronic reporting capabilities nationally.”

- “Funding restrictions were a barrier to H1N1 response at state public health labs. Provide more flexible funding guidelines to maximize and plan for workforce capacity issues as needed.”
- More research is needed to produce national standards (case definition and which other elements should be reported) for syndromic surveillance. Funding is needed for states to implement those standards with laboratory capability.

[Sources:                      Survey: X                      Meetings: X                      Environmental Scan: X                      ]

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## III.C Medical Care and Countermeasures

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### **Summary of Barriers Identified**

The primary barriers identified related to medical care and countermeasures were (numbering does *not* reflect a priority order for the barriers):

- C.1 Allocation, Priorities and Guidance**—Federal and state approval processes for guidance on medical countermeasures and gaps in information in guidance limited their distribution and utility during the response.
- C.2 Stockpiles, Inventory Management and Supply Chain**—Federal stockpiling decisions affected supply chains of key medical countermeasures, raising doubts about the ability of just-in-time supply mechanisms to respond to a widespread public health emergency.
- C.3 Stockpiles, Inventory Management and Supply Chain**—States had difficulty assessing the status and location of supplies of medical countermeasures because of limits on their ability to access information about private supply chains.
- C.4 Stockpiles, Inventory Management and Supply Chain**—Uncertainty over the ownership status of surplus medical countermeasures distributed from the SNS left states unable to deploy and use these materials quickly.
- C.5 Stockpiles, Inventory Management and Supply Chain**—The lack of closer federal/state consultations about the types of SNS assets distributed to states hindered the effectiveness of those assets during the response.
- C.6 Administration and Dispensing Sites/Practices**—States were uncertain about dispensing countermeasures to federal employee populations, fees for dispensing countermeasures, and the use of federal stockpile antivirals for prophylaxis.
- C.7 Tracking, Coverage and Adverse Events Reporting**—Data elements and systems necessary to assess the use and potential adverse effects of federal countermeasures stockpiles must be better defined, especially for determining if countermeasures are being equitably distributed to the vulnerable populations.
- C.8 Recovery, Destruction and Disposal**—States are concerned over the impending confusion and cost of recovering and disposing of expired and surplus countermeasures.
- C.9 PPE Mask Guidance**—Delays and conflicts in federal guidance on respiratory protection led to confusion, caused shortages in supplies, and delayed the release of state and local stockpiles.
- C.10 Emergency Use Authorizations**—Health care providers’ resistance to emergency use authorization (EUA) products may be limiting providers’ willingness to offer them to



patients. Information supplied to patients with EUA products may not ensure that informed consent is obtained.

- C.11 Medical Equipment Supplies and Tracking**—Alterations in the scope and frequency of HHS requirements for National Hospital Available Beds for Emergencies and Disasters (HAvBED) System reporting caused frustration and confusion among states, hospitals and vendors.

## ***Selected Successes/Mitigations Identified***

### *Medical Care and Countermeasures Generally*

- “The manufacture and delivery of the vaccine were well executed.”
- “New relationships/partnerships were established with pharmacies statewide.”

### *Medical Care and Countermeasures Guidance*

- “Once approved, federal and state clinical and countermeasures guidance was distributed widely via the state portals to health care providers and the state health agency website.”
- “As federal and state clinical and countermeasures guidance evolved, the state health agency began highlighting just the changes in lengthy documents, so that providers could quickly assimilate the new information.”
- “As guidance evolved, the state health agency began highlighting just the changes in lengthy documents, so that providers could quickly assimilate the new information.”
- “Convened a work group of public, private and academic experts to review and inform the health agency’s development of recommendations regarding infection control, treatment, and testing.”
- “Formed an influenza policy coordinating committee to draft guidance for addressing shortages of countermeasures in medical settings (including the use of N-95 masks).”

### *Supply Chain, Stockpiles and Distribution*

- “The SNS/state stockpile was used efficiently and local SNS receipt and distribution were well executed.”
- “The state developed and implemented a strategy for distributing the available SNS assets to the local jurisdictions.”
- “The direct delivery of vaccine to providers and pharmacies allowed efficiencies in transportation and workload during the event.”
- “One state worked with its hospital association and regional government and response organizations to make a bulk purchase of surgical masks that were then delivered to facilities experiencing supply shortages. The state health agency continued to monitor the situation until the pandemic became less severe and demand for these supplies lightened. However, had the pandemic continued and/or become more severe, managing the supply chain issues would have been a major problem.”
- “Personnel were dedicated to contacting every pharmacy in the state weekly to ascertain their antiviral stock levels and projected supply replenishment dates.”
- “As expiration dates came very close, some antivirals were distributed so they could be used before expiration.”

### *Administering Countermeasures*

- “Establishing practice standards and protocols to allow paramedics assisting local health departments administer vaccine were helpful.”
- “Private and chain pharmacies, and some FQHCs were provided with a cache of antivirals for under- and uninsured individuals; individuals were taken at their word if they stated they had no insurance.”
- New effective relationships and partnerships were established with pharmacies statewide. Private and chain pharmacies, and some FQHCs were provided with a cache of antivirals for under- and uninsured individuals. Individuals were taken at their word if they stated they had no insurance.”

### *N95s/PPE*

- “The state health agency published recommendations to use N95 masks for healthcare workers when performing aerosol-generating procedures.”
- “The state health agency worked with the state occupational health agency to declare an N95 shortage, thereby allowing the flexibility to prioritize the use of N95 masks.”
- “State had hospitals’ preferred N95 brands stockpiled in state cache due to prior surveying of hospitals.”
- “State health agency staff worked closely with over 750 nursing homes throughout the state to develop respiratory protection plans for staff.”

### *N95 Guidance Issues*

- “In the absence of a clear federal policy, our state health department issued our own policy, which more closely followed the WHO policy and took into account the known science, the reality of limited PPE supply, and CDC’s insistence that in most cases it was not necessary to distinguish between seasonal influenza and H1N1.”
- “The state health agency developed a series of recommendations that allowed for a greater level of discretion in the use of N95 masks. The state recommendations were based upon emerging evidence about the efficacy of surgical masks and the recognition that it had proved impracticable to follow the CDC guidance.”
- “The state reviewed and assessed, but did not use federal guidance. Instead it based its guidance on local epidemiology/circumstances.”
- “Risk assessments, policies and a massive fit-testing effort were rolled out to support the October 14th CDC recommendations. In the absence of clarity in the recommendations, and after heated discussion, the state health agency decided to require that anyone within 6 feet of a symptomatic patient would be required to wear a particulate respirator whether or not the symptomatic individual was masked.”
- “All the state health agency could do was point providers and employers to the most recently published federal guidance and reports. It did not attempt to provide a state recommendation due to the uncertainty surrounding the guidance and because of reports from other states that health facilities were being cited by OSHA for following a state-level recommendation and not CDC’s.”
- “Working with the state associations and the state’s health care regulatory agency, the health department developed new relationships that helped during the H1N1 response and will help in the future to work through these issues together. The delay in OSHA’s response to H1N1 N95 issues was seen as both a problem and a blessing: although uncertainty abounded, the bulk of the disease was gone before it was time to enforce the stricter rules that most did not want to adhere to.”

### *N95 Supply Issues/Shortages*

- “When the Strategic National Stockpile released millions of N95 respirators to be used in case of shortage, the public health agency had to create a process to work with the healthcare system to disseminate them in a fair and equitable manner. They also needed to work with the state labor/occupational health agency and several associations representing healthcare workers to ensure they were used per the federal guidance.”
- “The health agency worked closely with the state’s occupational safety and health agency to determine how hospitals could document if PPE was in short supply and even provided some facilities with state PPE stock, in order for them to meet federal guidance.”
- “State health department advised hospitals to use their best efforts to obtain N95s, and to carefully document supplies on hand, orders placed, etc. in order to defend against any future non-compliance action.”
- “The state surveyed hospitals two years ago to determine the brand of respirator they purchased. This brand was purchased for the state’s emergency response cache. When the SNS assets were deployed to the state, a percentage was placed in the state’s cache, and a corresponding percentage of the state assets (the preferred brands identified earlier) were distributed to hospitals.”
- “The state health agency developed a procedure/protocol for the healthcare facilities to utilize for requesting PPE. As part of the campaign rollout, an educational webinar was developed and offered which discussed the stockpile, hierarchy of controls and determinants for filling requests, education of SNS inventory management and ordering, and shipping information. These sessions were repeated five times to give hospitals/healthcare facilities ample opportunity to participate. Webinars were recorded and offered at later dates as well.”

### *Medical Equipment Tracking*

- “The state health agency requested hospitals to respond to both the HHS situational awareness report and the HAvBED requests.”
- “The HAvBED working group, formed by ASTHO, sent a letter and consensus documents, which were created in response to the new HAvBED data elements and consensus of operations (CONOPS) document, to HHS. The work group made recommendations on the HAvBED data elements and the CONOPS document, which contained both general comments as well as suggested revisions.”
- One state agency “provided health care facilities with templates designed to make reporting easier.”
- “Health agency executive management worked directly with LEMSAs and state hospital associations’ leadership to identify issues, delineate the appropriate reporting relationships, and reduce confusion and friction associated with the federal reporting requests.”

### *Emergency Use Authorizations*

- “The agency provided documentation of the Emergency Use Authorization and the FDA-approved fact sheets with each order the health agency shipped.”
- “Placed the EUAs, fact sheets and guidance on the state’s web site and communicated this information on the health agency’s weekly webcasts to partners.”

### *Alternate Care Sites*

- “The functional use of temporary triage shelters in hospitals was also identified as a benefit.”

## Waivers/EMTALA

- “The waiver process for temporary expansion of hospital bed space was effectively distributed by state health services regulatory agency.”

## **Barriers/Recommendations Identified Detail**

*[Please note that the sections below apply to all medical countermeasures (antivirals, personal protective equipment (PPE), medical supplies) with the exception of vaccine, which is addressed in Section III.D. Issues related specifically to PPE N95 guidances and supplies are addressed separately as identified below.]*

### **Allocation, Priorities and Guidance**

**Issue:** **C.1 Federal and state approval processes for guidance on medical countermeasures and gaps in information in guidance limited their distribution and utility during the response.**

**Issue Type:** Federal; State

**Level:** Policy

**Discussion:** *Medical Countermeasures Guidance*

States noted that “federal and state approval processes for guidance on medical countermeasures slowed their distribution of these guidances to clinicians.” One respondent observed that “clinical guidance from CDC was delayed at the federal level, with little information on the content and timeframe for release.” Another person noted that “the release of guidance was also slowed at the state level by the excessive length of time it took for review and approval, especially when executive-level approval was required from more than one agency.” It was felt that “state processes slowed the release of important information to clinicians in a timely manner, causing clinicians to rely on CDC guidance rather than on more state-specific guidance.”

- *Guidance for using antivirals from the SNS:* Federal guidance was not provided as to the appropriate use of the antivirals received as part of the SNS. One respondent noted that “guidance from CDC for treatment was excellent; however, guidance on how and when to use the stockpile was absent.” One state noted that “persons who were under- and uninsured may not have received treatment in a timely manner due to the lack of federal guidance regarding permitted recipients for stockpiled antivirals.” Another noted that “conflicting guidance for the use of antiviral prophylaxis left staff and the public confused.”
- *Intravenous antivirals/severe case guidances:* A respondent believed that: “The federal government provided slow and insufficient guidance on the use of intravenous (IV) antivirals and the management of severe

H1N1 cases. The issuance of the EUA for Peramivir was needed much sooner than it was provided. Additionally, alternate IV antivirals were needed if viral resistance developed. The state health agency was unable to provide recommendations to physicians on effective treatment and management of severe/life-threatening cases of H1N1, where oral and inhalational antivirals were not effective options (e.g., severely ill patient on ventilator).”

- *Determining alternative standards of care for MCMs:* The issue of alternative (or “alternate” or “crisis”) standards of care was also raised. As one agency observed: “With vaccine being sent primarily to local health departments because of initial short supplies and federal directives to hold local vaccination clinics, because physicians in medical care settings were not getting H1N1 vaccines, these practitioners were not being optimally used and were not equipped with supplies available in the community.” Concerns were raised that policy decisions seemingly directing vaccine away from providers in essence created an alternative standard of care for health care providers.

**Mitigation Strategies Employed:**

*MCM Guidance*

- “As guidance evolved, the state health agency began highlighting just the changes in lengthy documents, so that providers could quickly assimilate the new information.”

*Intravenous Antivirals/Severe Case Guidances*

- “Convened a work group of public, private and academic experts to review and inform the health agency’s development of recommendations regarding infection control, treatment, and testing. However, this group could not address provider questions on clinical management of individual cases of severe/life-threatening disease. Instead the health agency queried the few infectious disease physicians employed by the agency, as well as the Emerging Infections Network (EIN) of the Infectious Diseases Society of America. Members of the EIN were able to offer some guidance to clinicians about awareness and management of severe H1N1 cases, but they were unable to offer guidance on alternative antivirals to treat those cases.”

*Determining Alternative Standards of Care for MCMs*

- “Formed an influenza policy coordinating committee to draft guidance for addressing shortages of countermeasures in medical settings (including the use of N-95 masks).”

**Recommendations Suggested:**

*Medical Countermeasures Guidance*

- “Federal clinical guidance should be developed and disseminated more rapidly.”
- “State guidance approval processes should be streamlined to expedite information release to clinicians during public health emergencies.”

### *Guidance for Antivirals*

- “CDC should develop, standardize, and communicate consistent reporting policies for antiviral doses administered to states to ensure that those policies are in place before a public health emergency.”
- “Deploy antivirals as appropriate to pharmacies and health centers much earlier in an event; develop protocols and policies for community members to access the medication.”
- “Maintain and strengthen relationships with private and chain pharmacies.”

### *Intravenous Antivirals/Severe Case Guidances*

- “The nation could benefit from something akin to the Advisory Committee on Immunization Practices (ACIP), but for medical countermeasures. Such a group (an advisory committee on medical countermeasures or “ACMC”) would follow the ACIP model in structure and methods. The group would meet on a regular basis to review the latest evidence and make or update recommendations on medical countermeasures for biological, chemical and radiological events (natural or man-made). Rather than providers having to search for medical countermeasure recommendations from multiple, possibly not current, and possibly conflicting sources, the ACMC would provide the definitive and most current guidance for the nation.”

“Perhaps unlike ACIP, this group would also evaluate and recommend medical countermeasures not yet FDA approved, but in the latter stages of clinical trials, thereby offering emergency alternatives when there are no, or only inadequate, FDA-approved countermeasures. The group would develop standing EUAs for non-approved products (including those appropriate for use in pediatric and pregnant populations) that could be rapidly issued by the FDA in an emergency. The ACMC evaluations and recommendations would help drive consensus on policy and funding decisions related to research and development, and manufacturing of medical countermeasures.”

### *Determining Alternative Standards of Care for MCMs*

- “Federal and state agencies should work more closely with practitioners and the health care industry to reach agreement about countermeasures, who they apply to and when, as well as decisions around allocation decisions when MCMs are in short supply.”

[Sources: Survey: X Meetings: X Environmental Scan: ]

## Stockpiles, Inventory Management and Supply Chain

- Issues:**
- C.2 Federal stockpiling decisions affected supply chains of key medical countermeasures, raising doubts about the ability of just-in-time supply mechanisms to respond to a widespread public health emergency.**
  - C.3 States had difficulty assessing the status and location of supplies of medical countermeasures because of limits on their ability to access information about private supply chains.**
  - C.4 Uncertainty over the ownership status of surplus medical countermeasures distributed from the SNS left states unable to deploy and use these materials quickly.**
  - C.5 The lack of closer federal/state consultations about the types of SNS assets distributed to states hindered the effectiveness of those assets during the response.**

**Issue Type:** Policy

**Level:** State; Federal

**Discussion:** *Strategic National Stockpile (SNS) Ordering*  
States indicated that “the required data elements and process for resupplying antiviral medications from the SNS were not clearly outlined.” State health agency staff “spent valuable time answering data questions multiple times when information was submitted after the first request.” When one state experienced a commercial shortage of antiviral medications (as validated by wholesale distributors, retail pharmacies and local communities), the state felt “it was difficult to convince federal authorities the shortage existed.”

### *Supply Chain Visibility and Capacity*

- *Pharmacy supply chain visibility:* States identified the need for better supply chain visibility of antiviral stocks and dispensing through pharmacies. During the initial outbreak of H1N1 influenza, there was a shortage of antivirals in the pediatric formulation. A state noted that: “Often patients would have to go to multiple pharmacies to find one that had the antivirals in stock. This was particularly concerning for high-risk children because the pediatric formulation was in shorter supply than the adult formulation.”
- *Supply chain capacity:* States expressed concerns over “the ability of health care facilities to procure adequate amounts of medical supplies via commercial chains and the ability of commercial supply chains to produce ample supplies during a more significant pandemic event than H1N1 turned out to be.” There was a perception that the “federal

government purchased mass quantities of medical supplies for the SNS, which caused a supply shortage leading to a prolonged delay for health care facilities to obtain their standard supply of medical care items (i.e., sanitizer, surgical masks, N95 masks, bandages, syringes, etc.).” It was also reported that, because of supply shortages, “health care facilities experienced price gouging on items that were in limited quantity.”

#### *Inventory Management*

States believed that they “held antivirals in state stocks too long as they waited for the subsequent waves of the H1N1 pandemic to materialize.” This gave rise to the concern that some antivirals went/will go unused.

States encountered barriers when they tried to share SNS assets between states. One state reported: “Policies pertaining to interstate transportation of pharmaceuticals are very unclear. If SNS pharmaceuticals arrive in one state, transporting them to another state is not allowed and presents a significant policy barrier. A neighboring state requested pharmaceuticals from our state; the distributor refused to ship them across the border.”

#### *Distribution of SNS Assets*

States frequently commented on barriers arising from the types, timing and use of SNS assets distributed to the states. One state characterized it as: “The distribution of SNS materiel without a state request resulted in the delivery of excess assets. Some SNS assets received at the state level were not matched with state needs and resulted in excess resources. The public health need would have been better served if they had queried the states prior to SNS distribution.”

Another state, one that agreed to take SNS assets, voiced a different set of concerns: “When CDC asked states if they would like a shipment of SNS assets early in the pandemic, the state felt compelled to request these assets. However, the SNS assets became a burden when the PHER funds did not carryover and the state had to provide funding for management, transportation, and storage.”

#### *Ownership of Medical Countermeasures*

States expressed uncertainty about the ownership of federal medical countermeasures and assets sent to them such as antivirals, PPE, respirators, vaccine and ancillary supplies. Some states voiced ongoing questions about perceived “inconsistent answers about the ownership of those assets once they have been distributed to the states.” Specifically, states “needed to understand if they had to continue to treat the asset as a federal asset, a federal asset now in the possession of the state, a state or local asset once it was delivered, or something else.”

As one respondent noted that “the lack of clear answer made it difficult to know what decisions a state or local government could make regarding the materials once the state/local had taken possession of them.” States expressed that their ultimate desire was to “repurpose distributed medical countermeasure to avoid expiration, wasting, and disposal issues.”



**Mitigation  
Strategies  
Employed:**

*Strategic National Stockpile (SNS) Ordering*

- “After a period of time, additional Tamiflu oral suspension was pushed to all states when the shortage in commercial supplies was finally noted at the federal level. This resulted in many local communities in the states experiencing shortages early during the outbreak, but they were not resupplied for up to four weeks from the stockpile.”

*Pharmacy Supply Chain Visibility*

- “Personnel were dedicated to contacting every pharmacy in the state weekly to ascertain their antiviral stock levels and projected supply replenishment dates.”

*Supply Chain Capacity*

- “One state worked with its hospital association and regional government and response organizations to make a bulk purchase of surgical masks that were then delivered to facilities experiencing supply shortages. The state health agency continued to monitor the situation until the pandemic became less severe and demand for these supplies lightened. However, had the pandemic continued and/or become more severe, managing the supply chain issues would have been a major problem.”

*Inventory Management*

- “As expiration dates came very close, some antivirals were distributed so they could be used before expiration.”

**Recommendations  
Suggested:**

*Strategic National Stockpile (SNS) Ordering*

- “The federal government needs to: (1) clearly define the data it needs from states when requesting additional materials from the stockpile; (2) identify the timeline for receipt of order and response to the state; (3) maintain better communications with the state during the process to avoid duplication and to reduce the time between request and response; and, (4) make tools (such as a dashboard) available to SNS coordinators for managing stockpile assets.”

*Pharmacy Supply Chain Visibility*

- “Establish a federal-level system for monitoring stock levels of a specific set of pharmaceuticals such as antivirals and antibiotics in national corporate pharmacy chains. This information should be given to states at the regional level so that providers can be advised of stock levels on at least a regional basis.”

*Supply Chain Capacity*

- “SNS supplies should be purchased in advance of an emergency, rather than essentially limiting the national supply chain in the midst of an emergency. If medical supply providers continue just-in-time manufacturing, there will always be medical supply shortages during nationwide emergencies such as pandemics. If the federal government

drains available medical supplies when purchasing for the SNS, this defeats the SNS's primary purpose. Further, it causes an extra loop in the supply chain process for health care facilities; during an emergency, they are unable to obtain supplies through clogged supply channels and then are forced to go through SNS."

#### *Inventory Management*

- Regarding the interstate sharing of SNS assets, a state noted: "Although this barrier involves state laws, a federal policy that allows for SNS assets, including pharmaceuticals, to be transported across state borders would be very helpful in the coordination and implementation of response efforts. This policy should provide clear guidance on pharmaceuticals and medical devices, and could be part of the emergency declaration from the president."

#### *Distribution of SNS Assets*

- "The CDC policy for distribution of SNS assets to states should be more metered, thereby allowing more time for additional epidemiological analysis to better characterize what types of SNS assets are necessary."
- "Distribute assets based on needs through formal state requests following the established Division of Strategic National Stockpile (DSNS) protocol."
- "More accurate information regarding SNS delivery and disposal is recommended. The policy should be that SNS materials are delivered during business hours unless an emergent need is identified."
- "Allow dispensing of SNS products from non-traditional service providers during an event."
- "Develop policies and guidance on SNS disposal."
- "Clarify Receipt Stage and Storage Site (RSS) protocols."
- "The federal government should develop and implement policies regarding the use of SNS resources once delivered. These policies may need to be revised or specialized for each incident."
- "The state should develop policies regarding shipment of SNS resources to local receiving sites that are appropriate to the level of urgency of need."
- "Allow the use of National Guard staff, paid for by federal funds, to increase surge capacity for law enforcement during large national events requiring the distribution of SNS assets."

#### *Ownership of Medical Countermeasures*

- "A clear definition needs to be established by the federal government

regarding the designation of each federal asset that is delivered to the state. It should be specified if the materials are still considered to be federal assets and therefore must be treated in a certain way, or, if once it is released to the state or local entities, no federal involvement remains.”

[Sources: Survey: X Meetings: X Environmental Scan: ]

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## Administration and Dispensing Sites/Practices

**Issue:** **C.6 States were uncertain about dispensing countermeasures to federal employee populations, fees for dispensing countermeasures, and the use of federal stockpile antivirals for prophylaxis.**

**Issue Type:** Policy; Legal

**Level:** Federal

**Discussion:** *Administering MCMs to Federal Employees*  
Federal and state agencies need to better coordinate the identification of federal employee populations within each state and clarify how countermeasures will be provided to these populations. A state observed that “federal agencies need to reach out to states and locals to ensure they are accounted for in medical countermeasure plans.”

