



Framework for Disaster Preparedness and Response: Updated

OVERVIEW

In February 2021, the Healthcare Leadership Council (HLC) and the Duke-Margolis Center for Health Policy published a <u>Framework for Private-Public Collaboration on Disaster Preparedness and Response</u>. The report outlined key actions for private and public sector leaders to take in order to better prepare the U.S. for future public health emergencies. The report laid out three priority action areas:

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

Since that time, private and public sector leaders have made some progress on those priorities. The Administration has prioritized supply chain readiness and resilience, and a series of reports in 2021 and 2022 by the White House and the U.S. Department of Health and Human Services (HHS) set forth concrete steps for continued progress. Private sector stakeholders, both independently and through private-public partnerships, have pioneered innovative approaches for care delivery during emergency circumstances, especially through digital modalities of care. HHS <u>elevated the Administration</u> for Strategic Preparedness and Response (ASPR, formerly known as the Assistant Secretary for Preparedness and Response) to an operating division of the Department, and Congress established a new, permanent White House Office of Pandemic Preparedness and Response Policy.

Gaps in preparedness remain, however, as the U.S. still is not sufficiently ready for future disasters or to rapidly and effectively respond to emerging threats. Federal coordination for disaster response often lacks clarity and coordination, with no explicitly designated lead agency – particularly challenging for potential disasters that may require military and civilian response and care infrastructures to quickly integrate. Furthermore, real-time information is needed to guide disaster response – for example, using timely data on health system capacity, types of cases, and medical product inventories to inform responses, guide patient care, and direct supplies. And progress in health system resiliency is needed, with many facilities still encountering staffing

shortages and workforce burnout issues that hinder their capacity to handle the influx of patients that would accompany a future disaster.

Addressing these persistent issues will require further legislative action by Congress, policy and regulatory action from the Administration, and continued innovations by private sector stakeholders involved in disaster preparedness and response. It will also require more effective and sustained support for private-public partnerships, as health care organizations are an increasingly important part of disaster preparedness and response capabilities.

Given the need for further action and collaboration by private and public sector leaders, HLC and Duke-Margolis have updated recommendations from the 2021 report to identify the highest-priority areas for additional near-term action. This effort included two stakeholder workshops in October 2022 and February 2023, as well as expert interviews and focus group discussions. The result is a set of targeted, high-priority, broad-based recommendations to strengthen disaster response policy, with a specific focus on legislative and regulatory steps that can be achieved in 2023. Our recommendations leverage new medical and technological capabilities and insights from past emergency response efforts to enable:

- Coordinated, informed, scalable, and rapid national, state, and local responses by establishing a clear, collaborative, and coordinated leadership structure, with pre-specified divisions of responsibilities and information pipelines, for federal emergency response;
- Robust manufacturing and distribution practices, with better ability to anticipate and avoid shortages; and
- Greater health care resilience to respond to emergencies through improved rapid information-sharing capabilities to optimize deployment of health care resources and steps to enable more effective emergency care and reduce first-responder burnout.

Key recommendations are summarized in **Table 1**.

