American College of Emergency Physicians[®]

June 26, 2020

The Honorable Lamar Alexander Chairman Senate Health, Education, Labor, and Pensions Committee 428 Dirksen Senate Office Building Washington, D.C. 20510

Dear Chairman Alexander:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to respond and make recommendations to the Senate Health, Education, Labor, and Pensions (HELP) Committee regarding your "Preparing for the Next Pandemic" white paper. ACEP is a national organization representing emergency medicine physicians who provide the safety net of care to Americans when other options are not available. As such, our members have been on the frontline providing care to COVID-19 patients since this pandemic reached the United States. Our experience as both physicians providing direct patient care, dealing with the families of those infected with COVID-19, and as representatives involved in state, regional, and local planning of responses to all manner of threats and disasters has provided us with a unique perspective on the challenges, successes, and failures of our nation's response to COVID-19.

Over the years, this nation's response to infectious disease outbreaks, natural- and manmade disasters, and other public health emergencies has been and continues to be consistently reactive. The COVID-19 crisis has shown us that the world at-large was unprepared for the magnitude and speed at which this virus traversed the globe, although previous outbreaks, such as the Severe Acute Respiratory Syndrome (SARS) and the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), should have been warning signs that this type of catastrophe was possible, especially given the relative ease at which citizens can travel to other continents. It is our hope that action will be taken by your committee and the Congress to end this reactionary cycle and begin a new era where we proactively prepare for, and swiftly respond to, these serious public health challenges, many of which have been predicted and modeled and are rarely altogether unforeseen.

If there is an overarching theme identified by this crisis and our nation's response, it is the need for improved collaboration and communication, as well as a significant investment in the nation's community emergency departments (EDs), which provide the safety net of care in this country. We understand the challenge to bring the myriad federal, state, and local resources together to efficiently and effectively respond during times of crisis, especially when it is not isolated in a local or regional community but rather a national and international threat. However, this is an obstacle that we must overcome to both combat COVID-19 and to appropriately respond to the next outbreak or major incident.

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We are glad you have provided us with this opportunity to discuss these important issues and we look forward to working with you, the HELP Committee, and the entire Congress on ways to improve the efficiency and effectiveness of our nation's response to future infectious disease outbreaks or other medical emergencies.

Sincerely,

William pquis

William P. Jaquis, MD, MSHQS, FACEP ACEP President

ACEP Responses – White Paper Recommendations

Recommendation 1.1: Congress and the administration should identify and implement public-private manufacturing models to improve and maintain sustainable domestic vaccine manufacturing capacity and capabilities. One approach has been the advanced development manufacturing program.

Even before COVID-19, our daily medication shortages were crippling. We already face widespread shortages of daily medication needs for "routine" care, and these shortages are severely exacerbated during a surge. ACEP strongly urges Congress to identify a dedicated and reliable source of medications for essential emergency medications. COVID-19 has demonstrated that substantial reliance on foreign manufacturing, whether for medications or personal protective equipment (PPE), poses a serious risk to our nation's ability to respond to large-scale infectious disease outbreaks, as those countries have severely limited exportation of these products to focus their use on domestic cases. Consideration should be given to domestic production and preference clauses when commercial products are developed with the public assistance of the National Institutes of Health (NIH).

Recommendation 1.2: Congress and the administration should continue to support NIH research and its academic partnerships, which have provided key infrastructure to rapidly pivot to COVID-19 research and clinical trials.

NIH research and academic partnerships should certainly be supported. There have been numerous benefits to these relationships and ACEP strongly urges Congress to provide direct funding for the NIH Office of Emergency Care Research (OECR), which coordinates and fosters clinical and translational research and research training for the emergency setting. However, we suggest that whenever multiple NIH institutes have competing priorities, the National Institute of Allergy and Infectious Diseases (NIAID) be considered the lead agency.

Recommendation 1.3: Congress and the administration must work together to implement the Medical Countermeasure Innovation Partner program so tests, treatments, and vaccines can quickly be identified, researched, and developed for the next pandemic.

In addition to Congress and the administration, Non-Governmental Organizations (NGOs) should also be added as a collaborative partner in the Medical Countermeasure Innovation program so that more public-private partnerships can be forged moving forward.

Recommendation 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.