*Payment/Reimbursement Issues*  
States raised questions about their ability to allow MCM dispensers to charge a small fee to cover the cost of MCM dispensing. It was noted that “state legal counsel need to clarify if it would violate the federal Stark Act anti-kickback law if a physician were to charge a dispensing fee if they had also prescribed the MCM.”

*Exploring the Use of Antivirals for Prophylaxis*  
Some states expressed interest in “exploring the implications of expanding the use of stockpiled antivirals for post-exposure prophylaxis versus reserving them strictly for treatment purposes.” However, others noted that “it is feared that there will not be enough supply for those who really need antivirals.” One respondent concluded that “some believe that, although federal guidance says stockpiled antivirals are to be used for treatment only, at some point if the disease is severe enough, it will be appropriate to use them for post-exposure prophylaxis.”

**Mitigation Strategies Employed:** None identified

**Recommendations Suggested:**

*Administering MCMs to Federal Employees*

- “State and local health agencies should work with federal agencies to clarify the number of federal workers, contractors, and family members to be covered by federal continuity of operations plans (COOP) versus those covered as part of the general population of the jurisdiction. They should also clarify who will be responsible for administering the assets as well as assuring that assets are used according to recommended clinical guidelines.”

*Payment/Reimbursement Issues*

- “Clarify whether states can allow dispensers of MCMs to charge a small fee covering costs of dispensing MCMs like vaccine or antivirals.”
- “Clarify whether the Stark Act would be violated if a physician were to charge a dispensing fee while acting as both prescriber and dispenser.”

*Exploring the Use of Antivirals for Prophylaxis*

- “The federal government and the states should begin to explore issues surrounding the potential use of stockpiled antivirals for prophylaxis, including where such use should be limited to post-exposure scenarios or would also include prophylaxis of the general population.”

[Sources: Survey: Meetings: Environmental Scan: X ]

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## Tracking, Coverage and Adverse Events Reporting

**Issue:** **C.7 Data elements and systems necessary to assess the use and potential adverse effects of federal countermeasures stockpiles must be better defined, especially for determining if countermeasures are being equitably distributed to the vulnerable populations.**

**Issue Type:** Policy

**Level:** State

**Discussion:** *Tracking the Use of SNS Assets*  
States raised questions about the level of tracking required for SNS assets and the types of information that must be tracked. One respondent noted that “it is unclear whether SNS assets must be tracked to the patient level; states tracked assets to varying degrees.”

*Tracking Access to Antivirals by Special and Vulnerable Populations*  
There should be a way to determine if stockpile assets were distributed in an equitable way. States expressed concern that “under- and uninsured individuals will lack access to antivirals if the primary mode of distribution is through private providers.” Because these populations do not have

insurance or cannot afford treatment, “this causes distinct equity issues for those who may need antivirals.”

One state related that it had: “No process for local health departments to use the stockpile for under- and uninsured individuals. As a result, the state waited too long to push out antivirals to pharmacies for these populations. At-risk populations who used CHC/FQHCs did not receive antivirals in a timely manner. CHC/FQHCs were frustrated with their inability to access medication for their patients quickly and easily.”

*Tracking Efficacy and Harm of Antivirals*

State health officials acknowledged that “antiviral drugs have never been used on this scale before, so it will be important to track their efficacy and harm.” Data is also needed to determine if those taking antivirals received benefits from them. States believe that “there should be crucial clinical information about antivirals’ efficacy and/or harm that emerges from the H1N1 outbreak” which can be used to inform future decision making.

**Mitigation Strategies Employed:**

*Tracking Access to Antivirals by Special and Vulnerable Populations*

- “New effective relationships and partnerships were established with pharmacies statewide. Private and chain pharmacies, and some FQHCs were provided with a cache of antivirals for under- and uninsured individuals. Individuals were taken at their word if they stated they had no insurance.”

**Recommendations Suggested:**

*Tracking the Use of SNS Assets*

- “CDC should clarify whether states are required to track SNS assets to the patient level.”
- Options identified for tracking SNS included: “1) tracking vaccinated children through existing immunization registries; 2) tracking immunized adults in order to know who has received a first dose if two doses are recommended (some states track antivirals this way); and 3) tracking health care workers, including volunteer emergency workers, who receive immunization.”

*Tracking Access to Antivirals by Special and Vulnerable Populations*

- “Deploy antivirals as appropriate to pharmacies and health centers much earlier in an event; develop protocols/policies for community members to access the medication.”
- “Maintain and strengthen relationships with private and chain pharmacies.”

[Sources: Survey: Meetings: X Environmental Scan: X ]

## Recovery, Destruction and Disposal

**Issue:** **C.8 States are concerned over the impending confusion and cost of recovering and disposing of expired and surplus countermeasures.**

**Issue Type:** Policy; Legal

**Level:** Federal; State

**Discussion:** States' discussions about the recovery, destruction, and disposal of MCMs have focused so far on vaccine issues. See "Recovery, Destruction and Disposal" discussion in Section III.D, "National Vaccination Campaign."

**Mitigation Strategies Employed:** See "Recovery, Destruction and Disposal" discussion in Section III.D, "National Vaccination Campaign."

**Recommendations Suggested:** See "Recovery, Destruction and Disposal" discussion in Section III.D, "National Vaccination Campaign."

[Sources: Survey: X Meetings: Environmental Scan: X ]

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## PPE Mask Guidance

**Issue:** **C.9 Delays and conflicts in federal guidance on respiratory protection led to confusion, caused shortages in supplies, and delayed the release of state and local stockpiles.**

**Issue Type:** Policy; Legal

**Level:** Federal; State

**Discussion:** *Guidance*  
States' views were in consensus about balancing between the need for guidance based on sound evidence/revising the guidance as more information about the nature of the outbreak became available with practical implementation and response issues.

- *Guidance concerns/conflicts:* There were conflicting opinions as to the level of personal protective equipment required (N95 or surgical mask) for healthcare workers in the H1N1 response. States cited a range of potential guidances from CDC, OSHA, NIOSH, IOM, state health and occupational agencies, and even some from local health agencies

One state observed that: “The CDC recommendation that hospital staff treating suspected or confirmed cases of H1N1 use N95 masks was based in large part upon the recommendations of a committee formed by the Institute of Medicine (IOM), which did not consider issues associated with cost and logistics during their deliberations. At the time, there was inconclusive information associated with the relative benefits of N95 and surgical masks. IOM’s conservative recommendation reflected this lack of information. CDC used this recommendation as the foundation of their direction to the states despite the availability of conflicting opinions about the relative efficacy of these two options.”

Some states issued their own guidance addressing the N95 mask issue. Other states were not comfortable providing doing so. One state health agency noted that, while it “felt very comfortable providing general infection control guidance, it is not the agency regulating healthcare settings and therefore was not comfortable providing N95 guidance.”

States believed that “the indecision and uncertainty with the N95 guidance hindered planning and response activities.” Some states noted that there was “a lack of definitive clinical or other scientific data regarding mode of transmission and the effectiveness of facemasks vs. N95 respirators for healthcare and other at-risk workers.” A respondent observed that “health agencies were placed in the position of having to delay policy and procedure development, and postponing efforts involved in implementing statewide fit-testing programs as the clinical/scientific issues were resolved.”

The range of guidances and conflicts/inconsistencies among them left health care and other affected organizations wondering which guidance to follow (OSHA, CDC, IOM, state health departments, etc.). One person stated that “even if an organization followed CDC/state health guidance, it was not clear to states or health care providers whether OSHA was adopting any of these guidances as an employee health requirement or what would be the result if a provider adhered to a state guidance that was different than CDC's.”

- *Logistical and practical considerations:* Some states believe that “economic and logistical concerns (i.e., affordability and availability of N95 masks) did not seem to be taken into consideration when CDC created the mask guidance.”
- *Labor/employer issues:* Some saw that “the CDC recommendation put many organizations in awkward positions with employees and their unions who insisted that they comply with the N95 recommendations.” Other states wondered “how to encourage health care responders to continue showing up for work if they are not provided proper protection.” These states viewed it as “the duty of employers to ensure their workers are protected with specified PPE.”

- *Enforcement/legal uncertainties:* Conflicts among CDC, OSHA and state health and occupational directives/guidances on PPE/N95 masks raised concerns among providers about potential enforcement and other liabilities. It was noted that “hospitals and other institutions were concerned that OSHA could potentially penalize them for following their states’ PPE recommendations if they conflict with OSHA’s or other federal guidance on worker safety (e.g., NIOSH).” There was also concern raised that “lack of compliance with NIOSH recommendations, even when not officially adopted by OSHA, may give grounds for private litigation if a worker or patient is injured, especially if the institution has received an OSHA violation notice.” It was suggested that “better alignment between CDC and OSHA would reduce both confusion and legal risk for state and local health systems.”
- *Messaging/credibility concerns:* States encountered challenges with messaging effectively to/from key stakeholders, front line clinicians, hospitals regarding practice standards as mask guidances evolved and CDC/OSHA conflict issues arose. Some state respondents believe that “the length of time it took to resolve these issues and the confusion that was involved resulted in some credibility concerns regarding the guidance that was being proffered by CDC.”

Another state noted that “states with state OSHA programs had the flexibility to make policies less restrictive than federal OSHA guidelines, but this caused confusion in states with media outlets that covered multiple states.”

#### *Supply Issues/ Shortages*

The requirement to use N95 respirators for H1N1 resulted in supply shortages and required extra time and resources by providers using SNS-supplied N95s.

- *Inability to implement guidance:* States felt that “there was no way to operationalize or implement the CDC guidance standards given the supplies of N95 masks available.” Some expressed that “there was no need to have such restrictive standards given the nature of the H1N1 disease; the N95 guidance caused unnecessary confusion and complexity for health care providers.”
- *Types of respirators:* A respondent commented that: “N95 respirators from the federal stockpile were boxed and shipped by size and manufacturer, but health agencies would receive a mixture of different sizes from different manufacturers (e.g., Brand A in small and large only; Brand B in med-large only; Brand C in medium only). This made it difficult to provide the sizes and brands that hospitals regularly used. If hospitals could not get the brands/sizes to which their employees had been fit-tested, hospitals would have to fit-test to the new brands/sizes.”

In some states, “hospitals did not want to accept the federally-supplied



respirators from the SNS, as these were not approved for surgical settings.”

- *Fit-testing issues:* Early in the pandemic, there was confusion regarding the requirement for fit-testing of N95 masks obtained through the SNS. As one state noted, “healthcare facilities wanted to remain in compliance with NIOSH, but the protocol/guideline was not firmly established at the outset.” Another state noted that: “Had the health agency shipped hospitals a new type of respirator from the SNS that the hospital does not currently use, the hospital would have been forced to refit all of their employees. Because fit-testing takes about 30 minutes for each employee; this could have caused a serious delay in services for some healthcare systems with thousands of employees. Thus, this was not a realistic expectation to put on healthcare facilities.”
- *Distribution/supply chain issues:* States experienced significant challenges with the N95 mask supply chain throughout the pandemic response. State and local health agencies did not know what brands of PPE were in the stockpile.

Some states believed that: “CDC’s guidelines and the possibility of government purchasing a majority of manufactured N95 respirators caused a shortage of N95 respirators in hospitals. N95 manufacturers were unable to keep pace with the demand creating a huge backlog of orders and the exhaustion of local supplies. As local public health and health care facilities endeavored to comply with the CDC, they purchased a variety of makes and types requiring a new round of fit-testing for facilities receiving masks other than their usual brands.”

One state observed that: “Mid-way through distribution planning for N95 masks, CDC guidance with the hierarchy of controls was released, which made it difficult to change distribution plans to take the controls into account. It was also difficult to interpret and communicate the requirements that healthcare providers/hospitals had to meet in order to receive SNS N95 materials. States had very little time to develop an educational campaign for healthcare facilities around the Hierarchy of Controls used for determining which facilities would receive N95s. This guidance was released at the peak of the season, and thus was not as effective in communicating the intent and purpose for using this method.”

- *Competing demands for respirators:* A number of states also voiced the need to consider other sectors and instances in which N95 respirators should be used. Because respirators are essential components of infection prevention and control strategies for airborne pathogens such as tuberculosis, a shortage of respirators “could put healthcare workers at increased risk in the event proper respiratory protection is unavailable for the care of patients infected with airborne-transmissible pathogens.” One respondent remarked that “as more N95 masks were used for

H1N1, it became increasingly difficult for public health and health care organizations to find sufficient supplies for treating patients with TB and other communicable diseases for which N95 use is essential.”

Another state observed that “there was a dedicated focus on health care workers in the deliberation over N95 uses and supplies, but the focus also needed to be expanded to other professions likely at risk from H1N1.” One state agency noted that “there are political ramifications and relationships with other entities that use N95s that must be taken into account; police and fire departments as well as organizations such as OSHA and SHEA should be consulted about N95 supply needs.” One health agency representative concluded that “N95s are needed to be prepared for all hazards, not just H1N1; the entire N95 cache should never be depleted.”

**Mitigation  
Strategies  
Employed:**

*Guidance Issues*

*A number of states reported developing their own N95 guidance, while others used CDC guidance with other mitigation strategies:*

- “In the absence of a clear federal policy, our state health department issued our own policy, which more closely followed the WHO policy and took into account the known science, the reality of limited PPE supply, and CDC’s insistence that in most cases it was not necessary to distinguish between seasonal influenza and H1N1.”
- “The state health agency developed a series of recommendations that allowed for a greater level of discretion in the use of N95 masks. The state recommendations were based upon emerging evidence about the efficacy of surgical masks and the recognition that it had proved impracticable to follow the CDC guidance.”
- “The state reviewed and assessed, but did not use federal guidance. Instead it based its guidance on local epidemiology/circumstances.”
- “Risk assessments, policies and a massive fit-testing effort were rolled out to support the October 14th CDC recommendations. In the absence of clarity in the recommendations, and after heated discussion, the state health agency decided to require that anyone within 6 feet of a symptomatic patient would be required to wear a particulate respirator whether or not the symptomatic individual was masked.”
- “All the state health agency could do was point providers and employers to the most recently published federal guidance and reports. It did not attempt to provide a state recommendation due to the uncertainty surrounding the guidance and because of reports from other states that health facilities were being cited by OSHA for following a state-level recommendation and not CDC’s. The agency was not in complete agreement with CDC’s recommendations, so it did not endeavor to

publicly support the guidance by recommending the use of N95s. However, the health agency did not offer an official recommendation or guidance on the N95 issue. The agency simply assured that partners and stakeholder were made aware of new information as it was released.”

- “Working with the state associations and the state’s health care regulatory agency, the health department developed new relationships that helped during the H1N1 response and will help in the future to work through these issues together. The delay in OSHA’s response to H1N1 N95 issues was seen as both a problem and a blessing: although uncertainty abounded, the bulk of the disease was gone before it was time to enforce the stricter rules that most did not want to adhere to.”

#### *Supply Issues/Shortages*

- “When the Strategic National Stockpile released millions of N95 respirators to be used in case of shortage, the public health agency had to create a process to work with the healthcare system to disseminate them in a fair and equitable manner. They also needed to work with the state labor/occupational health agency and several associations representing healthcare workers to ensure they were used per the federal guidance.”
- “The health agency worked closely with the state’s occupational safety and health agency to determine how hospitals could document if PPE was in short supply and even provided some facilities with state PPE stock, in order for them to meet federal guidance.”
- “State health department advised hospitals to use their best efforts to obtain N95s, and to carefully document supplies on hand, orders placed, etc. in order to defend against any future non-compliance action.”
- “The state surveyed hospitals two years ago to determine the brand of respirator they purchased. This brand was purchased for the state’s emergency response cache. When the SNS assets were deployed to the state, 30% were placed in the state’s cache, and 30% of the state assets (the preferred brands identified earlier) were distributed to hospitals.”
- “The state health agency developed a procedure/protocol for the healthcare facilities to utilize for requesting PPE. As part of the campaign rollout, an educational webinar was developed and offered which discussed the stockpile, hierarchy of controls and determinants for filling requests, education of SNS inventory management and ordering, and shipping information. These sessions were repeated five times to give hospitals/healthcare facilities ample opportunity to participate. Webinars were recorded and offered at later dates as well.”
- “Additional fit-testing for different models took place. Because of the relative mildness of this pandemic, the workarounds were manageable but still time consuming when attention to other pressing clinical matters was needed. Had H1N1 been a more fatal disease, this issue would have

potentially been one of life-and-death circumstance.”

**Recommendations  
Suggested:**

*Guidance*

*A number of states recommended that CDC needs to improve its process for evaluating the science behind N95 versus surgical masks:*

- “CDC needs to take a more in-depth look into the need for N95s. HHS/CDC should implement a more streamlined process to evaluate and respond to these types of technical issues during an outbreak event.”
- “Infection control measures/recommendations should match findings about the new virus, as suggested by SHEA, IDSA, and APIC. [The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Association for Professionals in Infection control and Epidemiology (APIC)]. Once it was discovered that the H1N1 virus was transmitted similarly to seasonal influenza, infection control recommendations should have been adjusted to match those of seasonal influenza.”
- “Federal guidelines should be adjusted as new information and evidence becomes available.”
- “Federal research needs to focus on providing an alternative to current N95 models; need to be easier to wear for longer periods of time. N95s with exhalation valves may be a better resource for now.”

*States found that CDC, OSHA/NOISH and the states need to define the distinctions and interplay among federal and state health and occupational directives. Consensus should be reached and publicized about which directives are mandatory and which are guidances only:*

- “Definitive guidance from OSHA is necessary. States and health care facilities need to know whether CDC guidance is truly just recommendations or regulations.”
- “CDC’s infectious disease branch should work with NIOSH and OSHA to clarify and resolve how CDC recommendations interact with OSHA safety requirements. OSHA should clarify how it will handle hospitals and other institutions that follow their states’ worker protection recommendations if those recommendations conflict with CDC recommendations.”
- “Clarify the relationship between NIOSH recommendations and OSHA safety requirements. Clarify interactions between federal law/guidance and state regulations. Clarify guidance for worker safety practices if official recommendations cannot be met (e.g., if the supply of N95 masks is inadequate).”

- “States need clarification whether OSHA will penalize hospitals/institutions that follow their states’ worker protection recommendations if they conflict with NIOSH or other federal guidance for worker safety.”
- “Federal policies need to be clear to allow border states to work together at all levels, including infection control procedures and requirements.

*States also recommended that federal agencies need to consider the practical and implementation aspects of their directives/guidance on PPE as well as the science supporting it:*

- “Assuming that the scientific evidence continues to show that surgical masks are effective against transmission of flu, new guidance should recommend their use, given that N95s are significantly more expensive.”
- “Recognizing that more data is always helpful, CDC should issue such policies like N95 earlier and take into account not only the available science, but also the realities of the supply situation.”
- “The federal entities should work together ahead of an event to strategize on decision-making and realistic rules to be instituted in an emergency situation whether it is a mild communicable disease or something more severe. Develop a process that is timelier in an emergency situation.”
- “Clarify respiratory protection policies early and ensure that necessary PPE is available to implement this guidance.”
- “Policy-makers should make every attempt to realistically consider the full range of practical management implications involved in the process of providing health care for large numbers of individuals.”
- “In the future, the federal guidance must weigh all of the available medical information as well as the practical and financial impact to the medical and public health systems.”
- “The guidance regarding use of PPE from OSHA and CDC was clear, but not compatible, and practical obstacles to implementing CDC guidance arose in many settings. Better alignment between CDC and OSHA would reduce both confusion and legal risk for state and local health systems.”

*In clarifying mask guidance, states recommended addressing the following key issues:*

- “Action items should include creating a list of activities N95 respirators should be reserved for, defining criteria for states to determine and declare a N95 shortage, and planning and estimating N95 respirators needed considering different priorities/situations.”

- “Federal survey should be conducted of the states to determine the preferred brands of assets used by hospitals; stockpile these in the SNS.”
- “Clarify guidance for worker safety practices if official recommendations cannot be met (e.g., if the supply of N95s is inadequate).”
- “Guidance must consider alternate standards of care for PPE. Although the public health system should not plan to have insufficient numbers of respirators, contingency plans should be made if this is the case. The goal should be to always try to get more if there is a shortage, even if alternate plans exist to address a shortage.”

*Supply Issues/Shortages*

- “CDC and the states need to define what is meant by a ‘shortage’ of masks and its use as a trigger for releasing stockpiles and implementing protocols to deal with shortage conditions.”
- “Federal contracts with PPE manufacturers should be strengthened to prepare for such supply chain disruptions during future public health emergencies.”
- “Provide the SNS supply with various brands and sizes so that correct supplies can be shipped to healthcare facilities, enabling them to avoid having to re-fit test employees.”
- “The CDC should survey the states to determine the brand preferred by hospitals in their hospitals, and stockpile these brands.
- “FDA-approved respirators should be purchased without an expiration date, so they would not need to be released under an emergency use authorization.”
- “CDC needs to inform states about the types of respirators that are stockpiled to ensure that personnel are fit-tested on the models that may be sent during a large-scale disease outbreak.”
- “Various healthcare providers, including EMS, should enhance their current PPE stockpiles, including N95s.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Emergency Use Authorizations (EUAs)

[Note this section applies to all MCM (vaccines, antivirals, PPE, etc.)]

**Issue:** **C.10 Health care providers' resistance to emergency use authorization (EUA) products may be limiting providers' willingness to offer them to patients. Information supplied to patients with EUA products may not ensure that informed consent is obtained.**

**Issue Type:** Policy; Legal

**Level:** Federal

**Discussion:** *Emergency Use Authorizations (EUAs) Generally*  
The H1N1 outbreak response represented the first time EUAs were authorized, and states generally found that the EUAs occurred quickly. The EUA web site was considered a useful resource by the states. Antiviral deployment, particularly under the EUA for intravenous Peramivir, was described by the states as having worked well.

### *Provider Resistance to EUA Products*

An EUA allowed for the use of shelf-life extended drugs that were not relabeled. However, a respondent noted that “some clinicians refused to dispense these drugs.” States voiced the need to “conduct outreach to providers about the safety of dispensing drugs that had been shelf life-extended though an EUA.”

States cited “confusion over the interplay between the PREP Act and EUAs for labeling and dispensing of SNS antivirals as causing delays in their distribution.”

### *Content and Format of EUA Patient Information Sheets*

State legal counsels noted that: “Information sheets provided to patients did not explain several facets of EUA drugs: (1) that the antiviral did not complete the standard FDA drug approval process; (2) liability protections provided by the PREP Act; and (3) processes for how patients can file for compensation for adverse effects.” State health agency attorneys are “concerned that patients may give consent without full disclosure, thereby raising a potential issue about whether the patient gave informed consent.”

Agency counsel also raised questions about the impact of translating EUA patient information sheets. It was suggested that: “As long as the translation is consistent with the EUA it will not be considered a “change” to the content of the information, and therefore, will not be prohibited. Assuming that patient information sheets can be translated, counsel suggested that it would be more cost efficient and provide greater accuracy if the translation could be done at the federal level. The federal governments could translate the information sheet into more common languages rather than having each state translate the same information for the same languages and potentially reaching different translations.”