Recommendations for Legislative Action

- ASPR should serve as the operational lead for health-related components of disaster response to coordinate federal actions and integrate private and public health care capacity.
 - ASPR should be granted expanded hiring and contracting authorities and sufficient funding to grow its expertise in health care delivery.
 - ASPR should coordinate the disaster response activities of Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), and other U.S. Department of Health and Human Services (HHS) agencies and sub-agencies.
 - ASPR should create and maintain a two-way communications system with the private sector.
- Federal disaster preparedness should include pre-established mechanisms to rapidly support regional and state officials and private sector partners in areas affected by the emergency.
 - Through the Regional Health Care Emergency Preparedness and Response Systems program (RHCEPRS), the federal government should provide guidance and funding to states and/or regions to support coordinated state, local and private sector response.
 - Accountability for preparedness can occur through "stress test" exercises, key performance capabilities in Medicare Conditions of Participation (CoPs), and other mechanisms.
- ASPR should be granted the authority to require reporting of key information on drug and medical product supply and inventory in health-related emergencies to avoid shortages.
 - Hospital Preparedness Program (HPP) health care coalitions and RHCEPRS partnership pilot sites should be used to enable collaboration with private stakeholders on expectations for reporting in public health emergencies and options for data aggregation that reduce the risks of sharing for individual health systems, while still keeping the federal and state governments informed of priority allocation needs.
- The Strategic National Stockpile (SNS) should be substantially and consistently funded and should engage manufacturers in longer-term committed contracts with frequent, scheduled ordering rather than occasional bulk purchases.
- The HPP should provide additional resources to health systems to support mental health care for their staff, and the federal government should revise policies to ensure that health care workers are encouraged to seek mental health care without punitive action.
- The federal government should continue to support research into workforce issues arising from health emergencies to build an evidence base for appropriate interventions.
- Federal and state governments should allow flexibility for all healthcare professionals to practice to the top of their licenses during public health emergencies.

Recommendations for Regulatory and Executive Action

- ASPR, Federal Emergency Management Agency (FEMA), and the U.S. Department of Defense (DoD) should work together before and during disaster response to leverage FEMA/DoD expertise in emergency command and align authorities and appropriations.
- ASPR should be organized to deliver "command-line" capabilities with rapid decision-making and response as the priority competency.
- CMS should reform existing hospital emergency preparedness Conditions of Participation (CoPs) to align with the enhanced private-public response capabilities proposed in this report.
- GAO should conduct a review of previous and ongoing work by RHCEPRS, HPP, National Disaster Medical System (NDMS), and other effective private-public partnerships to identify and scale best practices for health emergency response.
- CMS should serve as ASPR's implementation entity within the federal government responsible for health care data collection in a public health emergency, which would allow for a single approach for standard data reporting for health systems.
 - CMS should consider contracting a third-party entity to support data collection and real-time "heat maps" for local and regional situational awareness.
 - ASPR and CMS should collaborate with other agencies, such as CDC's Center for Forecasting and Outbreak Analytics, for data analysis.
 - Relevant, de-identified, aggregate results should be shared with other federal partners, and state and local governments, and HPP coalitions or RHCEPRS sites, under existing or clarified authorities.
- CMS must ensure reporting is purposeful, with elements that can be extracted reliably and easily from existing hospital electronic data systems.
- CMS should develop a payment plan for additional provider payments for screening and counseling, "test to treat" capabilities for high-risk individuals, and timely electronic reporting for potential major public health threats (e.g., emerging infectious disease threat, radiation exposure, other hazards), in conjunction with the development of emergency data reporting and with consultation with health care providers.
- CMS should release a request for information to inform its proposed regulations related to how existing payment programs and its value-based payment approaches can support preparedness and how payment changes can support care innovations designed to prevent burnout and promote resiliency.
- CMS should develop timely processes for licensure flexibility during emergencies, such as the ability for qualified retired health care providers to support disaster response by boosting workforce capacity.
- CMS should work proactively with ASPR, state medical boards, and the Federation of State Medical Boards to create model waivers to allow for expanded telehealth, including across state lines, contingent on relevant performance measures.
- CMS should issue waivers for expanded home care services to improve access to care and reduce hospital stresses during a disaster contingent on appropriate quality safeguards.
- DoD should implement health emergency response training for National Guard members.
- ASPR should have the authority to call upon federal health care personnel to be brought in to increase the workforce during a surge.