**Mitigation Strategies Employed:**

- “The agency provided documentation of the Emergency Use Authorization and the FDA-approved fact sheets with each order the health agency shipped.”
- “Placed the EUAs, fact sheets and guidance on the state’s web site and communicated this information on the health agency’s weekly webcasts to partners.”

**Recommendations Suggested:**

*Emergency Use Authorizations (EUAs) Generally*

- “There should be national-level public messaging in lay terms to explain the ‘whats’ and ‘whys’ about EUAs.”
- “Different outreach and information materials about EUAs are needed when targeting the public and health professionals.”

*Provider Resistance to EUA Products*

- “State and federal agencies need to reduce health care providers’ resistance to EUA products.”
- “Better education for clinicians must take place regarding EUAs during an emergency.”
- “Efficacy data should be supplied to reassure clinicians that they are providing a viable product.”

*Content and Format of EUA Patient Information Sheets*

- “Information supplied to patients with EUA products should be revised to ensure that informed consent is obtained.”
- “Clarify that translation of EUAs are not prohibited under federal laws/regulations.”
- “Patient information sheets should be translated into the more common languages by the federal government rather than by states.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]



## Medical Equipment Supplies and Tracking

**Issue:** **C.11 Alterations in the scope and frequency of HHS requirements for the National Hospital Available Beds for Emergencies and Disasters (HA $\nu$ BED) System reporting caused frustration and confusion among states, hospitals and vendors.**

**Issue Type:** Policy

**Level:** Federal

**Discussion:** Alterations in the scope and frequency of HHS requirements for the National Hospital Available Beds for Emergencies and Disasters (HA $\nu$ BED) System reporting caused frustration and confusion among states, hospitals and vendors. As one state remarked, “the HHS/ASPR requirement that hospitals submit HA $\nu$ BED reports directly to HHS caused confusion about NIMS protocols for reporting to states and potentially lessened reporting of the information to states.”

- *Changes in scope and frequency of reporting:* States recounted that: “HHS repeatedly changed the scope (adding and changing a substantial number of new data elements and categories) and frequency of mandated HA $\nu$ BED reporting, which impacted health care facilities and state health agencies. Failure to coordinate federal data requests with ongoing state and local data collection efforts created duplicative reporting requirements, or required reporting of slightly different data elements that increased the data collection burden for health care facilities. Facilities and HA $\nu$ BED software vendors were impacted by having to change both the information queried as well as the frequency, and were therefore less likely to report their data. Local emergency medical services agencies (LEMSAs) and hospitals experienced frustrations in attempting to meet the moving targets, which also drove down reporting rates.”
- *Utility of reported data:* In seeking data related to H1N1 response, HHS changed some of the data items to be collected through the HA $\nu$ BED system. A respondent noted: “This compromised the ability to compare consistent data over time, required system changes, and provided data of limited utility. Moreover, although HHS permitted the use of supplemental H1N1 funding to support necessary system updates, HHS implemented the changes well after work plans and budgets for use of those funds had been finalized. By failing to work closely with state health departments, HHS collected data of limited situational awareness value.”
- *Direct reporting to HHS:* Another state noted that: “HHS failed to work with state health departments to define and address situational awareness

needs, and sought to gather data directly from local health care facilities. HHS required hospitals to directly report to HHS about ventilator supply and availability. HHS also encouraged direct reporting to HHS about hospitals' weekly HAvBED drills. This circumvented established response protocols as defined through NIMS and incident command, and created confusion about federal and state response roles. The federal government's direct querying of local facilities also strained the relationship of state and local health and EMS agencies. Hospitals questioned why they were required to report this information to the state since they had already been asked to provide the information directly to the federal government. This resulted in potentially lower response rates to states' HAvBED and other drill reporting."

**Mitigation Strategies Employed:**

- "The HAvBED working group, formed by ASTHO, sent a letter and consensus documents, which were created in response to the new HAvBED data elements and consensus of operations (CONOPS) document, to HHS. The work group made recommendations on the HAvBED data elements and the CONOPS document, which contained both general comments as well as suggested revisions."
- One state agency "provided health care facilities with templates designed to make reporting easier."
- "Due to the inability of HAvBED software vendors to keep up with the changing requirements, one state agency used large numbers of agency staff who worked many hours on each HAvBED drill to manually enter data submitted by hospitals."
- "Health agency executive management worked directly with LEMSAs and state hospital associations' leadership to identify issues, delineate the appropriate reporting relationships, and reduce confusion and friction associated with the federal reporting requests."

**Recommendations Suggested:**

- "The federal government should follow established protocol for coordinating directly with states for hospital information."
- "HHS should work through states to collect this information from hospitals. HHS should identify a standard set of questions that would be applicable to a number of situations and not modify the questions or frequency of reporting."
- "HHS and the states should analyze data collected over the last year to determine if overall levels of preparedness have been affected by weekly versus monthly reporting of HAvBED data."
- "Incorporate a public comment period before introducing changes to HAvBED reporting requirements and data elements."

- “Distribution of changes well in advance of mandatory reporting dates would give states time to implement the changes and minimize the impact on its partner LEMSA and health care facilities.”
- “Per NIMS, the appropriate requesting route is for the federal government to make requests on ventilator or similar supply/availability information through designated state agencies. The states will request information of the appropriate LEMSAs or local health departments, which in turn collect the information from the appropriate facilities. Since states have drilled this reporting many times, this process can be done expeditiously.”
- “The federal government should develop policies that clarify roles of the multiple response agencies and their responsibilities for data collection and support functions.”
- “States should be allowed to monitor bed capacity and other resource issues on their own and provide federal partners with updates on a weekly basis.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## III.D National Vaccination Campaign

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### **Summary of Barriers Identified**

The primary barriers identified related to the National Vaccination Campaign were (numbering does *not* reflect a priority order for the barriers):

- D.1 Availability, Allocation and Prioritization**—Delays in the production of the H1N1 vaccine caused shortages as public demand for the vaccine peaked.
- D.2 Availability, Allocation and Prioritization**—Delays in vaccine production and changing messages about their availability caused confusion among the public and hurt the credibility of governmental public health at all levels.
- D.3 Availability, Allocation and Prioritization**—Differing strategies used by states and localities for vaccinating priority groups and the general public caused confusion.
- D.4 Ordering, Delivery and Distribution**—Vaccine ordering systems were too complex and did not provide useful ways to manage ordering and delivery information.
- D.5 Ordering, Delivery and Distribution**—Requirements for ordering vaccines in minimum dose counts required states to engage in additional distribution activities and further delayed delivery of vaccines to providers and localities.
- D.6 Ordering, Delivery and Distribution**—Centralized state distribution systems for H1N1 vaccines ran counter to some states' existing immunization systems causing confusion and delay with providers and localities.
- D.7 Administering and Dispensing**—States employed various strategies to expand the pool of eligible vaccinators, but state statutory limitations and a generalized fear of liability persists.
- D.8 Administering and Dispensing**—School-based vaccination clinics, though an effective strategy to reach target populations, were limited by decentralized legal/policy authorities among education and health officials at the local level.
- D.9 Administering and Dispensing**—Payment and reimbursement issues and systems for H1N1 vaccine administrations costs were slow to be addressed and must be improved.
- D.10 Tracking, Coverage, and Adverse Events Reporting**—States encountered problems tracking H1N1 vaccines administered if they did not require mandatory reporting of vaccinations through state immunization registries.
- D.11 Tracking, Coverage, and Adverse Events Reporting**—Better systems are needed for tracking vaccine uptake, coverage, recall and adverse events.

- D.12 Recovery, Destruction and Disposal**—States are concerned over the impending confusion and cost of recovering and disposing of expired H1N1 vaccine.

### ***Selected Successes/Mitigations Identified***

#### *Vaccination Generally*

- “Vaccination efforts averted a third wave of H1N1.”
- “State and local levels demonstrated excellent teamwork; new cooperative partnerships were established, using local health departments as coordinating centers for local health care providers, and supportive partnerships with local Chambers of Commerce assisted in the execution of a successful vaccine operation.”
- “Additional successes included the value of the PREP Act in the dissemination of information, making health care workers a target group, and a high vaccination uptake reported in the Latino population.”

#### *Vaccine Identification and Formulations*

- “In less than a year, the federal government developed and delivered a vaccine for a novel influenza virus.”

#### *Vaccine Availability and Allocation*

- “Vaccines were available fairly rapidly (via weekly allocations).”
- “The state credits the federal government for permitting state and local health officials to oversee and determine H1N1 vaccine allocation and distribution needs.”
- “The state allocated a percentage of its vaccine allotment to the Tribal Nations. In addition to working with local public health departments, the state health agency coordinated distribution of the vaccine by working directly with IHS and tribal communities.”
- States communicated as much as possible with partners. Some states used weekly webcasts to answer questions and provide information. Others set up nurse-staffed hotlines to handle concerns. States postponed public communication campaigns and rescheduled many public and school-based clinics.
- One state health agency “used its communication channels and media to assist local county health departments in explaining the delay in vaccine and in maintaining public interest in obtaining vaccinations as they became available.”

#### *Vaccine Prioritization and Guidance*

- “There were pre-established, clearly defined priority policies for vaccination delivery and ordering.”
- “Opening up vaccination in November to all community members markedly increased vaccination rates in the state.”
- In some states that targeted sub-priority groups first, “additional information was given to providers that the state was following sub-target groups’ recommendations, despite CDC national messaging about all target/priority groups.”
- States also “tried to coordinate with local health departments on when to expand coverage uniformly within the state.” Some “waited until local public health and providers were nearly unanimous in saying they were ready to move to the general population and assuring that those that wanted to do school-based clinics had the vaccine to do so before vaccination was opened to all.”

- “The health agency encouraged local health agencies to work across jurisdictional boundaries in vaccinating priority groups and to realize that some groups would not get their vaccine in their county of residence. Many healthcare workers got the vaccine at their place of employment, which may have been different from their county of residence. Many pregnant women, especially those from rural areas, sought vaccination at their doctor’s office, which would likely not be in their county of residence. The state health agency encouraged all providers to follow the recommended priority groups and to realize that the overall goal was to vaccinate as many people as possible as quickly as possible. Therefore, if no priority group members needed or wanted the vaccine, the agency permitted vaccinators to offer the vaccine to other groups. As more vaccine became available and priority group needs were met, the state health agency changed the vaccine distribution algorithm to pro rata share based on population.”

#### *Minimum dose orders*

- One state “encouraged local health departments to work together to combine allocations into a single 100-dose order, which was shipped to a single location and sub-distributed in a multi-county area.”
- Another state “subdivided allocations for local health departments based on population.”
- States stored some vaccine at the state level to make sure all providers, regardless of size, would have some vaccine.
- States also reported “contracting with third-party distributors to allow shipment of less than 100-dose increments.”

#### *Vaccine Distribution and Supplies*

- “The national vaccine manufacturing and distribution process was seen as effective.”
- “The quality of the federal vaccine supplies was adequate.”
- “The state health agency distributed vaccine to both providers and local health departments, with local health departments taking on the role of redistributors, allowed for sharing mechanisms between providers within a county.”
- “The state health agency provided local health departments with spreadsheets to inform them as to which providers in their jurisdiction were getting vaccine.”
- “In addition to working with local public health departments, the state health agency coordinated distribution of the vaccine by working directly with the Indian Health Service and tribal communities; the state health agency allocated a percentage of the state’s vaccine allotment to the Tribal Nations.”

#### *Administering Vaccine*

- “At the state and local level, public health agencies successfully provided H1N1 immunizations to a large number of people.”
- “Recruiting additional community providers to facilitate vaccine administration, expanding pharmacists’ role in vaccinating patients ages 14+, as well as including paramedics to assist local health departments with vaccine administration were critical components in the success of the vaccination efforts.”
- “Using Vaccines for Children [VFC] providers, school-based vaccination clinics, and direct shipment of vaccines to providers also facilitated vaccination efforts.”
- “All healthcare providers who administered H1N1 vaccine were required to pre-register; pre-registration was available online and accounted for the majority of enrollees.”
- “The state drafted several draft executive orders to be implemented during a declared emergency, which orders expand public health authority to improve response. A few of these draft executive

orders delegate authority for vaccination to healthcare practitioners, such as EMS providers, that do not have this responsibility under their normal scope of practice. The state did not declare a state emergency and did not implement any of the draft executive orders. The state health agency and local public health agencies agreed that vaccinator-staffing shortages could be addressed on a case-by-case basis. At no time during the outbreak were additional vaccinators requested.”

- “State health agencies communicated about state fiscal support for the cost of treatment/vaccination for the uninsured in weekly webcasts with local health departments, hospitals, etc.”

#### *Authority to Administer Vaccines*

- To address local emergency declaration requirements for using EMS as vaccinators, one state health agency reported “drafting guidance and working with all county EMS medical program directors to get the message out to counties on using this allowable change during an emergency. Because the vaccine came in slow and the disease was not severe this allowed this process to happen and personnel to register as emergency workers. Several counties did declare emergencies in order to use EMS staff to help vaccinate.”

#### *School-based Clinics*

- “Along with general vaccination marketing efforts, state and local health departments identified key members of the education leadership community to provide situational awareness and guidance to their respective entities and to encourage and support on-site vaccination.”
- Partnerships in many school jurisdictions were developed, including K-12, community colleges, universities (student health) and university athletic associations.
- Other states reported “engaging and collaborating with their states’ volunteer medical reserve corps to provide staffing at school-based clinics.”

#### *Vaccine Tracking/Recall/Adverse Events*

- “Reporting through Vaccine Adverse Event Reporting System (VAERS) and the state immunization registry were cited as beneficial systems utilized during the incident.”
- “Manufacturers provided information directly to providers on recalled and expired vaccines which were helpful in the vaccination process.”
- To mitigate the effects of not having mandatory reporting to the state immunization registry, one state: “Developed and implemented easy data entry options for the immunization registry to reduce the time needed to input the numbers of doses administered and extended automated data upload capabilities. In lieu of required reporting into the registry, the state also initiated a variety of methods to collect, compile, and authenticate data, including aggregate data reporting by some provider partners, as well as other surrogate sources of data.”
- “To address temporary connectivity issues for pharmacy chains, local health departments input the required data entry into the immunization registry on behalf of the pharmacies.”
- One state reported that: “Where possible, local public health staff administered vaccines in school-based clinics in order to avoid problems with FERPA and the associated problems with school employees reporting vaccinations to the state immunization registry. However, this was not possible in all areas.”
- “The state reported successfully using poison control centers during the H1N1 response for such things as medical errors and adverse reaction reporting.”

### *Recovery, Destruction and Disposal*

- “The health agency has been working at the state level with the state’s environmental protection agency to sort through all these laws and identify a viable solution for local providers. The state has also been coordinating with CDC and BARDA to determine if the federal program will work in this state. If not, the state may need to take on the responsibility of ensuring proper disposal of expired H1N1 vaccine.

## **Barriers/Recommendations Identified Detail**

### **Availability, Allocation and Prioritization of Vaccines**

- Issues:**
- D.1 Delays in the production of the H1N1 vaccine caused shortages as public demand for the vaccine peaked.**
  - D.2 Delays in vaccine production and changing messages about their availability caused confusion among the public and hurt the credibility of governmental public health at all levels.**
  - D.3 Differing strategies used by states and localities for vaccinating priority groups and the general public caused confusion.**

**Issue Type:** Policy

**Level:** Federal; State

- Discussion:** *Vaccine Availability Estimates and Shortages*
- States uniformly saw delays in production and the resulting shortages of H1N1 vaccine as a fundamental barrier to quick response, causing the inability to seize upon public interest to maximize the numbers vaccinated. One person captured the barriers as: “vaccine availability peaked when public concern/interest waned.”
- *Raising expectations:* States acknowledged that the federal government is dependent on a vaccine manufacturing process that is outdated and dependent on private manufacturer’s capabilities. States noted that reliance on this system and “the erroneous and changing estimates of the amounts of vaccine available put states/locals in a difficult position.” Some states felt that, “given our nation’s system for vaccine production, the federal government should not have set the expectation that such large amounts of vaccine would be available so quickly.”
  - *Delay/cancellation of vaccination clinics:* Planned vaccine clinics had to be delayed or cancelled. State and local health departments were repeatedly faced with “hurry up and wait.” They had to get staff and the public ready for the arrival of vaccine which was repeatedly delayed. A number of states commented that “vaccination clinic efforts were not as effective because of shortages or a lack of vaccines for clinics.” One



person commented that “those turned away early on, when vaccine was limited, may never have returned when vaccine became readily available.” Other respondents suggested that “low vaccination levels may also be attributed to public perceptions that the vaccine had safety issues resulting in its delayed release/availability.”

- *Supplies directed to vaccination clinics:* Some states noted that “federal recommendations to prioritize vaccine supplies to vaccination clinics interfered with state/local practices targeting vaccination through health care providers.” One state reported that: “State, local and health care entities were executing a series of plans to vaccinate the state’s most at-risk populations using hospitals, clinics and other direct providers. In complying with the federal recommendations from the White House and CDC urging states to publicize vaccination clinics, vaccine was diverted to local public health departments in quantities too small for them to open effective public clinics. As a consequence, local public health held onto resources that could have been more efficiently used within the health care provider system.”
- *Vaccine delay challenges:* States also noted that: “Delays in vaccine availability resulted in messaging challenges for states and loss of credibility of public health with media, policymakers and the public. Seemingly futile efforts to vaccinate the population despite concerted efforts by immunization and other agency staff hurt employee morale. By the time there was sufficient vaccine, infection peaks had passed, the public lost interest, and vaccine supplies were not used.”

#### *Vaccine Allocation*

Some states viewed the allocation system as far too complicated; “an initially small number of variables increased significantly over time.” States reported that they “learned allocation amounts on a daily basis, impacting the amounts that could be distributed to providers, particularly because the CDC-estimated availability of vaccine was usually higher than actual allocations.”

States reported that “decision-making and communication to health care partners regarding quantity and timing of vaccine distribution was undependable” due to uncertainties about the amount and timing of vaccine available in the states. A respondent concluded that “this resulted in problematic ordering processes, lack of trust by the health care industry and local public health partners and ultimately, a slower and more confusing process for getting the public vaccinated.”

Another state reported that: “Established vaccine allocation and distribution protocols between the federal government and Tribal Nations were not followed. The federal government has an established protocol for vaccine allocation and distribution to Tribal Nations. During the H1N1 response, the mandate to begin working with state and/or local health was problematic due to need to register their providers with the central distribution system.”

Although some states have “established collaborative relationships with the Tribal Nations, they were asked to circumvent an established process with the Indian Health Service (IHS) thereby creating a challenge for state and local public health departments to coordinate vaccination efforts.”

#### *Vaccine Formulation*

One state noted that “allocation of vaccine initially was very problematic due to public demand, target groups and injectable vaccine not available early on for those in target groups for whom the nasal spray was not indicated.” The state suggested that “rules tied to vaccine type (age; thimerosal-free; FluMist) limited vaccination of priority target populations when insufficient quantities of a particular type were received.” It was commented that “variety in vaccines (nasal spray – live attenuated, thimerosal-free, multi-dose with thimerosal, pediatric-specific) lead to public confusion and concerns about whether they were receiving the “right” (safest) vaccine.”

#### *Prioritization and Guidance*

States likewise noted that the “disconnect between federal announcements of vaccination priority groups and state/local needs to broaden groups eligible for vaccination caused major uncertainty in the states.” A respondent commented that: “Targeting of high-risk groups created operational problems that included a need to screen people for eligibility; denial of vaccination to high-risk elderly individuals and family members of the target groups; complexity of administration; and difficult public information messages that created confusion.” As a result of tightly adhering to priority group categories and diminishing public demand, states were left with unused vaccine.

- *Conflicting direct messaging to providers:* States noted that: “Direct communication from the CDC to health care providers promoting the administration of vaccines to people in the priority target groups when states were employing a sub-target group strategy caused confusion for providers regarding which guidance to follow and how to set up clinics. State agencies received a lot of calls requiring them to clarify the issue.”
- *Inconsistent prioritization for first responders:* States also noted that the “failure to include all ‘first responders’ in Tier 1 [*Editor’s note: Tier 1 refers to ACIP H1N1 ‘initial target groups’*] priority group caused confusion and ill-will among public responders and volunteers. While EMTs and other EMS personnel were included in Tier 1, other first responders such as law enforcement, fire, etc., were not. One respondent noted that: “As a result, public health took a lot of criticism from first-responder groups that were not part of Tier 1. This may have damaged some existing professional relationships as those first-responders who were not part of Tier 1 took the issue personally and viewed it as minimizing their role in the response/society.”

It was noted that: “Compounding the situation was the fact that these groups were regarded as ‘essential services’ in past pandemic influenza planning efforts. This disconnect created confusion as to why they were not considered as ‘essential services’ during this particular ‘pandemic’ influenza outbreak.” One person observed that: “State health agencies tried to stand behind the CDC priority groups and explain the science behind the Tier 1 priorities as much as possible. Similarly, not allowing those in the SNS distribution network to get vaccinated ahead of time disrupted public health's relationship with those it needed for the mission.” One respondent concluded by saying that the “state fears they have lost the trust and respect of crucial volunteers, so much so that some may not volunteer in the future.”

- *Confusion between priorities in neighboring jurisdictions:* Confusion occurred between neighboring jurisdictions that were targeting different priority groups and/or the general population. Some expressed that “there was a sense of unfairness among the public because they could not get vaccinated in their jurisdiction whereas similarly situated individuals could get vaccinated in other jurisdictions.” It was frequently noted that “individuals would cross jurisdictional boundaries trying to get vaccinated through another health department.”
- *Delays in guidance:* States also noted that “delays in issuing vaccination guidance, as well as changing vaccination protocols and formulations, caused confusion with providers and required significant state health agency time to address and clarify.” It was viewed that “the lack of standard regarding when to expand vaccine coverage led to fragmented response strategies and confusion within the general population.”

**Mitigation  
Strategies  
Employed:**

*Vaccine Availability Estimates and Shortages*

- States communicated as much as possible with partners. Some states used weekly webcasts to answer questions and provide information. Others set up nurse-staffed hotlines to handle concerns. States postponed public communication campaigns and rescheduled many public and school-based clinics.
- One state health agency “used its communication channels and media to assist local county health departments in explaining the delay in vaccine and in maintaining public interest in obtaining vaccinations as they became available.”
- Another state “launched an expansive multi-media campaign once vaccine supplies became adequate. This activity was minimally effective in encouraging individuals to seek out vaccination, as the public concern and overall media interest about the disease were waning.”
- “Nationally, state health agency directors, ASTHO, and AIM petitioned to have promotional efforts delayed until a sufficient volume of vaccine was available for people who wanted it.”

### *Vaccine Allocation*

- To deal with initial shortages, some states further prioritized within the priority target groups to sparingly administer vaccine. However, the “use of 'sub-populations' early in the vaccination process caused even more confusion as to eligibility.”
- One state placed “significant limits on the size and number of orders it filled for local health agencies and providers.” States had to “routinely substitute vaccine from different manufacturers rather than what providers had requested, depending on amount and type of vaccine the state received. This significantly slowed the process of vaccination.”
- “Some local health officers did not want to use their vaccine supply, which was allocated based on their population, for outsiders. Health officers sought legal advice to be able to deny vaccine to individuals who do not live in their jurisdiction.”
- “The state allocated a percentage of its vaccine allotment to the Tribal Nations. In addition to working with local public health departments, the state health agency coordinated distribution of the vaccine by working directly with IHS and tribal communities.”

### *Prioritization and Guidance*

- State remedies for dealing with priority groups varied. In some states that targeted sub-priority groups first, “additional information was given to providers that the state was following sub-target groups’ recommendations, despite CDC national messaging about all target/priority groups.”
- States also “tried to coordinate with local health departments on when to expand coverage uniformly within the state.” Some “waited until local public health and providers were nearly unanimous in saying they were ready to move to the general population and assuring that those that wanted to do school-based clinics had the vaccine to do so before vaccination was opened to all.”
- “The health agency encouraged local health agencies to work across jurisdictional boundaries in vaccinating priority groups and to realize that some groups would not get their vaccine in their county of residence. Many healthcare workers got the vaccine at their place of employment, which may have been different from their county of residence. Many pregnant women, especially those from rural areas, sought vaccination at their doctor’s office, which would likely not be in their county of residence. The state health agency encouraged all providers to follow the recommended priority groups and to realize that the overall goal was to vaccinate as many people as possible as quickly as possible. Therefore, if no priority group members needed or wanted the vaccine, the agency permitted vaccinators to offer the vaccine to

other groups. As more vaccine became available and priority group needs were met, the state health agency changed the vaccine distribution algorithm to pro rata share based on population.”

**Recommendations Suggested:**

*Vaccine Availability Estimates and Shortages*

- “Have one federal entity in charge of communicating supply information.”
- “It would be better to be cautious in making projections rather than causing unrealistic expectations. Do not communicate unrealistic vaccine supply expectations.”
- “Delay public communications about vaccine availability until sufficient supplies are available to engage in meaningful vaccination activity. Vaccine distribution on the mid-October target would have eliminated many of the problems experienced with the October 1 release announcement.”
- “Approve vaccine manufacturing technology improvements to more quickly produce vaccine for new flu strain. Until technology fixes are addressed, federal agencies need to improve their communication strategies and present realistic representations of vaccine availability to the public.”
- “Federal, state and local agencies need to improve their ability to plan, organize, and communicate when production and delivery of the essential piece of the response strategy (i.e., sufficient vaccine) is outside of governmental control.”
- “Vaccine should be ready for distribution when a national campaign effort goes into effect.”
- “CDC needs to provide better projections on vaccine availability, demanding better estimates from vaccine manufacturers.”
- “Vaccine manufacturers need to be held accountable for their estimated vaccine production.”

*Vaccine Allocation*

- “Explore ways to distribute vaccine by risk group when supplies are limited. Clarify sub-populations through the guidance process.”
- “There should only be three types of vaccine available: FluMist, thimerosal-free for pregnant women, and one formulation for ages six months and above.”
- “There is a need to determine if variations in availability among states and localities were from vaccination allocation or differences in implementation. If allocation is the problem, need to improve the

allocation methodology. If implementation differences are the problem, better coordination/identification of best practices should be pursued.”

- “Consider employing state-level allocation for consistency or providing more direction from the state level regarding allocation. However, a state-driven approach is not always feasible, especially when funding and policy is directed at planning and coordination among all of the stakeholders on the local level to best meet the needs of local population.”
- “There needs to be a clear delineation between the roles of federal, state and local governments. The recommendation to initiate local public health clinics is tactical and is best left as a discussion between the state and municipal entities. The federal government should concentrate on national strategic recommendations, but leave it to each state to identify the best local tactical response.”
- “Review plans, policies and procedures for providing direct public health resources to Tribal Nations. Follow the established federal protocol for vaccine allocation and distribution to Tribal Nations.”

#### *Vaccine Formulation*

- “Limited vaccine formulation should dictate target group allocation.”
- “The federal government should develop and communicate clear policies on the use of vaccine presentations.”
- “There should only three types of vaccine available: FluMist, thimerosal-free for pregnant women, and one formulation for age six months and older.”

#### *Prioritization, and Guidance*

- “When using vaccine priority groups, provide guidance/identify triggers that detail when jurisdictions can expand beyond the priority groups.”
- “Make recommendations for high priority groups, but do not restrict vaccination to those groups. Vaccinate anyone seeking vaccination; if supplies run out at a clinic, they run out. The vaccination campaign could still have been targeted by providing supplies first to those providers serving children, pregnant women and other high risk groups.”
- “Further consideration of the status of EMT/EMS as Tier 1 priorities versus other first responders in establishing the priority groups for a national vaccination campaign. If necessary, amend the state response plans to have a tiered approach to vaccination/prophylaxis. Educate volunteers ahead of time regarding the tiered vaccination scheme so there are no surprises. Do not withhold advance vaccination from the SNS distribution team.”

- “The CDC needs to take the states’ views and vaccine supplies into consideration when developing material. States have seen/experienced similar problems with seasonal influenza when vaccine availability is painted with a broad brush.”
- “Policy should be developed to include laboratory staff as health care workers.”
- “The federal government should develop policies regarding service delivery to undocumented workers while they are in the U.S.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Vaccine Ordering, Delivery and Distribution

- Issues:**
- D.4 Vaccine ordering systems were too complex and did not provide useful ways to manage ordering and delivery information.**
  - D.5 Requirements for ordering vaccines in minimum dose counts required states to engage in additional distribution activities and further delayed delivery of vaccines to providers and localities.**
  - D.6 Centralized state distribution systems for H1N1 vaccines ran counter to some states existing immunization systems causing confusion and delay with providers and localities.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** *Vaccine Ordering Concerns*

- *Ordering systems:* State reported: “Using immunization systems (VacMan) for ordering and tracking vaccine allocation and delivery was complex, time intensive and required extensive training to use. The intricacies of setting up providers and entering the orders were too complex making it difficult to have people without in-depth system experience perform the functions causing significant drain on staff trained on the system.”

One agency found that: “There was no way to define the priorities of order fulfillment based on vulnerable populations and other factors. There was no way to track order backlogs, orders vs. shipments, or transfers of vaccine by providers. The system is not able to be replicated within a single jurisdiction and was not co-located with public health emergency preparedness staff that was responsible for allocation of the

vaccine, management of the mass immunization clinics and the overall H1N1 response including messaging, coordination with healthcare and immunization providers, etc.”

Another state reported that: “The state could not give local health departments accurate information about expected vaccine deliveries. As a result, local health departments felt inhibited in their ability to schedule vaccination clinics without knowing for certain when and how much vaccine they would receive. Some counties received large supplies while other counties received none or little of their supplies, which initially caused confusion among local health departments and the public.”

- *Minimum dose-count orders:* One respondent captured a frequently identified barrier by the states: “CDC/McKesson’s decision not to direct-ship vaccine allocations less than 100 doses to providers caused an immediate problem.” States noted that: “Providers needing less than 100 doses/shipment had to wait longer to receive shipments. This created inequity among larger and smaller volume providers since state agencies were not initially able to supply vaccine to all providers. This created frustration/panic in parents. This requirement also forced some states to implement programs with local distributors who may not have been fully prepared for frequency of vaccine distribution/delivery.”

In states with smaller populations and very limited vaccine allocations, respondents noted that “it was impossible for many providers to order vaccine in 100-dose increments when the vaccine first became available.” In these instances, some states “had to warehouse vaccines and break down orders into smaller increments to ship or drive them out to healthcare providers.” Yet it was noted that “this required significant staff time and funding, caused storage and handling issues for the vaccine, and caused a delay in providers receiving the vaccine.”

#### *Vaccine Delivery and Distribution Concerns*

- *Differing agency distribution criteria:* One state commented that: “Independent agencies that received vaccine used different criteria to distribute H1N1 vaccine. Some agencies used local health department resources exclusively, while others used pharmacies and health care providers. This caused public confusion as to where and how to receive an immunization. Once the federal pharmacy distribution program started, public confusion and frustration grew as large chains were seen as competing for vaccine supplies with local agency clinics.”
- *CDC NCIRD vs. DSNS distribution:* One state captured a perceived “continued lack of coordination between NCIRD and other divisions at CDC, especially DSNS, and the controlling role that NCIRD played in vaccine distribution”, as a barrier experienced by the states. The state commented that: “DSNS is the primary force in public health



preparedness and countermeasure distribution at the state and local level and its mission and work parallels the National Response Framework and NIMS. State and local governments have developed plans for distribution of SNS supplies and other countermeasures.” The respondent felt that “NCIRD maintained control of the H1N1 vaccination campaign, and ...its initial internal logistics work was impressive (implementation of a robust distribution system);” however, the respondent believed more guidance was needed on “rapid and equitable ordering, distribution, and allocation of vaccine.” The respondent concluded: “This resulted in state immunization programs attempting to distribute vaccine outside of the state and local response plans. These issues complicated the vaccination campaign as many of the established state and local roles and responsibilities, communication channels and response systems were set aside in favor of developing a new state-centric distribution system.”

Another state discussed challenges with vaccine ordering: “Significant time and resources were spent setting up complex pre-booking, order verification, and allocation systems that mirror the VFC system but are not appropriate for rapid, equitable vaccine distribution. Local health departments and providers were assigned random numbers that determined the order of filling their orders; however, this weeks-long process coupled with slowed vaccine production resulted in very uneven distribution. The complexities and gaps of the ordering system resulted in many erroneous orders and too much variance in the time that providers, and even geographic regions, received initial doses. The centralized ordering and distribution system did not give local health departments or tribes the authority that had been planned for in a mass prophylaxis response.”

- *Centralized vaccine distribution:* Some states noted that “federal plans for centralized control over vaccine distribution placed a heavy administrative burden on state public health agencies to recruit willing providers, allocate scarce vaccine, and manage the distribution process.” This was, however, seen as: “An improvement over the initial federal plan to send vaccine only to the states for public health to administer or distribute. By circumventing the usual practice in which providers order their supplies directly from their suppliers or the manufacturers, the distribution process made it necessary to contract for an expensive federal vaccine storage and distribution system and required state bureaucracy to allocate and control distribution of vaccine and supplies. This drew state resources away from planning and implementing the vaccination campaigns.”

#### *Supply Chain Visibility and Inventory Management*

Visibility of the location and inventory of public and private supplies of vaccines was identified as important data for state/local allocation decision-making. It was commented that: “State and local health departments did not have complete information on which to base vaccine allocation decisions. Frequent system difficulties and crashes, requiring additional hours and

repeated ordering, delayed ordering and shipment.”

Several states raised questions about the ownership of H1N1 vaccines after they have been distributed, including what the states may and may not use excess vaccines for. (See also discussion of this issue in the Medical Care and Countermeasures section)

**Mitigation  
Strategies  
Employed:**

*Vaccine Ordering Concerns*

- *Ordering systems:* States “tried to mitigate the burden of using the ordering system by delegating non-VacMan related duties to other staff, yet this did not result in efficient processes.” One agency noted that “in order to overcome severe staff shortfall on such short notice, they requested additional support from CDC to assist in the data entry process into VacMan.”
- *Minimum dose-counts:* States had to develop and employ alternate distribution strategies to deal with orders for less than the minimum dose count. One state “encouraged local health departments to work together to combine allocations into a single 100-dose order, which was shipped to a single location and sub-distributed in a multi-county area.” Another state “subdivided allocations for local health departments based on population.” States stored some vaccine at the state level to make sure all providers, regardless of size, would have some vaccine. States also reported “contracting with third-party distributors to allow shipment of less than 100-dose increments.” However, “because of slow state contracting processes, the contracts were delayed, which exacerbated the issue.”

*Vaccine Delivery and Distribution Concerns*

- *CDC NCIRD vs. DSNS distribution:* “Several local health departments opted out of the primary vaccine ordering and distribution system in order to manage the vaccine distribution within their counties. Among local health departments that remained with the centralized distribution system (providers placed orders with the state, and vaccine was shipped directly to the providers), over 90% still coordinated or assisted with redistribution between providers, using local time and resources. Many local health departments shared with neighboring health departments in order to vaccinate priority groups and work around the random number system.”

**Recommendations  
Suggested:**

*Vaccine Ordering Concerns*

*Ordering system:*

- “Develop a new, more highly functional system (which in the process of being done by the CDC and a contractor).”
- “In the future, additional funding should be incorporated into federal immunization grants requiring training of additional personnel, including public health emergency preparedness staff, on using the

current and new vaccine ordering system to ensure that during an emergency requiring vaccine there is not a lengthy start-up time to compensate for the dramatic increase in workload.”

*Minimum dose-counts:*

- “In the future, CDC should be more flexible with vaccine shipment allocations.”
- “Allow for states to order vaccine shipments in smaller than 100-dose counts. Consider 50-, 25- or 10-dose increments.”

*Vaccine Delivery and Distribution Concerns*

*CDC NCIRD vs. DSNS distribution:*

- “CDC needs to distribute all countermeasures (including vaccine) out of one division, or at a minimum select an appropriate lead division. The appointed division needs to be well-versed in emergency preparedness, national systems and frameworks, all elements of supply-chain logistics in a biological response, and the ability to provide helpful guidance to states.”

*Centralized vaccine distribution:*

- “An approach that follows normal distribution channels could have been used, with the initial limited supplies sent to the public health departments and identified priority vaccination providers (i.e. those participating in VAFAC). This approach would have allowed all willing providers to participate without requiring them to go through unnecessary bureaucratic hoops. Use normal vaccine distribution channels as much as is feasible, so that providers do not have to do unusual things to get vaccines and public health departments are not forced to serve as middle-men in the distribution process.”

*Supply Chain Visibility and Inventory Management*

- “Establish guidance on the benefits and most appropriate course of action regarding maintaining state-based stockpiles of residual H1N1 vaccine for possible future use.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Administering and Dispensing Vaccines

- Issues:**
- D.7 States employed various strategies to expand the pool of eligible vaccinators, but state statutory limitations and a generalized fear of liability persists.**
  - D.8 School-based vaccination clinics, though an effective strategy to reach target populations, were limited by decentralized legal/policy authorities among education and health officials at the local level.**
  - D.9 Payment and reimbursement issues and systems for H1N1 vaccine administrations costs were slow to be addressed and must be improved.**

**Issue Type:** Policy; Legal

**Level:** State, Federal

**Discussion:** *Authority to Administer Vaccines*  
States took various approaches to authorizing nonmedical professionals to administer vaccinations. Some states noted that “public health built and/or expanded wide-ranging partnerships to immunize people, including with pharmacies; physicians; clinics; hospitals; medical and professional associations; schools; colleges and universities; Medical Reserve Corps (MRCs); community and faith-based organizations (CFBOs); tribes; and others.” Expanding the pool of vaccinators was important in all states, but “especially in those states with insufficient state and/or local public health workforce capacity to execute a statewide initiative for school-based flu vaccination clinics.”

One home-rule state, in which local health directors have the authority to declare public health emergencies, noted that: “EMS can only act as supplemental vaccinators if an emergency declaration is in place. Some categories of EMS personnel are trained to give injections, but may only give vaccinations under certain criteria, which includes a state or local declaration of emergency and being registered as an emergency worker under state law. Many jurisdictions do not have sufficient personnel in their county to run mass vaccination clinics and must rely on other sources to accomplish this task in an emergency. If a jurisdiction has not pre-planned this or is hesitant to declare an emergency for other reasons this limits immediate response in an emergency situation.”

Another strategy being considered by states for expanding the pool of vaccinators was to “qualify school nurses as public health employees to administer vaccines.” Having “MOUs in place to qualify school nurses as public health agency employees” was identified as a potential strategy to alleviate school nurse liability concerns. (See related issue in the “Tracking” section below.)

### *School-based Clinics*

School-based clinics were seen as effective ways to vaccinate children. One state reported that “holding H1N1 vaccination clinics in schools and during school hours allowed some localities to capture a large percentage of target groups.” In that state, “one quarter of its counties immunized children in schools and reached nearly 60% of the target groups immunized in those counties.”

However, states also noted: “Decentralized legal/policy authorities among education and health officials at the local level reduced the potential effectiveness of school clinics to maximize the numbers of children vaccinated. Despite coordinated efforts among state and local health departments and their state and local education counterparts to implement school vaccination clinics, a number of local school districts (including large metropolitan areas) chose not to conduct vaccination campaigns in their schools.”

States identified several common concerns about school vaccine clinics, including “how to increase vaccine uptake, particularly LAIV, and how to overcome administrative hurdles such as staffing, consent forms, and managing second doses.” One state noted that “among the biggest successes were school clinics and the vaccination of pregnant women.”

### *Vaccination Clinics Generally*

States frequently noted that “delays in vaccine production and distribution hindered the ability of state and local governments to conduct timely and effective H1N1 vaccination clinics. Some also noted that “delays in developing the provider agreements stalled efforts to hold clinics and otherwise expand the pool of vaccinators.” Several agency counsels noted that “outstanding questions persist regarding liability coverage under the PREP Act and other laws, and under what conditions different health care providers can act as vaccinators.”

One state commented that: “State and local health departments were told that the U.S. Department of Defense (DOD) would be vaccinating their own personnel; however the DOD did not receive vaccine in time to vaccinate their personnel prior to or during the peak of the outbreak. Local health departments could vaccinate dependents of active duty personnel, but not active duty personnel themselves– including those that were pregnant or had other high-risk conditions.”

### *Payment and Reimbursement*

States found that “payment and reimbursement issues and systems for H1N1 vaccine administration costs were slow to be addressed and must be improved.” States noted that “as PHER funding phases out, third-party payers will be needed to help continue vaccination services and vaccine uptake.” A respondent commented that “business processes must be revamped and simplified to allow more efficient third-party billing to insurers to recover allowable costs for the administration of the vaccine.”

State insurance laws do not mandate the coverage of vaccines during declared public health emergencies.

States identified the need to “reduce/remove barriers such as vaccine administration co-payment and administration fees, which were clearly identified as conditions impeding vaccine uptake of and coverage rates of at-risk populations.” Some states reported delays in “state-provided fiscal support for cost of H1N1 treatment/vaccination for the uninsured.” Once this benefit was in place, “there was a lack of adequate publicity to reach out to covered persons.”

**Mitigation Strategies Employed:**

*Authority to Administer Vaccines*

- To address local emergency declaration requirements for using EMS as vaccinators, one state health agency reported “drafting guidance and working with all county EMS medical program directors to get the message out to counties on using this allowable change during an emergency. Because the vaccine came in slow and the disease was not severe this allowed this process to happen and personnel to register as emergency workers. Several counties did declare emergencies in order to use EMS staff to help vaccinate.”

*School-based Clinics*

- “Along with general vaccination marketing efforts, state and local health departments identified key members of the education leadership community to provide situational awareness and guidance to their respective entities and to encourage and support on-site vaccination. Partnerships in many school jurisdictions were developed, including K-12, community colleges, universities (student health) and university athletic associations. Other states reported engaging and collaborating with their states’ volunteer medical reserve corps to provide staffing at school-based clinics.”

*Payment/Reimbursement*

- “State health agencies communicated about state fiscal support for the cost of treatment/vaccination for the uninsured in weekly webcasts with local health departments, hospitals, etc.”

**Recommendations Suggested:**

*Authority to Administer Vaccines*

- “Federal and state officials should review and assess the various approaches states took to authorize nonmedical professionals’ to administer vaccinations, including modifying state licensing requirements during an emergency.”
- “Plans should be reviewed and possibly revised regarding expanding the use of pharmacists as vaccinators in future planning efforts for pandemic response.”

- “Participants desired a clear policy on the roles of pharmacists (when/what they can be used for) during an incident.”
- “State health agencies should continue to work with counties and EMS to recommend registering this type of personnel as emergency workers and educate county leadership on when and how to declare an emergency for that specific purpose. Anything from the federal government that supports expanded roles for EMS in declarations or guidance will assist the states.”
- “The state health agency will continue to provide the existing legal guidelines defining what different classes (EMT-B, EMT-I, etc.) of EMT’s can do under specific circumstances during a declared vs. non-declared disaster.”
- “State should develop policies for practice standards of non-traditional vaccinators/dispensing practitioners for use during an emergency.”
- “State should improve interagency cooperation especially with the non-traditional responder community to develop policies real-time during an incident. This non-traditional responder community includes agencies that have a regulatory function.”
- “State should develop policy standards for local agencies regarding policies that allow emergency certifications or expansion of practice for professionals and liability protection. Local governments should develop policies that enable professionals who are not health department staff assist with expanded roles as provided by state policy.”

#### *School-based Clinics*

- “Due to the local authority/autonomy of school districts in some states, promotion of school-based vaccination programs through joint health and education efforts and coalitions is the best course of action.”
- “Coordinate and plan with state public health preparedness programs, state immunization programs, and school districts to fund and train school nurses and personnel to immunize their student populations in the future. Exercise plans created with seasonal flu vaccine or other identified vaccines provided by state 317 funds.”

#### *Vaccination Clinics Generally*

- “The role(s) of public health in vaccination efforts needs to be defined and the efficacy of using school-based clinics, local health department clinics, hospitals and clinics, and other venues should be evaluated, with recommendations communicated to states.”
- “U.S. DoD needs to provide vaccine to all military personnel as promised in a timely fashion or enable state and/or local health departments to vaccinate military personnel with financial and

operational support from DoD.”

*Payment/Reimbursement*

- “State insurance laws should mandate the coverage of vaccines during declared public health emergencies.”
- ”Provide recommendations surrounding cost-reimbursement issues prior to vaccine distribution to enable state/local health departments to plan accordingly.”
- “Provide states with total, unrestricted funding amounts prior to vaccine distribution to allow public health agencies to anticipate immunization administration fees.”
- “The federal government should develop and communicate clear policies regarding the use of federal grant funds that can be used for operations and the intersection of the uses and other reimbursement programs (such as Medicare and Medicaid).”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Tracking, Coverage, and Adverse Events Reporting

<b>Issues:</b>	<b><u>D.10</u> States encountered problems tracking H1N1 vaccines administered if they did not require mandatory reporting of vaccinations through state immunization registries.</b>
	<b><u>D.11</u> Better systems are needed for tracking vaccine uptake, coverage, recall and adverse events.</b>
<b>Issue Type:</b>	Policy; Legal
<b>Level:</b>	State; Federal
<b>Discussion:</b>	<i>Tracking Vaccinations Administered</i> States reported a number of challenges in <ul style="list-style-type: none"><li>• <i>Reporting vaccinations:</i> It was observed that: “States that failed to require all public and private providers that received H1N1 vaccine to report their doses-administered data through the state immunization registries encountered a variety of problems related to tracking and accountability of vaccine administration and populations served. This led to incomplete data and inefficiencies in collecting information that was later requested for national reporting. Additionally, lack of consistent reporting of doses administered into the state immunization registry limited information regarding the total population protected. In significant disease outbreaks, it is critical to determine the population</li></ul>



most susceptible (e.g., ensure that the at-risk population may be distinguished from the protected population). Such efforts cannot be done well without accurate centralized reporting of doses administered.”