Federal Coordination and Support for Local Response

There is general consensus among private and public sector experts on the need for a single point of contact and coordination within the federal government that is responsible for the health components of disaster response policy. Designating a lead federal agency would help establish a clear line of incident command, better delineate roles and responsibilities of federal agencies, and streamline private-public communication. The White House Office of Pandemic Preparedness and Response Policy, recently established by the **Consolidated** Appropriations Act of 2023, will coordinate preparedness and response for future biological threats across departments, but has not yet received appropriations. Given its mission and resources, the ASPR should have its remit expanded to lead operations and serve as the point of coordination for the health components of any disaster response, not just biological threats. ASPR has a history of partnering with key leaders in private sector health care and public health as well as the capability to rapidly mobilize for emergency response.

This should include clarifying ASPR's disaster-based operational command where there are overlapping areas of responsibility among agencies. However, ASPR should continue to leverage other agencies' expertise through close collaboration to support effective public messaging, incident command structures, data sharing, and timeliness of decision-making and response. Additionally, critical to advancing preparedness and response is ensuring effective communication channels between the federal government and regional and state officials and their private sector partners before and during disaster response. ASPR should work with federal public health authorities, the Centers for Medicare and Medicaid Services (CMS), state and local public health and departments of health, and health systems to improve these channels of communication and strengthen and pressure-test regional and state abilities to quickly allocate needed supplies, coordinate emergency care, and communicate with private sector partners and the general public, among other key capabilities.

The following actionable recommendations could achieve a more organized and coordinated federal response reflecting these goals:

RECOMMENDATIONS FOR LEGISLATIVE ACTION

- ASPR should serve as the operational lead for health-related components of disaster response, including coordinating
 federal health agency actions, while the White House can amplify messaging and assure cross-department
 collaboration. ASPR should also serve as an organizing entity for seamless integration of private and public health
 care capacity in emergent disasters.
 - ASPR should be granted expanded hiring and contracting authorities and funding sufficient to enable the agency
 to grow its expertise in health care delivery in preparation for future emergencies and build connections to rapidly
 scale up its efforts as needed when an emergency occurs.
 - During a public health emergency, ASPR should be given clear authority to serve as lead coordinator of the disaster response activities of CMS, CDC, and other HHS agencies and sub-agencies as they become involved in broader health-related disaster response efforts.
 - ASPR should be accountable for creating and maintaining a two-way communications system with the private sector (building on its existing regional preparedness programs), to ensure that the expertise and engagement of the private sector is firmly incorporated in ASPR's work.
- Federal disaster preparedness should include an effective, pre-established mechanism to rapidly and reliably support key regional and state officials and private sector partners in each locality affected by the emergency, including area health systems, to identify critical pain points and ensure that disaster response policy works for those on the front lines.
- Through RHCEPRS, the federal government should provide accountable funding to states and/or regions to establish emergency response mechanisms that effectively coordinate state and local responses, including as appropriate governors' officeor designate, departments of health, public health agencies, county and/or mayoral offices, working with regional private health care leaders.
- Accountability for preparedness can occur through "stress test" exercises for major types of health disaster response, key
 emergency performance capabilities in Medicare Conditions of Participation (CoPs), and other mechanisms as appropriate.

RECOMMENDATIONS FOR REGULATORY AND EXECUTIVE ACTION

- ASPR, FEMA, and DoD should work together more closely before and during disaster response to leverage FEMA/DoD
 expertise in emergency command, and authorities and appropriations must be aligned.
- ASPR should be organized and staffed to deliver "command-line" capabilities, with rapid and informed decision-making and response as the priority competency. Organizational culture should promote situational awareness, local support, and, critically, a communication team and strategy that is able to convey fast-moving guidance based on evolving information.

Avoiding Shortages and Promoting Supply Chain Resiliency

A disaster may cause an immediate spike in demand for certain medicines, and could also drastically reduce supply. As such, near real-time information on medical product inventories and supply chain capacity is needed – a clear and up-to-date understanding of potential shortages enables decisionmakers to allocate existing national inventory or surge manufacturing as needed. Data collection should be conducted as efficiently as possible to reduce burden on those asked to report it, and proprietary

data must be protected appropriately. Implementing a process that builds shared understanding of data uses and trust with health system leadership is also critical – for example, to address concerns about inventory being seized and reallocated, rather than coordinated steps to mitigate shortages and increase supply when needed. This likely requires continued collaboration, education, and tabletop exercises or other stress tests between emergencies.

The following recommendations can achieve these aims:

RECOMMENDATIONS FOR LEGISLATIVE ACTION

- ASPR should be granted the authority, with public comment and collaboration, to require reporting of some key
 information on drug and medical product supply and inventory in health-related emergencies. Greater transparency
 on these points along with greater coordination as described in the preceding and following sections will allow private
 sector entities (such as distributors, wholesalers, group purchasing organizations, and health systems) and public sector
 entities (such as ASPR's Strategic National Stockpile) to make more informed decisions and surge supplies to where they
 are needed most.
 - Existing Hospital Preparedness Program (HPP) health care coalitions and RHCEPRS partnership pilot sites should be used to enable collaboration with private stakeholders (group purchasing organizations, wholesalers, and distributors as well as hospitals and health systems) on expectations for reporting in potential public health emergencies (PHE), what conditions will trigger the start and end of such emergency reporting requirements, how the information they share will be used to provide local and national situational awareness and guide allocation of Strategic National Stockpile (SNS) supplies and federal procurement, and how proprietary information will be protected.
 - ASPR and other relevant HHS components should work with health system leaders through RHCEPRS and HPP to explore options for aggregation of data in ways that reduces the risks of sharing proprietary or confidential information for the individual health systems, while keeping government agencies informed regarding priority allocation needs. It also may be possible to have a tiered system, so as emergencies escalate more extensive data would be available.
- During emergencies, ASPR should require reporting of key information for avoiding shortages and maintaining supply
 such as inventory of commonly used products that may experience significant competition and supply chain constraints
 in major types of disasters, as well as prespecified disaster-specific supplies (e.g., PPE needed after a radiologic event,
 supplies and treatments required when there are widespread crushing injuries, etc.).
- The SNS should be more substantially and more consistently funded, and should engage manufacturers in longer-term
 committed contracts with frequent, scheduled ordering rather than occasional bulk purchases. This will ensure a fresh
 supply of products to the SNS and will maintain a "warm base" manufacturing capacity for certain essential medicines
 and supplies, allowing more rapid scale-up of production in case of a sustained surge in demand caused by an emergency.

Promoting Health System Resiliency, Improving Care Delivery, and Avoiding Burnout

Creating health system capacity responsive to an allhazards approach for disaster preparedness is challenged by pressures to use resources efficiently and stresses on the health care workforce under nonemergent conditions. Experts agreed further policy action is necessary to develop more resilient health systems, especially policies that can strengthen care delivery pathways that mitigate overwhelming the health system during surges, but also noted eliminating the stresses of emergency surges is not realistic. To protect the workforce from burnout and reduce the stresses of emergency surges, federal and private sector efforts should focus on supporting a dynamic health system with relevant operational capabilities, such as care management for higher-risk patients, telehealth, and remote monitoring services, linked to readiness to surge, such as scalable staffing structures and cross training.

Timely and reliable sharing of key, limited data for situational awareness is also critical for the effectiveness of a comprehensive approach, with particular emphasis on guiding operational response. In times of crisis, it is critical to implement essential data-sharing without unnecessary diversion of vital resources or the creation of counterproductive administrative burdens. An effectively designed and implemented system can help optimize deployment of valuable health care resources when and where they are needed most. It would reduce, rather than exacerbate, administrative burdens - such as manual case reporting, searching for open beds, or combing sources for drugs and medical devices - that contribute to burnout and divert staff time and energy from patient care. Frontline staff and local response partners need to be well-informed and supported in their efforts through access to critical

The following recommendations can achieve these aims:

data, but without being diverted from treating sick and injured patients to perform administrative tasks.