In some states, health agencies are legally required to seek consent from individuals before their vaccination data can be entered into the state’s immunization registry (“opt-in” systems). States using this system noted that “the opt-in type of system placed an enormous burden on states using their state immunization registry as the tool for tracking doses administered.” It was believed that “states with ‘opt-out’ or mandatory systems were more effective tools for tracking H1N1 vaccinations.”

One state that did mandate that H1N1 providers use the state-wide immunization registry to track doses administered reported that: “Several pharmacies had technical issues with connecting to the state-wide immunization registry because of internal corporate policies that forbade access to Internet systems outside of corporate Intranets. There was considerable lag-time that pharmacies had to deal with while these technical issues were addressed. This lag-time prevented pharmacies from offering H1N1 vaccines for several weeks while these pharmacies dealt with these connectivity issues.”

- *School-based clinics and FERPA:* During the H1N1 outbreak, questions and uncertainties persisted regarding the ability of school-based clinics to report vaccinations to state immunization registries due to Family Educational Rights and Privacy Act (FERPA) concerns. States explored “qualifying school nurses as public health employees to administer vaccines and report immunizations.” It was thought that “by having MOUs in place to qualify school nurses as public health agency employees this was seen as a potential way to alleviate liability concerns and authorize them to report immunizations.”
- *Veterans Administration:* One state commented that: “The federal Veterans Administration prohibited individual doses-administered data from being entered into statewide immunization registries. This resulted in incomplete records on individuals, inability to follow on adverse events, and the inability to fully evaluate the H1N1 vaccination program.”

#### *Vaccination Coverage*

- *Improving health care coverage rates:* States voiced a desire to “see a concerted effort to improve vaccine acceptance among health care providers to increase vaccine coverage rates of health care workers.”
- *Uptake and coverage data/monitoring:* States observed that: “There was limited vaccine uptake and coverage data to guide local public health efforts. Monitoring doses administered was problematic. A better system is needed for tracking, including obtaining more robust and useful data from private sector providers.”

**Mitigation  
Strategies  
Employed:**

*Adverse Event Reporting*

Having a better system to track when vaccinations are administered was identified as crucial for determining if vaccinees are having adverse effects related to the vaccine.

*Vaccine Recall*

A state commented that: “CDC recalled vaccine during the outbreak due to degrading vaccine, quality, expiration dates, etc. When the public hears the word ‘recall’, they believe something is wrong—that the vaccine is dangerous. The use of the word ‘recall’ can lead to people refusing to be vaccinated due to misinformation.”

*Tracking Vaccinations Administered*

*Reporting vaccinations:*

- To mitigate the effects of not having mandatory reporting to the state immunization registry, one state: “Developed and implemented easy data entry options for the immunization registry to reduce the time needed to input the numbers of doses administered and extended automated data upload capabilities. In lieu of required reporting into the registry, the state also initiated a variety of methods to collect, compile, and authenticate data, including aggregate data reporting by some provider partners, as well as other surrogate sources of data.”
- “To address temporary connectivity issues for pharmacy chains, local health departments input the required data entry into the immunization registry on behalf of the pharmacies.”

*School-based clinics:*

- One state reported that, “Where possible, local public health staff administered vaccines in school-based clinics in order to avoid problems with FERPA and the associated problems with school employees reporting vaccinations to the state immunization registry. However, this was not possible in all areas.”

*Veterans Administration:*

- “The health agency reported contacting the VA with a letter seeking their participation in the registry for the H1N1 data. A reply has not been received yet.”

*Adverse Event Reporting*

“The state reported successfully using poison control centers during the H1N1 response for such things as medical errors and adverse reaction reporting.”

**Recommendations  
Suggested:**

*Tracking Vaccinations Administered*

*Reporting vaccinations:*

- States offered several suggestions for improving vaccination reporting through immunization registries. “States with opt-in systems should seek to change their state law to either a mandatory or opt-out system.”
- “All providers participating in a pandemic influenza vaccine campaign should be required to use the statewide immunization registry for reporting vaccine accountability data as a matter of policy. This could be made a condition of acceptance of vaccine by providers.”
- “States should work with pharmacies and other private providers with restrictive Internet security policies that preclude access to state immunization registries to remove this barrier. States need to increase the functionality and interoperability of electronic immunization registries to track and monitor vaccinations.”

*School clinics:*

- The U.S. Department of Education issued guidance on FERPA and H1N1 issues in October 2009. “States need to evaluate the guidance to determine if it satisfies the questions they have about FERPA and whether it makes it easier to track H1N1 vaccines administered at school-based clinics.”

*Veterans Administration:*

- “Changes are needed in federal policy/practice that prohibits VA participation in state immunization registries.”

*Vaccination Coverage*

- To further expand vaccination coverage rates among health care workers, “states should investigate potential partnerships with large HMOs to capitalize on their approach and track records in positively influencing physician beliefs and behaviors.”
- “States should evaluate the effectiveness of lowering patient age for vaccination to increase the reach of an expanded pool of authorized vaccinators. Federal and state staffs need to (1) assess the impact of the varying patient age requirements and limitations on the authority to administer influenza vaccines among states; and (2) assess the related impacts in states that issued emergency orders lowering the allowable age for the express purpose of increasing vaccination coverage. These assessments will inform future decisions and possible reform and national harmonization of this public safety requirement.”

*Adverse Event Reporting*

- “Vaccine tracking systems must be enhanced to monitor for adverse

reactions.”

#### *Vaccine Recall*

- “CDC should never use the word ‘recall’ in association with vaccine unless there is a clear safety issue.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Recovery, Destruction and Disposal

**Issue:** **D.12 States are concerned over the impending confusion and cost of recovering and disposing expired H1N1 vaccines.**

**Issue Type:** Policy; Legal

**Level:** State; Federal

**Discussion:** States expressed concern regarding the “potential costs and lack of guidance regarding proper recovery and disposal of vaccines.” It was noted that “states and providers with expired vaccine are facing potential costs to establish contracts to dispose of vaccine.”

The treatment of expired vaccines as “hazardous waste, medical waste (or some other classification required by state law) will have significant implications for states’ recovery activities and potential disposal costs for public and private providers as each has separate disposal requirements.”

In one state with environmental laws that are more restrictive than federal laws, it commented that “There are multiple categories of waste defined by statute/regulation (e.g., dangerous waste, state-only dangerous waste, dual waste, pharmaceutical waste, RCRA hazardous waste). Only certain entities are allowed to collect and dispose of some categories of waste as defined in state law and the disposal process is very confusing and cumbersome. Depending on how the expired vaccine is classified, local health agencies may not be allowed to act as a collection point. Even some commercial collectors who dispose of their waste in other states may not be allowed to be used.”

It was noted that “many of the providers who gave H1N1 shots do not typically handle items that are classified in ways that cannot be disposed of through sharps’ containers or similar processes.” Another potential concern is that “providers who volunteered to assist with H1N1 vaccinations, but who might not typically vaccinate, may not volunteer again due to the hassle of disposal of these assets.”

**Mitigation Strategies Employed:**

- “The health agency has been working at the state level with the state’s environmental protection agency to sort through all these laws and identify a viable solution for local providers. The state has also been coordinating with CDC and BARDA to determine if the federal program will work in this state. If not, the state may need to take on the responsibility of ensuring proper disposal of expired H1N1 vaccine. With the potential for funding to help pay for the disposal ending July 30, 2010, states need to get this issue resolved.”

**Recommendations Suggested:**

- “The creation of a demobilization plan that thoroughly addresses the many logistical and financial issues around disposal of vaccine was identified as a high priority for many states. This plan should include identifying a funding source to cover the attendant costs, especially if this will take place after July 30th when PHER funds are expected to terminate.”
- “States would prefer material be classified as medical waste because the cost associated with disposal will be less than if it is deemed “hazardous waste.” Further recommendations from the state representatives included consistent labeling across states; medical or hazardous waste; use Public Health Emergency Response (PHER) carry-forward funds to store or centralize vaccine that will not expire; and using PHER funds to recollect vaccine.”
- “Expired or non-viable vaccine should be able to be returned to the manufacturers or the distributor for proper disposal.”
- “Since government supplied vaccines and materials for free, the administration fee that providers collected giving the vaccine was meant to cover disposal costs, too.”
- “Vaccines need to be designated so that states that have strict environmental rules know which category these products fall into. When not designated, they automatically fall into stricter category in some states, thereby requiring a more complicated disposal process.”
- “It is recommended that CDC proactively work with other federal agencies to ensure disposal options are addressed at the front end of a response. This will likely be an issue for antivirals in the future especially if they are not designated under the environmental rules yet.”

[Sources: Survey: X Meetings: Environmental Scan: X ]

## III.E Workforce, Capacity, and Infrastructure

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### **Summary of Barriers Identified**

The primary barriers identified related to workforce, capacity and infrastructure were (numbering does not reflect a priority order for the barriers):

- E.1 Public Health Workforce Surge Capacity**—Flexing and surging the public health workforce was a challenge, especially as repeated rounds of budget cuts and hiring freezes have shrunk standing capacity in state health agencies.
- E.2 Health Care/Medical Surge**—Surge capacity in the health care sector is limited and could be quickly overwhelmed during a prolonged pandemic event.
- E.3 Volunteer Surge Capacity**—Volunteers participating in the H1N1 response expressed fears about their potential legal liabilities during the response.
- E.4 Volunteer Surge Capacity**—Volunteers provided important surge capacity to the H1N1 response, but they are not appropriate for all public health positions in a response.
- E.5 Worker Protection and Employment**—Public health recommendations were not universally supported by employee sick leave/employee absentee policies in business and industry. Workers feared losing their wages or jobs.
- E.6 Workforce Mandates**—Ongoing questions and concerns about mandating vaccination for health care and other workers continue to affect pandemic response preparedness.

### **Selected Successes/Mitigations Identified**

#### *Flexing Existing Staff*

- “The existing health agency staff was flexible, well organized, dedicated and efficient during the event.”
- “In addition to performing routine tasks, medical and public health staff carried additional duties.”
- “To address laboratory staff capacity issues, additional cross-trained staff were utilized to process the H1N1 specimens and perform administrative duties; at times, staff were obtained from temporary workforce agencies and local health departments.”

#### *Public Health Surge Capacity*

- “PHER funding allowed an increase in the local health department’s surge capacity by allowing and facilitating the hiring of temporary employees during the event.”
- “Insufficient staff was available for vaccination during the event and retired public health veterans at the local health department level offered expert assistance during the surge.”

- “State public health laboratory work spaces, changes in work schedules and functional teams facilitated capability to meet an increased demand for testing, mailing of kits, and test result reporting.”
- “Many public health agencies across the state conducted response efforts with minimal personnel and shortages of credentialed staff.”
- PHER grants provided vital funding to supplement public health workforce capacity, particularly in key areas such as surveillance and immunization. States used PHER funds to hire additional, but temporary, staff.
- Some states reported “paying overtime as an incentive for staff to work longer hours, and hire, when available, private contractors.”
- One state reported “establishing a pool of staff that were trained to ‘adequate’ levels within each of the ICS needed. The agency attempted to rotate people in/out on a 7-day cycle, although it took several weeks to refine this process.”
- Other states created “strike teams composed of seasoned public health workers/champions functioned as trainers and organizers for community and school-located vaccination clinics.”
- “State and local health drew heavily on volunteer resources to extend departmental capacity. This was effective for the short-term, but would not have been sufficient for a more severe H1N1 outbreak.”

#### *Health Care/General Surge Capacity*

- “When accessible, the use of school nursing staff, translators for non-English speaking patients and existing contracts and services with private vendors (i.e. trucking companies for distribution), as well as the individual training and agency cross-training conducted prior to the event proved advantageous during the incident in achieving a high level of collective preparedness.”
- One state noted using “a significant portion of the PHER funds to contract with private health care providers to assist with the statewide vaccination campaign.”

#### *Volunteers*

- “Response efforts from volunteer nurses at the local level and, at the state level, from state universities, were a large part of existing, collaborative partnership efforts.”
- “In general, the use of volunteers at the local level was effective; however, state and local public health found that they could not use volunteer staff as effectively for fulfilling key public health roles. Individuals with an intricate knowledge of the state’s public health system should have filled these roles internally.”
- “The state used volunteers to deal with staffing shortages; they saved counties tens of thousands of dollars, and remained committed and engaged in PODs throughout the vaccination campaign.”

#### *Employment Issues*

- “The health agency was not able to directly affect labor laws relating to wages and benefits, therefore, it addressed the issue indirectly by stressing basic infection control practices. Information about hand hygiene and respiratory etiquette were widely available and free seasonal and H1N1 vaccines were eventually offered to the public.”

## ***Barriers/Recommendations Identified Detail***

### **Public Health Workforce Surge Capacity**

**Issue:** **E.1 Flexing and surging the public health workforce was a challenge, especially as repeated rounds of budget cuts and hiring freezes have shrunk standing capacity in state health agencies.**

**Issue Type:** Policy; Legal

**Level:** State

**Discussion:** *Existing Capacity Strained*  
Flexing the existing public health workforce was a challenge, especially as “repeated rounds of budget cuts and hiring freezes have shrunk standing capacity in state health agencies.” In some states, a “lack of depth in key positions due to retirements and unfilled position vacancies hindered response activities.” One person commented that “the inadequate and thin public health workforce resulted in key staff working 16 hour days, with all program staff participating in just the H1N1 response activities.”

#### *EOC/ICS Capacity*

Some states reported “insufficient state staff capacity to sustain activation of emergency operations centers (EOCs) for long periods of time.” States acknowledged that “many staff had to be pulled in from other public health agency programs beyond preparedness to staff the EOC.” As a result, “many public health programs were forced to put their regular activities and responsibilities on hold, or on reduced staffing levels, which put them further behind.”

#### *Supplementing Capacity*

PHER funds helped tremendously in staffing needs “but the overall public health force was substantially small at the beginning of the H1N1 outbreak.” Even with PHER funds, states noted that “because of states’ fiscal crises, there was reluctance on the part of state personnel agencies to hire staff, even for a limited term.” One person commented that “temporary employees required intensive training by staff already taxed with response activities.”

One state noted a distinction in its laws between “state health agency staff who were detailed to assist at vaccination clinics versus those who volunteered their time to assist.” Staff who volunteered were treated as private citizens and were not required to be compensated as per the volunteer agreement they signed. The state noted that “assigning staff to details in support of the mass vaccination clinics caused discontent among the workforce and created labor union issues with compensation for the time and attendance.”



### *H1N1 Surge Impacted Agency Programs and Staff*

A respondent observed that “state agency staff in areas such as immunization, preparedness, epidemiology, and laboratories was generally unable to address any program elements other than H1N1 response for several months.” One state’s immunization program revealed the “significant programmatic and staff impacts caused by the H1N1 response: Staff was overtaxed and its requests for help were not acknowledged within the agency until the situation had progressed to an unacceptable level. The lack of responsiveness to many requests for help took an emotional and physical toll on many immunization staff members.” It was felt that “the health agency upper management’s failure to act upon or recognize program staff’s need for assistance has led to long-term consequences ranging from staff illness to lack of trust.”

### *Tracking and Compensating Surge Activities*

One state noted that “staff with critical skills was not identified prior to the event and it was difficult to make these decisions in the middle of a response.” Restrictions on H1N1 funds resulted in “difficulty flexing staff to fill needs directly or backfill for staff diverted to the response.” The state also noted that: “The extended and intense response by staff members left many exhausted as dedicated staff was not prepared for the change in work schedule. With individual exceptions, epidemiology and immunization staff carried the brunt of the workload for an entire year.” It was concluded that “human resource policies need to be further developed and improved in order to track and compensate for time spent on response.”

### *Lack of Sustained Public Health Workforce and Infrastructure Support*

States uniformly acknowledged that the “lack of sustained, ongoing funding to support public health infrastructure resulted in limited capacity to respond without supplemental funding.” It was observed that “short-term, supplemental dollars are not an adequate alternative to thoughtful, consistent funding geared to building core capacity, ensuring the availability of a trained workforce and adequate laboratory and health system surge capacity.” As a result of shrinking federal and state dollars, “state and local health departments have cut back on core public health components, leaving them without the staff and resources required to mount a quick and coordinated response to an event such as H1N1.”

One respondent acknowledged that: “Communities without a full-time health director lacked the capacity to organize and conduct mass vaccination campaigns. While PHER dollars helped to address gaps, the restrictions on the use of funds hampered efforts to meet local needs.”

### **Mitigation Strategies Employed:**

#### *Supplementing Capacity*

- PHER grants provided vital funding to supplement public health workforce capacity, particularly in key areas such as surveillance and immunization. States used PHER funds to hire additional, but temporary, staff.

- Some states reported “paying overtime as an incentive for staff to work longer hours, and hire, when available, private contractors.”
- One state reported “establishing a pool of staff that were trained to ‘adequate’ levels within each of the ICS needed. The agency attempted to rotate people in/out on a 7-day cycle, although it took several weeks to refine this process.”
- Other states created “strike teams composed of seasoned public health workers/champions functioned as trainers and organizers for community and school-located vaccination clinics.”
- “State and local health drew heavily on volunteer resources to extend departmental capacity. This was effective for the short-term, but would not have been sufficient for a more severe H1N1 outbreak.”

**Recommendations Suggested:**

*Supplementing Capacity*

- “More highly trained staff (epidemiologists, laboratory technicians, and budget staff) is required during surges for a sustained period; surge capacity cannot be addressed with just in time training.”
- “CDC needs to be very explicit in their grant guidances concerning the expeditious hiring of personnel so the overall intent of grants can be realized in a timely manner.”
- “Develop training programs to allow the use of non-health personnel to vaccinate or dispense medications during an emergency response.”
- “Develop future agreements with medical schools to provide public health surge capacity.”
- “Training additional nurses who are prepared for public health roles, training local health departments to outsource flu clinics at non-traditional sites, schools and including more basic staff to keep programs running are strongly recommended.”
- “Rebuild the public health infrastructure during non-emergency times, so that there is adequate staffing to rely on in during a pandemic or other emergency event.”

*Tracking and Compensating Surge Activities*

- “Participants proposed that policies be developed to provide clear direction on flexing hours, overtime and shift flexibility (how long staff are eligible to work), compensation, and sick-leave for all employees.”
- “State and local governments should further develop Human Resource policies regarding compensation, tracking personnel time and workplace needs for state/local employees.”

- “Participants also identified that local government should consider allowing non-health department staff to receive compensation for extra hours worked for future incidents.”
- “State should further develop standards for human resource policies that can be used by local agencies in the development of their policies.”

*Funding Public Health Surge Capacity*

- “Ensure that public health preparedness is recognized as a key component of the nation’s homeland security strategy, and is treated on a par with federal and state funding for other national security response.”
- “More staff will need to be identified for various EOC/ICS positions, routinely trained, and provided opportunity to remain engaged. This will require more funding beyond what can presently be accomplished with base funding.”
- “Some of the PHER money should have been kept at the state level to use to hire additional help, rather than sending the majority to local health department.”
- “Sustained investments by local, state and federal government to fund public health infrastructure and surge capacity across county lines to meet vaccination program needs, as well as for SNS receiving and distribution is recommended.”
- “Increase funding levels and resources for public health infrastructure to sustain required services.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Health Care/Medical Surge

**Issue:** E.2 **Surge capacity among in the health care sector is limited and could be quickly overwhelmed during a prolonged pandemic event.**

**Issue Type:** Policy; Legal

**Level:** State

**Discussion:** *Health Care Surge Capacity*  
 Health care medical surge capacity is limited in many jurisdictions. This presents a challenge in mounting a community-wide response. Many states fear that “had the H1N1 outbreak been worse, public health agencies and health care organizations would have been severely taxed.”

In states with minimal local public health infrastructure, it was seen as a “challenge to enlist enough medical personnel to conduct a sustained, statewide vaccination effort.” Other states reported that: “Fortunately, the private health care sector was able to significantly supplement public health’s efforts through contracts using PHER funds. Without supplemental federal funding, the situation would have been drastically different.”

At many hospitals, the “worried well” overwhelmed emergency departments. One state health agency official commented that “H1N1 has changed the thought behind what a hospital needs so H1N1 policy may help drive decisions on hospital flow and the way people are moved through the hospital.”

*Community Health Centers*

A state noted that: “Community health centers (CHC) cannot legally work outside their scope of practice (assigned zip codes and populations) due to legal and insurance constraints. They are limited in their ability to offer support to hospitals and clinics experiencing patient surge.”

**Mitigation Strategies Employed:**

- One state noted using “a significant portion of the PHER funds to contract with private health care providers to assist with the statewide vaccination campaign.”

**Recommendations Suggested:**

*Health Care Surge Capacity*

- “The Institute of Medicine has documented that emergency departments are in trouble. There is a need for sustained funding for hospital preparedness and trauma centers.”
- “Increased and consistent federal funding to the states to augment public health infrastructure is necessary.”

*Community Health Centers*

- “Legal and policy restrictions regarding CHCs need to be changed to allow for a more coordinated response and increasing community surge capacity.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Volunteer Surge Capacity

**Issue:** **E.3 Volunteers participating in the H1N1 response expressed fears about their potential legal liabilities during the response.**

**E.4. Volunteers provided important surge capacity to the H1N1 response, but they are not appropriate for all public health positions in a response.**

**Issue Type:** Legal

**Level:** State; Federal

**Discussion:** *Volunteer Liability Concerns*  
See related discussion and recommendations in Section III.A above regarding liability concerns.

*Role of Volunteers in Response*

One state acknowledged that maintaining public health and hospital staffing during the peak of the H1N1 outbreak was a challenge. It noted that “using volunteers at the local level was generally effective; however, state and local public health found that they could not use volunteer staff as effectively for fulfilling key public health roles.” The state believed that “individuals with an intricate knowledge of the state’s public health system should have filled these roles internally.”

It was also commented that: “Surge capacity for hospitals continues to be an issue, as hospitals do not want to divert their staff to off-site facilities. Staffing continues to be the biggest barrier to alternate care facility planning. The solution may be to surge as much as possible in the hospital where staff capacity already exists in addition to using retired medical personnel and students.”

**Mitigation Strategies Employed:** *Volunteer Liability Concerns*  
See related discussion and recommendations in Section III.A above regarding liability concerns.

**Recommendations Suggested:** *Volunteer Liability Concerns*  
See related discussion and recommendations in Section III.A above regarding liability concerns.

*Role of Volunteers in Response*

- “The use of volunteers needs to be restricted to non-critical public health roles.”

- “Need to re-evaluate roles for volunteers and contractors during an emergency event, clearly defining those roles for public health staff vs. volunteers and ensuring the proper staffing is available for emergency response needs.”
- “Local health care coalitions need to look at using retired medical personnel as well as medical and nursing students for surge staffing.”
- “Conduct federal background checks for all ESAR-VHP volunteers. This should be done by HHS; states cannot afford to conduct these background checks using current funds.”
- “Engage volunteers in additional preparedness training and exercises.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Worker Protection and Employment

**Issue:** **E.5 Public health recommendations were not universally supported by employee sick leave/employee absentee policies in business and industry. Workers feared losing their wages or jobs.**

**Issue Type:** Legal; Policy

**Level:** State; Federal

**Discussion:** *Concerns about Sick Leave; Loss of Wages, Jobs*  
 States expressed concern about “workers who do not have paid sick leave or who may have sick leave but were required to produce a medical note following an illness-related work absence.” A respondent noted that: “Working people in the affected groups would not easily be able to remain home from work while ill or avoid a visit to a healthcare provider (thus burdening the medical sector and potentially exposing the worker to H1N1). Workers exempt from federal overtime and minimum wage standards, such as home care workers, are also unlikely to receive paid sick leave. These workers would likely continue to work while ill to preserve their wages and jobs, and would not be able to comply with public health recommendations. The health agency was not able to devise direct remedies to address this barrier. Neither federal labor law nor private and public sector workplace rules were within the control of the agency.”

Other states noted that: “Workers with sick leave had questions about whether their employers’ sick leave policies would cover persons who have been exposed to or are quarantined for a communicable disease. People in quarantine are not yet sick but must be absent from the workplace. They may not be eligible for sick leave status under their employers’ sick leave policies.”

### *Employer Privacy/Disclosure Obligations*

States expressed uncertainty as to: “Whether an employer is obligated to or may otherwise divulge the nature of an employee’s illness (e.g., H1N1 influenza). Employers are faced with the dilemma of protecting a sick worker’s privacy but also may want/need to advise other employees about their possible exposure to illness. Employers also have concerns about potential liability arising from their failure to inform well employees of potential risks from sick co-workers. The answers to these issues may differ with the field or industry in which the employer operates (e.g., healthcare and non-healthcare employers and between public and private employers). One state’s law authorizes the employer to inquire about workers’ health status, but require hospitals to exclude ill healthcare workers.”

### **Mitigation Strategies Employed:**

#### *Concerns about Sick Leave; Loss of Wages, Jobs*

- “The health agency was not able to directly affect labor laws relating to wages and benefits, therefore, it addressed the issue indirectly by stressing basic infection control practices. Information about hand hygiene and respiratory etiquette were widely available and free seasonal and H1N1 vaccines were eventually offered to the public.”
- “Six states have existing statutory protections for employees by prohibiting the termination of an employee subject to isolation or quarantine. Another state requires that an affected employee must be reinstated following quarantine or isolation. Another state requires an employer to grant either paid or unpaid leave to an employee who is subject to quarantine or isolation.”

### **Recommendations Suggested:**

#### *Concerns about Sick Leave; Loss of Wages, Jobs*

- “Clear guidance is needed on the intersection of employee legal protections and employer actions. This includes workplace policies on leave usage (e.g. sick time, vacation, etc.), loss of income due to leave taken, workplace restrictions (e.g. when to send staff home when sick, how to monitor staff for illness), and workplace provisions regarding vaccinations, antivirals, and personal protective equipment (PPE). Each state and local government addressed these independently, resulting in lack of coordination.”
- “Consider federal reimbursement for lost wages as Toronto did following the SARS outbreak.”
- “Changes in federal labor laws that require employers of domestic workers to provide benefits that are in line with those provided to other classes of worker.”
- “Consider seeking revisions to federal and state unemployment compensation law, such as authorizing payment of unemployment compensation during a declared public health emergency so that workers

will be more likely to remain home and reduce the risk of transmission of the disease.”

- “Review other potentially relevant laws, such as the Family Medical Leave Act, for possible revisions that would encourage employees to comply with isolation, quarantine or social distancing measures.”
- “Review options for issuance of guidance for employers regarding quarantine and sick leave policies as well as other options that may be available (such as administrative leave) to reduce the potential spread of the disease through the worksite.”
- “Federal, state and local governments as well as the business community should develop flexible leave policies which include the ability to suspend the requirement for a doctor’s note during a public health emergency that has the capacity to severely overburden the healthcare system.”
- “Employers should not require medical verification for H1N1 absence.”
- “Work with private organizations to change corporate culture; employees should be encouraged to stay home when they are sick and HR policies should not require documentation from a physician confirming H1N1 or other widespread illnesses.”
- “Provide federal support for low-income families to stay home when kids are sick.”
- “State and local governments should continue to communicate with the business community and share public health guidance and recommendations.”
- “Department of Education, in partnership with state and local public health, should work more closely with the private sector to provide information on school closures and other school issues that potentially impact parents/private sector employees.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

**Issue:** **E.6 Ongoing questions and concerns about mandating vaccination for health care and other workers continue to affect pandemic response preparedness.**

**Issue Type:** Policy; Legal

**Level:** State; Federal



**Discussion:**

*Workforce Vaccination Mandates*

One state related that: “Many health care workers expressed concern that there were limited numbers of personnel in their facilities that chose to be vaccinated against H1N1. Hospital partners questioned whether mandating vaccination in this situation [H1N1] would work, as other vaccines (MMR) are mandated in order to work in a healthcare setting.”

A state noted that “mandatory vaccination policies in selected workplaces resulted in significant challenges.” The “lack of vaccination policy for laboratory workers and state employee vaccination opportunities were not addressed until late in the vaccination campaign.” It was observed that with “early employee vaccination, the state would have led by example.”

*FluMist Concerns*

One state reported that: “FluMist was the first vaccine presentation available for health care workers. In the past, health care workers were told that if they were vaccinated with FluMist, they could possibly transmit live virus to patients; thus many healthcare workers were not willing to be vaccinated with FluMist during H1N1. Many hospitals sent the FluMist presentation back without vaccinating their healthcare workers.”

**Mitigation Strategies Employed:**

None identified

**Recommendations Suggested:**

*Workforce Vaccination Mandates*

- “Directives to vaccinate healthcare workers should come out from the federal level and not from the state, local or facility level.”
- “During future pandemics, the federal government should mandate that influenza vaccination be required of all healthcare practitioners.”
- “Develop policies on mandatory workforce vaccinations for various categories of workers.”

*FluMist Concerns*

- “CDC needed to provide more specific information on FluMist and other intranasal presentations for healthcare workers.”
- 

[Sources:

Survey:

Meetings: X

Environmental Scan: X ]

## III.F Federal/State/Local Coordination

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### ***Summary of Barriers Identified***

The primary barriers identified related to federal, state and local coordination issues were (numbering does *not* reflect a priority order for the barriers):

- F.1 Intergovernmental Coordination**—Coordination between and among federal, state, and local governmental entities was inconsistent over the course of the H1N1 response.
- F.2 Federal Grants and Cooperative Agreements**—PHER grants provided states with the resources necessary to mount H1N1 response activities, but requirements for managing the grants were cumbersome and time-consuming.
- F.3 Federal Grants and Cooperative Agreements**—Federal grant and cooperative agreement requirements generally did not allow the states’ enough flexibility to surge personnel and resources in mounting H1N1 response activities.
- F.4 State Systems/Operations**—Some state governmental policies and procedures, as well as the internal operations of state agencies, tended to delay the rapid deployment of funds and personnel designated for pandemic response activities.
- F.5 Pandemic Influenza Planning**—Pandemic influenza planning has been geared toward a worst-case scenario but must become more flexible and scalable to allow for pandemics of less virulent influenza viruses.

### ***Selected Successes/Mitigations Identified***

#### *Intergovernmental Coordination*

- “Overall, interagency collaboration was successful at all levels.”
- “Constant internal communication channels of federal, state and local agencies seemed to improve the efficiency and effectiveness of the H1N1 response.”
- “Federal, state, and local partners swiftly coordinated H1N1 response efforts.”
- “Although setbacks at all levels of government occurred, public health agencies diligently succeeded with administering H1N1 vaccine to the public.”

#### *Coordination of Federal and State/Local*

- “States supported ASTHO’s efforts to work with HHS to develop a workable concept of operations and more clearly identify protocols for gathering and sharing situational awareness information.”
- “To address the perceived lack of a national common operating picture, state emergency operation centers tried to pull information from a variety of sources, but left untapped data in other federal, state, and local emergency operation centers.”

### *Coordination of States and Locals*

- “In home rule states, state health agency staff attempted to gather input from local health departments before making decisions in order to achieve some uniformity at the state level. The state also worked individually with those localities that did not follow state policy.”
- “State legal counsel addressed local health agencies’ concerns about liability risks during weekly health agency H1N1 conference calls.”

### *Common Operating Picture*

- “Webinars, websites and weekly telecasts using the state’s telecommunications agency assured common operating goals.”
- “To mitigate conflicting information from various federal and state agencies, the state utilized a cross-agency unified command structure to determine all policy issues.”

### *PHER Grant and Federal Funding Generally*

- “Under the Public Health and Social Services Emergency Fund, Congress allocated response funding to prepare for and respond to the novel influenza A (H1N1) virus.”
- “As the lead federal coordinating agency for H1N1 response, the U.S. Department of Health Services (HHS) provided funding resources to states.”
- “Access to funding permitted the utilization of additional staff in assisting with the vaccination efforts.”
- “PHER funding also supported temporary laboratory personnel.”
- “The infusion of federal funding was extremely helpful.”
- “The total federal funding amount distributed to the state was sufficient.”
- “Funding obtained through the PHER grant was used to quickly hire additional regional health department staff to assist with response efforts.”
- “Public health officials agreed previous funding resulting from avian influenza established a foundation for a national response, requiring states and local governments to identify pandemic planning as a priority.”
- “Hiring additional fiscal and grant management staff helped with some of the fiscal and grant management issues; however, program staff were diverted from program work to develop/amend multiple contracts for the various phases of PHER funding and were required to work extensive hours to accomplish both grant management and program response requirements.”
- “Streamlined local application processes and issued advance payments to allow work to begin expeditiously. This helped some local health departments but others were unable to take advantage of the advanced payments due to local governing body (e.g., town council, board of supervisors) requirements for approved budgets and work plans before any funds could be expended.”

### *State Systems/Operations*

- “The state found it more expedient to hire temporary, yet less skilled, workers to meet immediate response needs rather than attempt full-time hires.”
- “To mitigate the effects of being unable to immediately access PHER funds because of state budget and procurement processes, the health agency used other existing funding streams for procurement actions until the H1N1 supplemental funding was available. Once the PHER funds were available, H1N1 expenses were re-journaled to PHER funds; however, this practice restricted use of the original funding streams until the re-journaling could occur. This delayed implementation of normal programmatic activities until late in the grant year.”

- “Health agency program staff tried to educate fiscal staff within the health agency and in the state’s department of administration about the necessity to process H1N1-related requests quickly.”
- “The federal government needs to recognize that state requirements can impose obstacles to speedy implementation of federal goals. Frequently, the principal remedy was issuance of executive orders under the emergency powers of the Governor to suspend procedural requirements for H1N1 activities. However, such executive orders can be difficult to obtain.”

*Coordination with Stakeholders*

- “Public health and health care sector interaction, as well as health department interaction with local health care providers, hospitals, and EMS collaboration were rated “extraordinary”.”
- “The state medical/ethical societies and the state judiciary committee, along with key stakeholders, convened a task force for the utilization of scarce critical care resources during the pandemic which proved advantageous.”
- “Within the state’s laboratory forum, stakeholder engagement and lab response to members’ questions provided valuable feedback via impromptu conference calls, as well as the FAQ’s that were published.”
- “The state has established strong working relationships with tribal nations, state and local agencies, and healthcare providers.”

*Technical Assistance*

- “Communication vehicles, such as regular conference calls with federal officials (the Department of Homeland Security [DHS], Federal Emergency Management Agency [FEMA], CDC, etc.) for PIO’s as well as technical assistance calls from the Association for Public Health Laboratories (APHL), proved critical for specific technical issues.”

*Pandemic Planning*

- “The state recognizes the federal government for establishing a priority for pandemic readiness and planning.”
- States adjusted their strategies based on the less severe circumstances posed by H1N1. States revised their strategies for community mitigation and recommendations related to school attendance/closures.

***Barriers/Recommendations Identified Detail***

**Intergovernmental Coordination**

<b>Issue:</b>	<b><u>F.1</u> Coordination between and among federal, state, and local governmental entities was inconsistent over the course of the H1N1 response.</b>
<b>Issue Type:</b>	Policy; Legal
<b>Level:</b>	Federal; State
<b>Discussion:</b>	<i>Coordination of Federal and State/Local</i> States found that coordination between federal and state/local agencies was inconsistent. Some linked poor coordination with the lack of a clear Incident

Command Structure (ICS) through which to work on a combined federal and state response. The perception was that “Homeland Security, CDC, and FDA had different messages to some of the same audiences, frequent uncoordinated requests of states, and different information-sharing distribution lists and protocols.” Consequently, the “lack of a coordinated front on the federal level made it more difficult to have a coordinated front at the state level.” Different state agencies responded to the requests/needs of different federal agencies, “often without knowing what the others were doing.” One state noted that “tracking so much confusing information from so many sources impeded prudent decision making and even caused response partners to work at cross purposes.” (See also Section III.A above, “ICS, Command and Control, and Authority.”)

While states did acknowledge frustrations with the lack of coordination among federal agencies, states also gratefully acknowledged CDC’s efforts to coordinate the public health response, and affirmed the value of CDC’s frequent conference calls to share timely information and clarify key information. Also noted was the value of on-the-ground technical assistance provided by federal employees.

- *Concept of Operations/Common Operations Platform:* Some found that: “There was a lack of a clearly defined federal concept of operations that specified federal and state responsibilities and mechanisms for coordination. CDC, HHS, state and local emergency operations centers did not obtain information from each other to build a common operating picture. Information for situational awareness was derived from other sources in a work-around fashion.”
- *Understanding Differences in State Approaches:* Some states expressed the view that: “At times, federal personnel/agencies lacked a basic understanding of and appreciation for states’ different policy/legal approaches and requirements in their emergency response activities.” A lack of federal understanding about state legal schemes regarding health care professionals licensing, emergency management acts, and pharmaceutical regulations were given as examples. According to some states, “many fundamental questions were repeatedly asked by many people many times.”

Differences in state statutory requirements made it more difficult for some states compared to others in providing information or approaching issues uniformly across the states. For example, opt-in requirements that require a person’s consent before they are included in state immunization registry imposed a considerable burden on state staff that needed to use registries to track H1N1 vaccination coverage. States using opt-out or mandatory inclusion principles for their immunization registries could more readily track H1N1 vaccinations using this mechanism.

- *Coordination of state and federal legal counsel across federal agencies:* State legal counsel have expressed the need to “expand relationships among legal counsel in federal agencies.” It was noted that: “State health agencies frequently work with counsel in CDC, but state and local public health agencies sometimes pose legal questions that fall under the domain of HHS agencies other than CDC, such as FDA and CMS, or under the domain of agencies in other departments, such as DHS/FEMA. They need ways to communicate effectively with such agencies during public health emergencies.”

#### *Coordination Among States*

Better systems should be developed for real-time sharing of approaches and innovations across different states, communities, and jurisdictions. In addition, neighboring communities should share and coordinate to the extent possible plans for providing care and information, and if necessary, resources.

#### *Coordination Within States*

The need for improved coordination among and within state agencies was also identified. More “frequent and proactive coordination among legal and programmatic staff during a response was identified as a priority by legal counsel.” This was especially noted “when decisions are being made as to whether to address a problem with a legal and/or a policy solution.” The need for better intrastate coordination also arose in the context of expediting state procurement and hiring practices during the H1N1 response. (See “Grants” discussion below in this section.)

#### *Coordination of States and Locals*

State and local coordination issues were also identified as a significant facet of the H1N1 response.

- *Managing communications with locals:* States with larger numbers of local health districts needed to use multiple and frequent communication mechanisms to coordinate with local responders. It was reported that “local home rule policies in some states resulted in many jurisdictions making decisions that differed from statewide guidance and the actions of neighboring jurisdictions, requiring considerable coordination and communication activities by the state health agency.”
- *Continuing local liability concerns:* Ongoing liability concerns of local health departments and volunteers required repeated intervention by state agency counsel. A respondent noted that “despite robust liability protections in the law, local health departments, and the providers and volunteers working with them, were not fully informed about the protections and therefore very concerned that their response activities would expose them to liability risk.” In one community, a “large provider demanded that a local county issue an emergency declaration as added protection, even though state health agency counsel informed the parties it was unnecessary.”

- *Coordinating with local health agency counsel:* Better coordination and communication with legal counsel to local public health agencies is needed. State and local public health counsel noted that: “Communication channels with legal counsel at the local level are not as well developed as they should be. Some local level legal counsel are faced with unique challenges, such as not being focused/specialized in public health law, being on retainer and only contacted as needed over more frequent involvement, frequent turnover, and not receiving as much communication from state or federal public health agencies or counsel.”

*Coordination with National Public Health Partner Organizations*  
HHS, CDC and the states recognized the role of the national public health partner organizations during emergency response activities. States acknowledged that: “A regularly scheduled check-in among ASTHO, its affiliates, and partner organizations to share information among the states during the response would further improve the response. Information should also be shared among the national public health partner associations on a regular basis. Coordination efforts should also include the staff at national public health partner organizations. National organizations must work together to provide federal partners with state and local situational awareness, including communicating needs and identifying areas of collaboration and guidance prior to an event.”

**Mitigation  
Strategies  
Employed:**

*Coordination of Federal and State/Local*  
“States supported ASTHO’s efforts to work with HHS to develop a workable concept of operations and more clearly identify protocols for gathering and sharing situational awareness information.”

“To address the perceived lack of a national common operating picture, state emergency operation centers tried to pull information from a variety of sources, but left untapped data in other federal, state, and local emergency operation centers.”

*Coordination within States*  
“State agency legal counsels were not automatically included in H1N1 after-action reviews due to simple oversight by program staff. Once the oversight was identified, program staff gladly included state counsel. Since the legal team may not be as visible during a response, they may not be immediately thought of as part of the response team.”

*Coordination of States and Locals*  
“In home rule states, state health agency staff attempted to gather input from local health departments before making decisions in order to achieve some uniformity at the state level. The state also worked individually with those localities that did not follow state policy.”

“State legal counsel addressed local health agencies’ concerns about liability risks during weekly health agency H1N1 conference calls.”

**Recommendations Suggested:**

*Coordination at the Federal Level*

- “Ensure federal agencies adhere to national incident management standards and collectively make appropriate policy decisions when guidance crosses into more than one federal agency.”

*Coordination of Federal and State/Local*

- “Information flow could be improved through more streamlined messaging and greater predictability in the release of information.”
- “Create a “common operating picture” as a means to more effectively share standardized data and information between the different levels of government.”
- “Convene a federal/state/local working group to develop a concept of operations document that is vetted by stakeholders.”
- “Build a set of data elements that develops a common operating picture for local, state and federal public health and medical operation centers and move the information up and down the chain.”
- “Improve information flow between federal and state/local public health attorneys.”
- “CDC’s Public Health Law Program and the Office of General Counsel should establish permanent mechanisms for state and local public health counsel to communicate rapidly with counsel across a range of federal agencies.”

*Coordination with States*

- “State health agency attorneys need to be better connected within their agencies in both planning and implementation so that the attorneys are aware as issues/problems develop and how they will be resolved. This would save counsel time in exploring a legal solution when the agency has decided on a policy fix.”
- “Better coordination is needed between state public health and homeland security/emergency management.”

*Coordination of States and Locals*

- “During a response, state health agencies should continuously gather input from local health departments and work towards decisions that will allow for some consistency and uniformity when appropriate, while still respecting local autonomy.”
- “Need to better reach and educate local health departments’ and health care providers’ legal counsel so they can assure their clients of the



existing liability protections in place.”

- “The CDC Public Health Law Program should consider developing additional ways to facilitate communication among legal counsel to local public health agencies.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## Federal Grants and Cooperative Agreements

**Issue:** **F.2 PHER grants provided states with the resources necessary to mount H1N1 response activities, but requirements for managing the grants were cumbersome and time-consuming.**

**F.3 Federal grant and cooperative agreement requirements generally did not allow the states’ enough flexibility to surge personnel and resources in mounting H1N1 response activities.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** *PHER Grants*  
States indicated that federal Public Health Emergency Response (PHER) grant funds were appreciated by state and local health departments and made many of their response activities more robust. However, PHER grant concerns were the most frequently identified barrier related to intergovernmental coordination issues. Overall, states found the PHER grant processes to be “inflexible and cumbersome, consuming considerable staff time that could have been better spent on H1N1 planning and response activities.” States identified a number of specific pre-award and post-award challenges associated with managing PHER grants.

- *Multiple funding periods and application processes:* The complications of multiple PHER phases and “the unique requirements of each phase further exacerbated already difficult bureaucratic procedures including multiple local health department applications to the state for each phase, multiple requests for state expenditure authority during a difficult economic environment, and multiple contracts and purchase orders for each funding phase.” One respondent commented that “because the requirements for each phase were not known sufficiently in advance, each new phase of funding meant that state planning had to be revised numerous times.”
- *Allowable uses of funds ill-defined and changing:* Changing restrictions and requirements on the use of PHER funds in each grant phase made it difficult for states to plan for funding streams over the life of the grant.

A number of states indicated they “found the grant guidance to be ill-defined; some found that grant guidance only specified unallowable costs.” Concerning allowable costs, one respondent noted that “guidance from CDC seemed to put limitations on certain allowable costs relative to the stage of H1N1 response.” The uncertainty in allowable costs negatively affected how quickly and accurately states could respond to inquiries from local health departments and other sub-grantees. Another respondent reported that “local health departments had to wait for decisions concerning purchases pending CDC approval, which took weeks in some instances.” Other states reported that “some expenditures for purchases clearly allowed in the grant guidance were disapproved by federal PHER project officers.”

- *Slow approval of applications/spending requests:* Use of a cooperative agreement format did not allow for an efficient approval process to respond to the emergent circumstances of H1N1. As a result, states found there were delays in PHER funding approval from CDC. Concerns were also voiced about CDC’s Procurement and Grants Office’s (PGO) inability to keep up with the volume of administrative responsibilities such as processing award notices, redirection requests, etc.
- *Unclear direction for carryover and redirection:* There were conflicting interpretations of the PHER grant guidance regarding the duration of the grant as a one-year grant with a two-year carryover period. States planned their use of the grant with that understanding. States overwhelmingly expressed concern over CDC’s potential decision not to allow use of PHER funds past July 31, 2010. Because states had developed plans to use the funds over a longer period, the inability to use carryover funds would put these state plans, and therefore states’ preparedness in jeopardy. One respondent indicated that “states are unable to determine the appropriate responses for the remainder of this fiscal year and cannot conduct program planning for next year because of uncertainty over the PHER carryover funds.”
- *Problems with reporting requirements:* States identified unrealistic reporting requirements given the timing of the PHER grants. States indicated that “reporting requirements were changed mid-grant, resulting in situations in which states’ had not collected required data elements from the start of the response making reporting difficult.”
- *Too much emphasis on vaccine purchases to the detriment of other medical countermeasures and laboratory needs:* A number of states had the perception that: “The PHER funding and tracking activities were primarily focused on vaccine and vaccine delivery. The multi-faceted response—antiviral distribution, community mitigation, infection control, and public aware activities— undertaken by states were not adequately recognized given the focus of grant tracking activities.” Other states expressed frustration that “so much of the PHER grant went to the

purchase of vaccines, the arrival of which were late and did not match with public demand; states are now faced with disposing of significant amounts of unused H1N1 vaccine supplies.”

One state noted that PHER funds were not available for laboratory expenses after Phase 1. Since most of these funds went to cover spring 2009 costs, the state was “unable to hire needed lab staff and was limited as to the types and amounts of supplies it could buy.”