Such a system can be implemented by building on current standardized health care information-sharing mechanisms supported by CMS and the Office of the National Coordinator for Health Information Technology (ONC). This approach would reduce public health regulatory reporting burden while sharing only minimum necessary, anonymized information. Health care facilities would report only key information such as caseloads, staff, and bed capacity, along with disaster-specific information on patient information relevant to the response, using existing electronic data systems. Timely standardized laboratory reports of test results would inform responses to certain public health emergencies such as bioterrorism events and infectious disease outbreaks. CMS or a third-party contractor would use the standardized data to produce anonymized, aggregated health care data to provide timely and accurate localized "heat maps" on the state of a disaster to those supporting response on the ground. That information would support better public health analytics and forecasting, and would enable federal, state, and local response coordinators to, for example, quickly identify where there is space to take in a new patient, or where providers or medical products are or will be most urgently needed. Clear, actionable updates and analyses from existing health care data systems are critical to optimizing the use of regional health systems' capacity to treat those sick or injured for a variety of acute injuries related to the emergency, as well as other urgent health care needs if normal care has been disrupted.

RECOMMENDATIONS FOR LEGISLATIVE ACTION

Reduce health care workforce burnout

- The HPP should provide additional resources to hospitals and health systems to support mental health care for their staff, and, together with state medical boards, the federal government should revise policies to ensure that health care workers are encouraged to seek mental health care without facing unnecessary punitive action.
- The federal government should continue to support research into workforce issues arising from health emergencies and disasters to build an evidence base for appropriate interventions and identify opportunities to help address these issues in a more systematic way.

Workforce capacity

• Federal and state governments should allow flexibility for all health care professionals to practice to the top of their licenses during public health emergencies.

¹ This reporting should occur through CMS and HHS regulatory authorities, with clarifications as needed, using standard procedures during public health emergencies to report relevant test results from high- and medium-complexity labs.

RECOMMENDATIONS FOR REGULATORY AND EXECUTIVE ACTION

Enhance health system capacity for disaster response

- CMS should reform existing hospital emergency preparedness CoPs to align with the enhanced private-public response capabilities proposed here, such as having action plans to implement a more flexible and scalable staffing structure with cross-training procedures, increase bed capacity and services to other settings, and coordinate with new and existing preparedness private-public partnerships noted above (similar to how existing CoPs require plans to coordinate with emergency officials).
- GAO should conduct a review of previous and ongoing work by RHCEPRS, HPP, National Disaster Medical System, and
 other effective private-public partnerships to identify best practices for health emergency response (including treatment
 guidelines and clinical cross-training guidance), opportunities to scale up or expand those best practices, and any
 significant remaining gaps in private-public response capabilities.

Support timely data sharing for local and regional awareness, to direct additional resources to where they are most needed, and help regional organizations, funded through RHCEPRS or HPP, optimize patients' care across sites

- In order to ease burden and confusion, CMS should serve as ASPR's implementation entity within the federal government responsible for critical health care data collection and sharing in a public health emergency. CMS should use its existing authorities, including HHS authorities under the PREVENT Act if needed, to enable a consistent data reporting approach through existing electronic health care data systems. Implementation should be guided by notice and comment rulemaking in collaboration with health care organizations, ONC, and public health agencies. This single approach for standard data reporting for health systems would improve the quality of reporting, and quicken the bi-directional flow of reliable information.
 - CMS should consider contracting a third-party entity to support data aggregation and production of real-time "heat maps" for local and regional situational awareness.²
 - ASPR and CMS should collaborate with other agencies, such as CDC's Center for Forecasting and Outbreak Analytics, for analysis and timely, actionable insights from the aggregated data reports to inform local responses.
 - Relevant, de-identified, aggregate results should be shared with other federal partners, and state and local governments, and HPP coalitions or RHCEPRS sites.
- To avoid unnecessary burdens on providers, CMS must ensure that reporting is purposeful, focusing on key emergencyrelevant data that can be extracted reliably and easily from existing electronic data systems.