- *Other PHER grant concerns:* States also commented that “the timing of the funding awards did not match the states’ response needs.” Others noted that “the PERFORMS system was inefficient and required considerable staff time to use.”

The combination of the above issues slowed the states’ ability to deploy the PHER funds for response efforts, delaying both state and local activities.

#### *Flexing Federal Grants/Cooperative Agreements Generally*

States expressed the need for greater latitude in using federally-funded personnel and programs to surge the states’ response capacity during an emergency. As one state noted, “with limited numbers of individuals at the state level to serve in the ICS, it was difficult to assign individuals that are funded through other CDC programs to assist in the response when only 5% of their time could be utilized outside of their funded job duties.”

Furthermore, “federal categorical funding does not provide authority for staff to respond to a disaster that was a national public health emergency; staff funded by grants from CMS, WIC and other federal sources were unavailable for response.”

#### **Mitigation Strategies Employed:**

##### *PHER Grants*

States identified several mitigation strategies:

- “Hiring additional fiscal and grant management staff helped with some of the fiscal and grant management issues; however, program staff were diverted from program work to develop/amend multiple contracts for the various phases of PHER funding and were required to work extensive hours to accomplish both grant management and program response requirements.”
- “Streamlined local application processes and issued advance payments to allow work to begin expeditiously. This helped some local health departments but others were unable to take advantage of the advanced payments due to local governing body (e.g., town council, board of supervisors) requirements for approved budgets and work plans before any funds could be expended.”
- “Funding was used to quickly hire additional staff for regional health agency offices to assist with response efforts.”

- “There was no “work-around” possible to some of the PHER grant barriers. The funding was integral to H1N1 response, so states had to spend the time on the application process as it was presented.”

**Recommendations Suggested:**

*PHER Grants*

*States identified a number of recommendations to address some of the specific PHER grant-related barriers identified:*

*Multiple funding periods and application processes:*

- “Funds should be awarded in one phase with more flexibility on their allowable uses in order to permit states’ to use funds to cover their unique response efforts.”
- “Awarding the funds in one phase would streamline the purchasing and contracting processes at both the state and local levels.”
- “Identify more appropriate mechanisms for funding response activities. The grant process is better designed for funding long-term enhancement activities, not emergency response operations.”
- “Decrease the number of applications required to secure the same funds and reconsider using similar application processes that CDC used during the post 9/11 PHEP supplemental awards and pandemic influenza supplement in 2006. Specifically, use the methodology of releasing 20% of the funds, with authorization for use of the additional 80% based on a comprehensive application submission.”

*Allowable uses of funds ill-defined and changing:*

- “Clear and consistent direction should be provided as to the period of use of the funds including the ability to redirect and/or carryover funds.”
- “Allow the purchases of services and supplies as provided by the guidance during the full life of the grant cycle.”
- “Provide one guidance document at the outset for the entire funding stream.”

*Slow approval of applications/spending requests:*

- “Instead of following the usual steps for a grant application, exceptions should be made in order to free staff to work on planning and response activities when the country is in the midst of an emergency event.”
- “CDC should work with states to formulate templates for ‘emergency’ funding applications that still have elements of accountability, but do not take weeks to complete and can be quickly approved by CDC/PGO.”
- “Develop a system that provides a less restrictive process and that does not require the intervention and approval of project officers and PGO to approve budgets in the same way cooperative agreements are

implemented.”

*Unclear direction for carryover and redirection:*

- “CDC and OMB need to agree that the original grant guidance for all PHER Phases allow for carryover.”
- “Health departments are still in the process of responding to H1N1. Recovery efforts and improvement plans will be taking place long after July 31, 2010. This potential limitation on the use of PHER funds makes it very difficult to be good stewards of public funds.”

*Problems with reporting requirements:*

- “CDC should simplify the PHER reporting requirements to reduce the burden on staff already engaged in response and normal duties.”

*Too much emphasis on vaccine purchases to the detriment of other medical countermeasures and laboratory needs:*

- “Although vaccination was a primary role for every state, laboratory testing and surveillance were critical to ongoing monitoring of H1N1 and funds should have been made readily available for these purposes.”
- “Either have the guidance address the scope of response and recovery or provide more flexibility for state and local prioritization.”

*PERFORMS system required considerable staff time to use:*

- “The PERFORMS system should be programmed to allow the application and requests for redirection and/or carryover to be completed within the system as other forms and documentation lead to confusion and extended the workload for both the states and CDC staff.”
- “To avoid duplicative efforts for application submission through Grants.gov and PERFORMS, consider allowing a letter of intent submission by the state without full narrative or budget and budget justification through both systems. Since a letter of intent may not suffice for federal use of grants.gov, consideration could be made for submission first through PERFORMS, which would then provide output reports that could be uploaded into grants.gov following PERFORMS submission.”

*PHER Overall:*

- “Provide state and local public health with greater administrative flexibility for a fuller range of program activities and, in anticipation of future funding, be proactive in crafting simpler and more efficient administrative process to award funds and monitor and evaluate performance.”

*Flexing Federal Grants/Cooperative Agreements Generally*

- “Federal grants and cooperative agreement requirements and processes need to be more flexible during public health emergencies. The federal

funding process should allow federal agencies to advance a portion of emergency grant funds to state/local governments so they can initiate response activities immediately. Having to await the full application and review process delays initial response activities.”

- “CDC should allow for staff in positions that are funded by any CDC program to assist in a public health emergency response as long as they are needed.”
- “Federal authority should be provided to programs to allow use of already funded staff on categorical sources to participate in a response where there is a Public Health Emergency Declaration or a Stafford Act declaration.”
- “The federal government should lift restrictions on allowing states to reassign employees supported by federal funds so they could help with future emergency response efforts.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

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## State Systems/Operations

**Issue:** **F.4 Some state governmental policies and procedures, as well as the internal operations of state agencies, tended to delay the rapid deployment of funds and personnel designated for pandemic response activities.**

**Issue Type:** Policy; Legal

**Level:** State

**Discussion:** States frequently acknowledged that their “own state procurement and personnel systems hindered quick H1N1 response activities.” In some states, the lack of a state emergency declaration slowed state procurement and personnel requirements; in other states, the procurement/personnel processes were still slow despite state emergency declarations.

In states that did not declare an emergency during the H1N1 outbreak, normal budgeting and procurement processes remained in place. One respondent noted that “the timing of receipt of PHER grant funds in August 2009 did not allow some states to fully process the funds within their fiscal years ending September 30.” One state reported that, “since PHER funds were not forecasted by the health agency and were therefore unbudgeted, the agency had to first request authority to budget the funds and then budgets had to be loaded into the state’s procurement system before normal competitive contracting actions could begin.”

Even hiring temporary staff proved to be difficult in some states. One state that characterized itself as being in fiscal crisis noted that “the state’s department of administration was reluctant to hire staff, even for a limited term.” Overall, “delays in getting personnel in place to help with planning, call centers, and vaccine processing and tracking hindered the state’s H1N1 response.”

**Mitigation Strategies Employed:**

*Addressing state procurement and personnel systems:*

- “The state found it more expedient to hire temporary, yet less skilled, workers to meet immediate response needs rather than attempt full-time hires.”
- “To mitigate the effects of being unable to immediately access PHER funds because of state budget and procurement processes, the health agency used other existing funding streams for procurement actions until the H1N1 supplemental funding was available. Once the PHER funds were available, H1N1 expenses were re-journaled to PHER funds; however, this practice restricted use of the original funding streams until the re-journaled could occur. This delayed implementation of normal programmatic activities until late in the grant year.”
- “Health agency program staff tried to educate fiscal staff within the health agency and in the state’s department of administration about the necessity to process H1N1-related requests quickly.”
- “The federal government needs to recognize that state requirements can impose obstacles to speedy implementation of federal goals. Frequently, the principal remedy was issuance of executive orders under the emergency powers of the Governor to suspend procedural requirements for H1N1 activities. However, such executive orders can be difficult to obtain.”

**Recommendations Suggested:**

*Emergency declaration in place:*

- “Even where there is a gubernatorial declaration of emergency in place, the declaration must clearly include a waiver of procurement/hiring policies and laws. State agency staffs in relevant agencies must be informed and educated about the effects of the emergency declaration on their regular procurement and hiring activities.”

*No emergency declaration in place:*

- “States need to look at actions it can take in situations where there is not statewide emergency declaration, such as enacting an exemption from statutory and administrative contracting procedural requirements for federal funds expended for purposes of public health emergency preparedness and response. Absent that, the issuance of needed emergency orders could be facilitated by a requirement imposed by the federal funding agency that such orders, or statutory exemptions, are in place as a precondition to receipt of the federal money.”

- “Statutory changes both at the state and federal level will be necessary for some jurisdictions wishing to change their procurement/personnel processes, especially in states in which emergency declarations are narrowly defined and agencies are not permitted to bypass normal processes.”

*Expediting state processes:*

- “Changes are needed in state hiring and procurement processes, so that purchases made with federal funds necessary for the state’s response to an event can be expedited, as compared to the usual lengthy procedure required when purchasing using state funds.”
- “There is a need to identify and assess state and local laws or policies governing procurement and personnel to determine how these could be modified to improve emergency response activities. The relevant laws or policies would include those preventing the recruitment, hiring, or retention of the public health professionals necessary to respond to H1N1 (e.g., merit system, furloughs, hiring freezes, posting requirements, contractor v. FTE, etc.), as well as state/local procurement laws or policies hindering response to H1N1 (e.g. competitive bidding).”
- “There is a need to identify additional policy/legal strategies that states can use to expedite the use of federal grant funds issued in response to a national emergency, even if an emergency declaration has not been issued in a state.”

[Sources: Survey: X Meetings: Environmental Scan: X ]

## Pandemic Influenza Planning

<b>Issue:</b>	<b><u>F.5</u> Pandemic influenza planning has been geared toward a worst-case scenario but must become more flexible and scalable to allow for pandemics of less virulent influenza viruses.</b>
<b>Issue Type:</b>	Policy
<b>Level:</b>	Federal; State
<b>Discussion:</b>	A number of respondents acknowledged that “pandemic influenza planning has been geared toward a worst-case scenario; plans outlined courses of action that were not appropriate for this pandemic.” This disconnect between planning and the realities of the H1N1 outbreak “resulted in confusion when health department response actions did not reflect what was in the pandemic plans.” Because plans were developed under a worst-case scenario, “various assumptions and response strategies had to be changed to address the less virulent virus.” For example, “guidance for school closures and other



response activities had to be reworked to address the less severe H1N1 outbreak.” The H1N1 outbreak demonstrated the need for flexible and staged pandemic response plans that align with the severity of the virus.

States noted that “SNS pandemic response plans should be reviewed and revised to allow for graduated response levels.” It was noted that: “Since prior planning assumptions were based on a scenario that anticipated an H5N1 virus coming to the U.S. from Asia, plans had to be totally redeveloped. Plans that had focused on worst-case scenarios must now be considered from a less severe perspective with the potential to “ramp up.” Jurisdictions will need to exercise plans that are revised using the lessons learned from the H1N1 outbreak.”

**Mitigation Strategies Employed:**

- States adjusted their strategies based on the less severe circumstances posed by H1N1. States revised their strategies for community mitigation and recommendations related to school attendance/closures.

**Recommendations Suggested:**

- “Pandemic plans need to be revised to account for pandemic outbreaks with a less severe virus.”
- “Pandemic plans need to be updated to include differing levels of pandemic severity, with clearly defined actions for each level.”
- “Review and re-calibrate the current pandemic planning guidance, including the pandemic severity index and the definitions of the pandemic stages.”
- “Pandemic plans need to be more strategic and written to allow health departments to adjust response strategies based on the situation and its impact on the jurisdiction.”
- “In the future, federal plans must be more nimble, guided by situational awareness, real-world input from state and local stakeholders, and be based on the best available scientific expertise.”
- “Regarding SNS planning, states need to conduct flexible, scalable exercises that are based on scenarios that are less than worst case scenarios.”
- “Update the *HHS Pandemic Influenza Plan* to reflect new WHO phases and changes.”
- “Provide guidance to states seeking to revise state operational pandemic influenza plans.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## III.G Communication

Please see the introduction to Section III on page 34 for general information about the data contained in this subsection.

### ***Summary of Barriers Identified***

The primary barriers identified related to communication issues were (numbering does *not* reflect a priority order for the barriers):

- G.1 Messaging Coordination and Capacity**—Federal, state and local governments need to achieve and maintain more consistent communications practices and messaging during emergency responses.
- G.2 Ad Campaigns and Messaging**—Inconsistent and slow federal messaging and ad campaigns complicated state/local efforts to communicate about H1N1 response activities.
- G.3 Public and Media Outreach**—Delayed federal decision-making and inconsistent messaging created significant public and media outreach demands on the states.
- G.4 Public and Media Outreach**—Public health response activities were hindered by inconsistent messaging about the severity of the H1N1 outbreak.
- G.5 Communication with Stakeholders**—Federal, state and local agencies did not consistently and efficiently communicate with stakeholders during the H1N1 response.
- G.6 Outreach to Minority Communities and Special/Vulnerable Populations**—Federal, state and local agencies needed to use more effective strategies to reach minority communities and special and vulnerable populations during the H1N1 outbreak.

### ***Selected Successes/Mitigations Identified***

#### *Ad Campaigns*

- “The state created a robust media marketing campaign that focused on vaccine promotion and proper hygiene to prevent influenza spread. However, the delayed arrival of vaccine required state and local governments to adjust marketing strategies mid-course.”

#### *Media Relations*

- “Participants discussed and credited successful communication efforts during the H1N1 event with and/or between media outlets and state and local agencies.”
- “State and local public health officials acknowledge the federal government for coordinating public health information with the national media during the initial phases of the outbreak.”
- “The state health agency’s public information officer addressed media demands by setting a schedule of routine times for press briefings, and established conference calls for key groups involved on the response (e.g. local PIOs, local vaccine coordinators).”

### *Messaging Coordination*

- “Communications were strength during the nationwide response; however, some communication issues occurred.”
- “The coordination of information was massively improved from spring to fall, in large part because of a state health Google Group implemented at the state level. This was developed to ensure that healthcare workers only received H1N1 updates once a day rather than each time a federal HAN was issued (multiple times a day during the spring response).”
- “The state attempted to develop its own key message update when the daily CDC updates become too large and unmanageable.”

### *Public Outreach*

- “Early communication of event details provided by the CDC and the state health agency via public media messages, conferences, briefings, interviews, broadcasts, website access and information, outreach messages (specifically about vaccination), laboratory result communication, as well as a high level of state participation (Governor and cabinet secretaries) were among the most successful means of communication during the incident.”
- “The state successfully used a variety of mechanism to communicate about H1N1, including: state/local websites to control messages and provide information; activation of state/local call centers and hotlines; sharing of weekly disease reports on the state health agency’s public website; bimonthly calls with representatives of professional provider organizations; ongoing press briefings with the Governor and state health director; presentations at healthcare forums, community meetings and school activities; and use of reverse 911 for communicating school-based messages.”
- “The state health agency and local health departments used social media sites, including Twitter and Facebook, to distribute messages.”
- “The state health agency public website was designed to include a specific page for H1N1, information on which was updated regularly.”
- “The state agency, under the auspices of the state’s H1N1 ICS command, developed a unit to monitor social media.
- To overcome inconsistent messaging regarding federal versus state vaccination priorities, one state noted that it “issued repetitive statements, press, and sound bites both statewide and in local communities to reiterate the state’s priority strategy/approach.”
- “The state health agency staged an aggressive public information campaign to encourage vaccination and to refute the claims that the vaccine was somehow experimental.”

### *Communication with Stakeholders*

- One state health representative noted that it “conducted facilitated, structured conference calls with local health agencies during which updated written Q&As were distributed to provide H1N1 and related informational updates, and to address questions/concerns.” The state also “created a separate link on its HAN portal website for H1N1 guidance to facilitate local health departments’ ability to quickly find current H1N1 information from the state health agency.”
- “The state health agency created the ability for the public and providers to register on the state’s website for automatic H1N1 information alerts.”
- “The state shared relevant H1N1 materials to stakeholders through state distribution networks.”

### *Outreach to Minority Communities and Special/Vulnerable Populations*

- “Relying on health agency science experts to provide safety messages were not totally effective at dispelling vaccine safety concerns among all minority and special populations. States also had to get the word out to community leaders who could spread the message within their communities.”
- “To address some physicians' reluctance to recommend the vaccine, a state health agency attempted to identify and characterize the reasons for the resistance. The state health agency partnered with a hospital association and provider groups to create and deploy a brief internet-based survey about physicians' attitudes about the H1N1 vaccine and vaccines generally.”
- “To reach minority communities specifically, health agency staffs have organized meetings between agency leadership and pastors, local African-American elected officials and other minority community leaders. This allowed department managers to learn first-hand about the concerns of minority constituents and to seek guidance about how to effectively address those concerns.”

## ***Barrier/Recommendations Identified Detail***

### **Messaging Coordination and Capacity**

**Issue:** **G.1 Federal, state and local governments need to achieve and maintain more consistent communications practices and messaging during emergency responses.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** Coordination among governmental entities and maintaining agency capacity to effectively communicate were key issues for state health agencies.

#### *Federal Communications*

Large amounts of information were directed at state and local health agencies from multiple sources, and states found it was difficult to keep up with and take action on. Some commented that, “over time, CDC’s key message documents became too lengthy and this diluted their effectiveness as daily media updates”. Some also noted that “information for the public and providers on the CDC website could be confusing when the data and guidance was changing quickly.”

Respondents noted that “federal delays in issuing, and frequent revision of, guidance in key policy areas like vaccine availability and formulation, vaccine priority groups, and PPE, delayed state response activities and caused states extra work in dealing with confused and concerned stakeholders, media and the public.”

#### *Locally Focused Communications*

Coordinating messages to local communities was an important concern. States encountered challenges in effectively communicating with local private health care providers to ensure consistent messaging because local

health departments' knowledge and communications channels with providers varied greatly by locality.

States expressed the need for “consistency between federal and state agencies regarding publicly communicating the names of local providers with vaccine.” In some states, the federal release of provider names was contrary to some states' wishes; states were concerned about overwhelming local health care capacity.

#### *State Communications Capacity and Coordination*

States' communications capacity and coordination activities should be addressed. States indicated that they “need to better coordinate state program staff with public information officers to allow for more and improved proactive messaging, rather than reactive messaging as some felt happened with H1N1.”

- *Using social/new media tools for public outreach:* Some states were initially unable to use “new media” tools (e.g., Twitter, Facebook) for H1N1 outreach because of state information technology (IT) and records requirements. States noted that “use of such new communication vehicles were planned as part of their H1N1 media campaigns to reach targeted populations (i.e., children, adolescents, young adults).” One state noted, however, that its health agency and state IT policies did not generally allow use of social media such as Twitter, Facebook, MySpace, or instant and text messaging, in part because of difficulties in maintaining a public records trail as required by state policy and law. Although school-based and other community H1N1 vaccination clinics were generally successful, active use of and interface with social media tools could have further enhanced statewide outreach efforts to specific groups.
- *Balancing information release with privacy concerns:* States noted challenges in balancing the need to release information to the public with the need to maintain privacy and protect resources from becoming overwhelmed. States had to weigh the level of detail to publicly provide when reporting confirmed H1N1 cases against individuals' privacy considerations.

States also cited “the lack of coordination by HHS/CDC with states regarding the agency's intent to create a flu clinic locator.” One state noted that “CDC made public pronouncements anticipating the release of the names of vaccine providers without consulting states that had expressed a contrary point of view.” The state agency faced uncertainty while not knowing what CDC ultimately planned to do.

#### **Mitigation Strategies Employed:**

#### *Volume of Communication Issues*

- “The state attempted to develop its own key message update when the daily CDC updates become too large and unmanageable.”

### *Social/New Media Issues*

- “The state agency, under the auspices of the state’s H1N1 ICS command, developed a unit to monitor social media. That unit worked with the agency’s IT department to get permission to passively observe social media trends and gather information on a daily basis for specific event reporting related to the H1N1 virus, non-availability/availability of vaccine, and adverse events and safety concerns. The resulting “social media report” was widely read by the ICS command, agency staff and local health departments throughout the course of the outbreak. One benefit identified was that by monitoring social media outlets, the state health agency was able to gauge public perception and behavioral changes related to H1N1. A limitation, however, was that due to the agency’s inability to actively interface with targeted Facebook and Twitter subscribers, it missed an opportunity to effectively use this public information tool to promote H1N1 vaccinations, address safety concerns, and quickly dispels rumors.”

### **Recommendations Suggested:**

#### *Volume of Communication Issues*

- “CDC should prioritize its key messages, with focus on current issues, and include additional background in an attached document.”
- “CDC should summarize their revisions to HAN communications and guidance in bullets, clearly outlining changes made.”

#### *Federal Communications with States/Locals*

- “CDC should post a version number on every guidance document.”
- “Reduce the number of conference calls.”
- “Ensure that the same information is provided on all calls; make call notes available to everyone by posting these notes on a public website for everyone involved in the response effort to see.”
- “Keep conference call times and days consistent.”

#### *State Communication Capacity and Coordination*

- “Ensure that public information officers (PIOs) submit up-to-date information on a regular basis rather than only on an “as requested” basis. Regular communication reports should be included as a requirement in emergency response cooperative agreements.”
- “State health agency should continue to consolidate federal guidance for state and local partners during future large-scale events to ensure state and local partners are not overwhelmed by federal communications and to ensure that state and local communications are also being received.”

### *Social/New Media Issues*

- “The state is currently drafting a statewide social media policy. When

approved, it will be provided to all state agencies for implementation. Within the health agency, the office of communications, in coordination with the health commissioner/chief medical officer, will review, revise and ultimately implement the policy in the health agency. The state health agency office of communications will provide the policy to all local health departments as a template for future use.”

- “Develop guidance for use of social media so that stakeholders are not trying to learn how to best use it ‘on the fly’.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Ad Campaigns and Messaging

**Issue:** **G.2 Inconsistent and slow federal messaging and ad campaigns complicated state/local efforts to communicate about H1N1 response activities.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** *Role of Federal Messaging/Campaigns in States’ Activities*  
States acknowledged that federal messaging and ad campaigns were important elements in the states’ communication strategies for H1N1.

- *Need national presence to H1N1 ad campaigns:* One respondent expressed that: “H1N1 advertising campaigns lacked a national presence. CDC relied on public service announcements and earned media, instead of a paid advertising campaign.”
- *Need to quickly share national ad campaign materials:* There were delays in making nationally-produced advertisements available to states. For some states, “this greatly impeded the public education component of the overall response effort.” Additionally, once the advertisements were available to states, “it became clear that most were prohibited from being aired as paid advertisements, which was also problematic.”
- *Vaccination ad campaigns:* States felt the need to “better coordinate federal/state/local vaccine ad campaign activities.” A respondent noted that “CDC was slow to announce it would not produce a paid, national advertising campaign, delaying the effort of states to plan and implement independent media strategies.”

### *Inconsistent State/Federal Messaging*

Some states felt that state and federal H1N1 campaigns lacked consistent messaging, which could be confusing to the public.

- *Flu clinic locator messaging:* It was unclear early on that HHS would invest in a flu clinic locator. One state created a flu clinic locator on its own, which was ready and operating ahead of the federal system. This state indicated that its “media campaign tied into its flu clinic locator, causing confusion among the public when the federal locator was advertised.”
- *Messaging about national vaccination priorities vs. state/local priorities:* HHS/CDC presented messages nationally about vaccination priority groups, but each state and/or locality may have addressed priority groups differently (e.g., targeting some sub-priority groups first). States indicated that “these inconsistent messages presented challenges for the public and state/local agencies trying to implement vaccination clinics.”

**Mitigation Strategies Employed:**

*Role of Federal Messaging/Campaigns in States’ Activities*

- “To overcome CDC delays in issuing an ad campaign, some states eventually developed and aired their own public service announcements, but the delays in doing so hindered their effectiveness. State PSAs were also developed without the benefit of knowing what was planned by CDC.”
- “The state used paid advertising as another element of their overall communication plan, in addition to public service announcements and earned media.”

*Messaging About National Vaccination Priorities vs. State/Local Priorities*

- To overcome inconsistent messaging regarding federal versus state vaccination priorities, one state noted that it “issued repetitive statements, press, and sound bites both statewide and in local communities to reiterate the state’s priority strategy/approach.”

**Recommendations Suggested:**

*Ad Campaigns and Messaging*

- “CDC should actively partner with states, especially those with large media markets, to coordinate in planning federal influenza messages. A coordinated effort during the development of campaign themes would help assure that federal and state ad messaging is complementary.”
- “There should be a hybrid effort in which CDC has a national advertising presence in addition to the effort of individual states.”
- “The federal government should begin developing influenza-related public service announcements now (Spring 2010) to be available in Fall 2010.”
- “The rules regarding states’ use of federal ad materials should be made clear up front, even before they become available to the states.”



- “Allow CDC funds to be spent on media campaigns, as smaller counties could not afford PSAs and local politicians pushed back on placing this in local budgets.”
- “Streamline the clearance process at both the federal and state levels for messages to the public and to stakeholders.”
- “Allow greater flexibility with CDC funding, so that it can be used for timely messaging to the public.”

*Vaccination Campaign*

- “Establish public information campaigns early in the response utilizing a unified consistent message.”
- “Ensure that messaging for vaccine demand and excess vaccine supply are prepared ahead of time.”
- “Increase public awareness and interest on getting vaccinated (develop focus group on why people did not get vaccinated).”
- “Develop an outreach plan for the public to increase understanding of vaccine safety and the importance of being vaccinated.”
- “CDC, HHS, and other federal ad campaigns should make it a policy to address the safety and efficacy of the vaccine, and also include prevention strategies in their messaging.”

[Sources: Survey: X Meetings: X Environmental Scan: X ]

## Public and Media Outreach

**Issue:** **G.3 Delayed federal decision-making and inconsistent messaging created significant public and media outreach demands on the states.**

**G.4 Public health response activities were hindered by inconsistent messaging about the severity of the H1N1 outbreak.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** *Public/Media Outreach Activities and Needs*  
Some of the most significant issues identified by states were the need for constant health agency communications with other agencies (federal, state and local), stakeholders and community groups, the media, and the public.

One state characterized the H1N1 outbreak as a “media outbreak,” which overwhelmed state agency systems that needed to respond to national, state and local media inquiries, as well as communicate with federal and local agencies, minority communities, providers and responders. Delays and changes in various guidances at the federal level “caused a ripple effect in states’ communication activities; each change required multiple messages to multiple groups.”

States overwhelmingly identified the shifting timeline and changing messaging around H1N1 vaccine availability as causing significant communications issues. National efforts to push H1N1 vaccine before adequate supplies were available “created extra work and increased public distrust in government.” Others noted that “the lack of information about the status of vaccine supplies in the private health sector limited the state’s ability to effectively communicate where the public could be vaccinated.” Inconsistent messaging between federal and state/local health departments about vaccination priority groups likewise “caused confusion with the public, as did inconsistencies in vaccination priority strategies among neighboring states.”

#### *H1N1 Messaging/Severity Issues*

Differences in public health messaging about the H1N1 pandemic’s severity compared to how the outbreak was actually being experienced in various communities caused confusion and hindered the effectiveness of response activities. Public messaging “focusing on worst-case pandemic scenarios did not correspond with the public’s perception about the mild nature of the outbreak.” One respondent commented that: “Messaging that equated H1N1’s severity to that of seasonal influenza further complicated efforts at school closure/community mitigation activities. People did not take the direction to get an H1N1 vaccination as seriously as they should have because the severity of pandemic was low.” Some states noted that “inconsistent use and communication about the WHO pandemic phases and the HHS Pandemic Severity Index caused confusion relative to the H1N1 outbreak.”

#### **Mitigation Strategies Employed:**

##### *Public/Media Outreach Activities and Needs*

- “The state health agency’s public information officer addressed media demands by setting a schedule of routine times for press briefings, and established conference calls for key groups involved on the response (e.g. local PIOs, local vaccine coordinators).”

#### **Recommendations Suggested:**

##### *H1N1 Messaging/Severity Issues*

- “HHS/CDC should either use the pandemic response plan that it developed based on the Pandemic Severity Index or discard it and start over.”

##### *Messaging Coordination*

- “Need more consistent means of communication vetted with the public and public health partners (event naming and information, reliable

information on local media messages over local cable access and local government channel).”

- “More efficient methods of intra-agency communication between public health partners, public information officers (PIOs) and the public are needed.”
- “Need more efficient methods of communication between public health response partners (keeping certain information separate from public).”
- “Local governments need to enhance partnerships with local media and communications outlets.”

[Sources: Survey: X Meetings: X Environmental Scan: ]

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## Communication with Stakeholders

**Issue:** **G.5 Federal, state and local agencies did not consistently and efficiently communicate with stakeholders during the H1N1 response.**

**Issue Type:** Policy

**Level:** State; Federal

**Discussion:** *Communication with Health Care Providers*

States noted challenges in communicating with health care providers during the H1N1 response:

- *Outreach to local health care providers:* “Agencies encountered barriers to effectively communicate with non-health department providers across disciplines and across jurisdictions about H1N1 due to uncoordinated dissemination of information to private healthcare providers. The state health agency does not have current contact information for private healthcare providers or other local community organizations, or a process to maintain that information at the state level. Instead, the state health agency depends on local health departments to maintain communications with local healthcare providers. However, these communications are not always done consistently. As a result, some daycare providers received guidance late from the state about the importance of vaccination.”
- *Addressing misinformation:* States had challenges dealing with misinformation communicated by some local providers. This misinformation caused confusion with the public and may have delayed some people from seeking vaccinations. A state noted that “one of its biggest communication challenges was addressing persistent rumors of

people who had been told by their physician, including OBs, that they should not get the vaccine because it was not safe.”

- *Guidance slow in going to health care providers:* “From the perspective of health care providers, communication between the public health system and health providers was viewed as uncoordinated. During the outbreak, private practitioners reported that they did not receive CDC guidance documents in a timely fashion. Other providers noted that CDC guidance lacked clinically relevant information and was difficult to translate into practical instructions.”
- *Interaction between public and private health counsel:* “States identified the need for agency legal counsel and other agency response staff to develop and maintain communication with legal counsel and management to hospitals, health systems, and other traditional stakeholders, as well as with nontraditional organizations, such as churches, that assisted in the H1N1 response.”

#### *Communication with Stakeholders Generally*

States identified the need for better coordination and communication between federal and state efforts to distribute outreach materials to various stakeholder groups within the states and nationally. Some states indicated that they “were unaware of a coordinated approach to targeting stakeholders.” “CDC created materials for several audiences (e.g., church groups), but states were unclear about how and to whom CDC distributed those materials.”

“With each emergency response activity, there is a renewed and ongoing need for outreach and education to quell persistent concerns of local health departments and volunteers about potential liabilities for emergency response activities, despite the existence of robust federal and state liability protections.”

#### **Mitigation Strategies Employed:**

#### *Communication with Health Care Providers*

- One state health representative noted that it “conducted facilitated, structured conference calls with local health agencies during which updated written Q&As were distributed to provide H1N1 and related informational updates, and to address questions/concerns.” The state also “created a separate link on its HAN portal website for H1N1 guidance to facilitate local health departments’ ability to quickly find current H1N1 information from the state health agency.”

#### *Communication with Stakeholders Generally*

- “The state health agency created the ability for the public and providers to register on the state’s website for automatic H1N1 information alerts.”
- “The state shared relevant H1N1 materials to stakeholders through state distribution networks.”

**Recommendations Suggested:**

*Communication with Stakeholders Generally*

- “Coordination/communication among federal partners should be improved. Perhaps a national Joint Information Center could be established during national public health emergencies to improve real-time situational awareness and consistent messaging.”
- “To avoid duplication of effort, CDC should share its plan of distribution for stakeholder materials before they are distributed. This will alert the states about where the materials are being targeted, allow states to suggest additional distribution channels, and avoid the potential for inconsistent federal and state messaging.”

*Communication with Health Care Providers*

- “Federal organizations need to do a better job communicating to medical providers about when and how to use antiviral medications, including a clear statement about inappropriate use of antivirals as a mass prophylactic agent.”
- “Develop/identify contact lists for individual providers.”
- “Target providers who treat high-risk populations.”
- “Distill state guidance/changes to one page of bullet points that are sent with entire guidance document.”
- “Prepare FAQs for office staff who answer the phones.”
- “Establish relationships with pharmaceutical representatives to use them as an avenue for providing information to physicians/physician office staff.”

[Sources: Survey: X Meetings: X Environmental Scan: ]

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## **Outreach to Minority Communities and Special/Vulnerable Populations**

**Issue:** **G.6 Federal, state and local agencies needed to use more effective strategies to reach minority communities and special and vulnerable populations during the H1N1 outbreak.**

**Issue Type:** Policy

**Level:** Federal; State

**Discussion:** States noted the importance of outreach and messaging to minority and special/vulnerable populations. Federal, state and local agencies need to

“improve their outreach through trusted sources to address real and perceived problems with the H1N1 vaccine and public health vaccine activities in general.” States noted that “federal/state/local ad campaigns and messaging should be better coordinated.”

#### *Outreach to Minority Communities*

One respondent noted that “federal vaccine messaging to minority communities was conducted as a regular public health outreach campaign instead of using risk communication activities to assess areas of potential resistance and to construct messages to proactively overcome areas of resistance.” One state: “Experienced significant challenges in reaching some minority communities (particularly in metropolitan areas) and some rural populations with information about the need to be vaccinated against H1N1. African American and, to a lesser degree, Hispanic residents, expressed negative feelings or beliefs about the vaccine. Similar attitudes were observed in some rural communities. Feelings of fear, anger and distrust stemmed from a lack of confidence in the state and federal governments. Minority urban residents felt the vaccine was being forced on them without ample proof that the vaccine was safe. Some also expressed the belief that the severity of the pandemic did not warrant community-wide vaccination. These factors created a lack of trust in the vaccine’s safety, leading to very low vaccination rates among minority communities in the state. Internet blogs claiming that the vaccine was experimental or unsafe created further significant impediments to efforts to encourage widespread vaccination.”

A health department found that: “Some physicians in minority communities did not trust the H1N1 vaccine. These physicians often did not receive the vaccine themselves and therefore did not recommend the vaccine for their patients. Because family physicians and other local health care providers carry a great deal of credibility in their communities, their negative opinion created pockets of public resistance against vaccination.”

#### *Outreach to Special and Vulnerable Populations*

Delayed coverage of vaccination costs for the uninsured coupled with slow messaging about this benefit delayed and limited vaccinations among this group. Another state noted that “it had challenges in reaching some rural populations with information about the need to be vaccinated against the H1N1 flu virus.” Some residents of rural communities were skeptical about the safety of the H1N1 and the need to get vaccinated.

#### *Overall Outreach Challenges*

State and local public health agencies were challenged in engaging priority groups and other members of the public in vaccination efforts, particularly those in minority populations. States noted the: “Lack of education, rumors, and myths about vaccine, and other cultural and socio-economic barriers in these populations made it difficult to reach them efficiently in large numbers. This resulted in decreased vaccination rates, delays in seeking vaccination, spread of misinformation, and ultimately disparate percentages of hospitalizations and deaths in minority patients with H1N1 compared to

non-minorities.”

**Mitigation  
Strategies  
Employed:**

*Overall Outreach Challenges*

- “The state health agency staged an aggressive public information campaign to encourage vaccination and to refute the claims that the vaccine was somehow experimental.”
- “Relying on health agency science experts to provide safety messages were not totally effective at dispelling vaccine safety concerns among all minority and special populations. States also had to get the word out to community leaders who could spread the message within their communities.”
- “To address some physicians’ reluctance to recommend the vaccine, a state health agency attempted to identify and characterize the reasons for the resistance. The state health agency partnered with a hospital association and provider groups to create and deploy a brief internet-based survey about physicians’ attitudes about the H1N1 vaccine and vaccines generally.”
- “To reach minority communities specifically, health agency staffs have organized meetings between agency leadership and pastors, local African-American elected officials and other minority community leaders. This allowed department managers to learn first-hand about the concerns of minority constituents and to seek guidance about how to effectively address those concerns.”

**Recommendations  
Suggested:**

- “Follow well-established and proven risk communication strategies prior to launching public information and health education outreach campaigns focused on minority communities and special/vulnerable populations.”
- “Work with leaders of faith-based groups in African-American communities and churches serving significant Latino populations.”
- “Create greater engagement within minority communities by providing brochures to key social centers, such as churches, barber shops and beauty shops.”
- “Increase emphasis on alternative media, both through news articles and advertising, such as media with primarily minority audiences as well as media aimed at rural areas.”
- “Distribute general disaster preparedness materials to increase the state’s credibility among skeptical populations.”
- “States should develop communications policies that ensure outreach to communities that are culturally competent and address barriers to access

during an emergency. These policies should reflect input from these populations.”

- “Generate guidelines about undocumented and/or migrant workers.”
- “Provide information in languages besides from English and Spanish.”

[Sources: Survey: X Meetings: X Environmental Scan: ]

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# Appendices

## **Appendix 1: Project Advisory Panel Meeting Agenda and Attendees List**

## **Appendix 2: State Meetings Summary Report**

*ASTHO H1N1 Policy Barriers Project State Meetings: Summary and Analysis*

## **Appendix 3: Survey Report**

*ASTHO Survey of State Health Agencies on H1N1 Response Policy and Legal Issues: Summary and Analysis*

## **Appendix 4: Environmental Scan Report**

*Environmental Scan of H1N1 Reviews and After-Action Reports: Identifying Policy and Legal Issues*

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June 1, 2020

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Charles Schumer  
Minority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Nancy Pelosi  
Speaker  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Kevin McCarthy  
Minority Leader  
U.S. House of Representatives  
Washington, DC 20515

Dear Majority Leader McConnell, Speaker Pelosi, and Minority Leaders Schumer and McCarthy:

As the nation cautiously begins the initial phases of re-opening the economy and the scientific community works at an unprecedented pace to bring a vaccine to prevent COVID-19 to market, it is imperative that the federal government, in coordination with state, local, tribal and territorial government, as well as public health, primary care physicians, pharmacists, and other health care providers on the front lines in communities across the country, begin to prepare for the allocation, distribution, and administration of a new COVID-19 pandemic vaccine.

While current efforts focused on testing and contact tracing are essential, we believe that deployment of a safe and effective COVID vaccine is the ultimate key to fully re-opening the American economy. We expect this vaccination program will be the greatest public health effort of our generation, and greatly appreciate your leadership now to prepare the nation for this response.

While the existing public health preparedness and response and immunization program infrastructure in the United States provides a solid foundation, gaps in capacity and capability across public health and health care systems, due in large part to the magnitude of this effort, must be addressed to ensure that our nation is prepared to engage in a timely, comprehensive, and equitable vaccination campaign. Infrastructure investments must be made now to further strengthen, enhance, and scale up the ability of public health primary care physicians, pharmacists, and other health care providers in the community who currently provide immunization to meet demand for a future COVID-19 vaccine. This important work will be a multi-phase process that requires resources for planning, prioritization, expanding the public health workforce, and close collaboration between public health and existing primary care physicians, pharmacists and other health care providers within the immunization neighborhood to strengthen and enhance our immunization infrastructure and surveillance systems in anticipation of a new vaccine.

States, localities, tribes and territorial entities must immediately begin to assess current public health and primary care physicians, pharmacists and other health care provider capabilities, and prioritize

short, medium and long-term actions necessary to lay the foundation for a smooth and orderly vaccine procurement and distribution process at a scale necessary for mass vaccination during a confined period of time. Concurrently, electronic health record vendors and immunization information systems (IIS) must update and prepare these data reporting systems accordingly with consideration given to expected priority populations and phases of vaccine distribution across the health care system. Other essential factors that must be considered are onboarding and orientation of new primary care physicians, pharmacists and other health care providers to administer and report vaccines in settings, such as long-term care facilities, as needed and to supplement existing immunization providers and how to overcome specific challenges, such as transportation and storage issues for vaccines intended for rural and frontier areas as well as linguistic and cultural differences in traditionally medically underserved populations.

Concurrently, communication with, and engagement of the public through ongoing education and outreach efforts on the need to continue the stay up to date with the immunization schedules recommended by the Advisory Committee on Immunization Practices (ACIP), including the receipt of vaccinations for flu, pneumococcal disease, shingles and hepatitis; and what to expect when a COVID vaccine becomes available, is critical and must have a heightened focus on addressing vaccination hesitancy concerned and increasing public confidence in the safety and efficacy of vaccines as a potentially lifesaving medical countermeasure.

Public health, primary care physicians, pharmacists and other health care providers in the community should develop plans for managing the volume of procurement, storage, and distribution of ancillary supplies that will be needed for a successful pandemic vaccination effort, such as personal protective equipment (PPE), syringes and alcohol wipes. One can expect that there will be an unprecedented demand for vaccine across the country and across all segments of the population and there will be intense pressure on already fragile and overworked health care and public health systems.

**In order to support the multi-phase process that must be undertaken in advance of any nationwide COVID-19 vaccination campaign, our organizations urge Congress to prioritize the following funding recommendations as it considers COVID-19 response and supplemental funding packages.**

**At least \$3.6 billion in funding through the CDC-Wide Activities account for immediate immunization infrastructure support, including an estimated:**

- ***At least \$900 million for state, territorial, and local preparedness and response and immunization program planning and staffing.*** This includes funding for several technical tasks such as provider onboarding, vaccine distribution, inventory management, tracking of doses administered and enhancing health department communication efforts and their ability to serve as community immunizers.
- ***At least \$400 million for state immunization information systems (IIS) data modernization, upgrades and modifications.*** These resources are necessary for interoperability and bidirectional data exchange between IIS and community immunization providers to reduce the

administrative burdens primary care physicians, pharmacists and other health care providers face in many parts of the country. Such modernization efforts are essential to ensure that immunizers are able to capture every administered dose of COVID-19 vaccine accurately match doses to individual patients and report vaccine distribution and uptake by geographic area and special population, such as first responders or those with chronic health conditions.

- ***At least \$2.3 billion in funding to administer the COVID-19 vaccine through the governmental public health system primary care physicians, pharmacists and other health care providers.*** This will cover vaccine delivery to approximately 25% of the population at no cost to the individual, based on an estimated administrative cost of \$14 per dose and a two-dose regimen (i.e. 82,375,000 people x 14 per dose administrative cost x 2 doses = \$2.3 billion). This estimate assumes the vast majority of Americans will be able to be vaccinated via the private primary care sector or through commercial vaccinators that will be reimbursed by insurance, including pharmacies or other locations like occupational health clinics.

We believe that \$2.3 billion represents a critical down payment for this component of the response but may have to be adjusted depending on the changes in public and private health insurance coverage or primary care physician closings. Specifically, we want to highlight three major uncertainties that could substantially increase the need for additional resources to cover the costs of administering vaccine:

- 1) if there continues to be an increase in the number of Americans who lose their insurance before a vaccine becomes available
- 2) if social distancing requirements prevent significant numbers of Americans from safely accessing vaccine at their usual source of care; and
- 3) the potential loss of primary care capacity and the current fragility facing many primary care practices.

*NOTE: These estimates exclude the need for funding for primary care physicians, pharmacists and other health care providers and health systems to invest in upgrades and modifications necessary to allow for bidirectional communication and data exchange between electronic health record (EHR) systems and IIS. These estimates do not include the costs of vaccine purchase, shipment, storage units, and related supplies including needles and syringes, alcohol swabs, bandages, gloves, and any other personal protective equipment that may be needed for vaccinators. Similar to the H1N1 outbreak response, the recommendations assume primary care physicians, pharmacists and other health care providers will receive vaccine and necessary supplies at no cost from the government and will bill private or public insurance plans for an administration fee.*

- **At least \$2 billion in funding to support public health** primary care physicians, pharmacists and other health care providers **efforts to prepare for the 2021 and 2022 influenza season in the midst of the current COVID-19 pandemic.** \$1 billion in emergency supplemental appropriations funding for the 2020-21 flu season along with an advance appropriation of \$1 billion, designated as emergency funding for the FY2022 appropriations bill. For the 2020-21 flu season resources should be allocated as follows:

- **\$700 million** for the purchase of 50 to 60 million doses of influenza vaccine
- **\$300 million** for infrastructure grants through existing state cooperative agreements under the 317 program.

These resources will be absolutely critical to communities at a time when our nation could be called upon to manage vaccination campaigns to combat influenza and COVID-19 concurrently, including the challenges for public health primary care physicians, pharmacists and other health care providers who must counsel patients and manage messaging about the two conditions.

- **Medicaid:** Enhanced Medicaid FMAP for vaccine counseling and administration. Provide an enhanced payment for providers to adopt interoperable and bidirectional immunization reporting capabilities in their practices (to the extent these features are available through their area IIS). These additional resources will be essential to ensure that providers are able to provide preventive services through this critical safety net program.

We appreciate your thoughtful consideration of these recommendations and look forward to working with you to prepare the nation for the next phase in this fight against the COVID-19 pandemic.

Sincerely,

317 Coalition

Adult Vaccine Access Coalition (AVAC)

Albert and Mary Lasker Foundation

Alliance for Aging Research

American Academy of Family Physicians

American Academy of Pediatrics

American College of Preventive Medicine

American Immunization Registry Association

American Pharmacists Association

American Public Health Association

American Society for Microbiology

Asian & Pacific Islander American Health Forum

Association for Professionals in Infection Control and Epidemiology

Association of Asian Pacific Community Health Organizations (AAPCHO)

Association of Immunization Managers

Association of Maternal & Child Health Programs

Association of State and Territorial Health Officials

Biotechnology Innovation Organization (BIO)  
Families Fighting Flu  
GSK  
Hep B United  
Hepatitis B Foundation  
Immunization Action Coalition  
Infectious Diseases Society of America  
IPPF  
Johns Hopkins Center for Health Security  
Lupus and Allied Diseases Association, Inc.  
March of Dimes  
Medicago  
National Association of County and City Health Officials  
National Foundation for Infectious Diseases (NFID)  
National Meningitis Association  
National Minority Quality Forum  
National Viral Hepatitis Roundtable  
Novavax  
Sepsis Alliance  
Seqirus USA, Inc.  
STChealth LLC  
The Gerontological Society of America  
Trust For America's Health  
Vaccinate Your Family