Support care delivery models that enable equitable early interventions to prevent surges from overwhelming health system capacity

- CMS should develop a payment plan for additional provider payments for screening and counseling, "test to treat"
 capabilities for high-risk individuals, and timely electronic reporting for potential major public health threats (e.g.,
 emerging infectious disease threat, radiation exposure, other hazards), in conjunction with the development of
 emergency data reporting and with consultation from health care providers.
- CMS should release a request for information to inform its proposed regulations related to (1) how existing payment programs and its value-based payment approaches can support preparedness and (2) how payment changes can support care innovations designed to prevent and mitigate burnout and promote resiliency.
- CMS should develop timely processes for licensure flexibility during emergencies, for example through streamlined enrollment in billing, such as the ability for qualified retired health care providers to support disaster response by boosting workforce capacity.

² In conjunction with electronic reporting of deidentified data, a third-party entity could promote the use of such data for more advanced analysis. For example, the MITRE Corporation operates the Center for Aviation Safety Information Analysis and Sharing (ASIAS) initiative through a private-public partnership with the Federal Aviation Administration (FAA). The ASIAS initiative allows for confidential, anonymous reporting and analysis of potential safety incidents from airlines in order to improve safety systems and reduce the likelihood of future incidents. Alternatively, a third-party entity could facilitate analysis of deidentified data by expert groups to identify opportunities to improve threat analysis and response.

- CMS should work proactively with ASPR, state medical boards, and the Federation of State Medical Boards to create model waivers to allow for expanded telehealth, including across state lines. Waivers should be tied to data sharing and performance measures around continuity of care and, in the case of public health-related emergencies, to provide access to appropriate treatments.
- CMS should issue waivers for expanded home care services to improve access to care and reduce hospital stresses during a disaster.
 - Waivers should be contingent on adequate regional pre-disaster planning for how to prioritize home care patients based on medical need, risk levels, etc., as well as appropriate safeguards to ensure quality is not compromised.
- DoD should implement health emergency response training for National Guard members.
- ASPR should have the authority to call upon federal health care personnel to be brought in to increase the workforce during a surge.

Toward a Long-Term Vision for Coordinated Private-Public Health Emergency Response³

These legislative and regulatory actions to improve federal coordination, avoid shortages, and promote health system resiliency should be undertaken in the near term to shore up key vulnerabilities in U.S. emergency response capabilities. There is, however, more work to be done in the longer term to build a robust capacity to address both repetitive strains on health care and public health systems (such as seasonal Flu or RSV surges) and less predictable but serious emergency threats (such as radiological events or natural disasters). With concerted policy making and

sustained private-public collaboration, the United States has the opportunity to create a more robust and equitable preparedness and response strategy capable of handling the next health-related disaster or emergency. The Duke-Margolis Center and Healthcare Leadership Council stand ready to help stakeholders move these recommendations into reality and achieve that aim.

³ During our discussions many longer term recommendations were identified and we will continue our work to build out these recommendations.

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Disclosure

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Mark B. McClellan, MD, PhD, is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

About

Duke Margolis Center for Health Policy

The mission of the Robert J. Margolis, MD, Center for Health Policy at Duke University is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. The Duke-Margolis Center for Health Policy values academic freedom and research independence, and its policies on research independence and conflict of interest are available here.

Healthcare Leadership Council

The Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American healthcare, who care about a shared vision for the future. We provide the only forum of its kind, convening industry leaders to collaborate on policies, plans, and programs that will bring positive change to the healthcare system. Since HLC was founded in 1988, our purpose has been to bring together key stakeholders and decision makers from across the healthcare industry to create a healthcare system that is accessible, affordable, and patient-centered; that prizes innovation; and that delivers value to all. If you share this vision, please visit www.hlc.org to join us.