Although the development of vaccines can occur through a variety of biochemistry and pathophysiology mechanisms (receptors, antigens, etc.), knowledge and communication of the fundamentals related to diagnostic testing should be better coordinated. This may account for some recent concern and confusion as to why there have been asymptomatic patients who "recovered" from COVID-19 only to have subsequently tested positive. Furthermore, providing adequate diagnostic testing supplies should be prioritized – during the initial weeks of the outbreak in the U.S., for example, Seattle facilities had to slow down specimen collection and processing because of inconsistent availability of test reagents. Today, while some areas have improved access to testing, other areas and new "hotspots" still face limited testing availability that undermines our ability to truly understand the scope of infection and anticipate future new hotspots.

Unfortunately, the delays that resulted from the internal difficulties experienced by the Centers for Disease Control and Prevention (CDC) to develop its own test highlight this issue at the national/federal level. The problems with the CDC version of the initial test must be clearly understood so they are not repeated.

Early reliance on state lab agency testing will be dependent on the agency's capabilities and capacity. For example, in the case of COVID-19, the Washington State lab could not ramp up coordinated specimen collection, testing/processing, confirmation, and communication of results. During the initial weeks, Seattle facilities waited two to four days for

confirmed results. Although this may be facility specific and may not be pertinent during limited events, a mechanism should be available that allows federal, state, and regional agencies to rapidly increase testing and reporting.

There needs to be a much better plan for rolling out new tests quickly and effectively when they are designed. A standard testing plan to roll out testing at scale is absolutely essential and we should consider having dual-track development for new tests so if one test fails in development there is a potential back-up. Quality standards can vary, but the establishment of a guiding set of principles (or another framework) could be helpful here.

Recommendation 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.

It is essential that the federal government use its authority (voluntarily if possible, but mandatorily if necessary) to require effective and efficient cross-communication between electronic health record (EHR) systems.

Instead of utilizing time, effort, and summaries by on-the-ground personnel, select sanctioned government agencies (such as the CDC) should be able to collect and analyze clinical data as already recorded in EHR systems – whether via a unique identifier, select data fields, or algorithm/program compatible with the various electronic health record system platforms. We would encourage the CDC to work with private industry to develop a mechanism to track these relevant data points seamlessly behind regular EHRs. We need to maximize our use of technology to improve this nation's syndromic surveillance capabilities to get as close to real-time data collection and reporting as possible. This would not only be helpful during an infectious disease outbreak, but for tracking and decision making regarding many other types of public health issues as well.

The results of the data collection need to be widely available to all health care systems and providers immediately, not just to state and federal officials. Health care systems cannot plan effectively if they do not have access to the same models and data as the governmental leaders. Perhaps the CDC can be tasked with modifying the Health Alert Network to provide a daily recap of the latest data collection in a "what's new" (with the current disease/outbreak/incident) announcement or section.

In the area of disease surveillance, we need a much better set of national definitions for both the diseases that emerge as well as about our health care and public health capacity. Not only have we had trouble knowing where the COVID-19 cases are, but we have also had many problems knowing where the system has been under strain and where it has not. Surveillance needs to include both the supply and demand sides of the equation. Equally important to "how emerging infectious diseases affect populations" is the reverse – how populations affect emerging infectious diseases (in the context of social determinants of health, even a zip code can guide authorities on food availability, living conditions, population density, etc.).

Recommendation 2.2: CDC, states, and health professionals should work together to identify barriers to earlier identification of cases, including whether case definitions and testing recommendations were overly narrow for too long.

The case definition for COVID-19 remained tragically narrow for far too long. It was abundantly clear to clinicians in the Northeastern states (especially New York, New Jersey, and Connecticut) that community spread was occurring, but the case definition lagged weeks behind.

Frequent updates for case definitions, diagnosis, and guidelines are critical to disease surveillance and identification. Some ancillary signs and symptoms of COVID-19, including ophthalmological (conjunctivitis), gastrointestinal (nausea, vomiting, diarrhea), and dermatological (rash, toes) were known by some health care practitioners who had communicated with their counterparts in China and Italy or monitored the medical literature. However, weeks elapsed before they were more broadly acknowledged, incorporated, and communicated. Also, several weeks passed between the now erroneous recommendation that if influenza, and later other respiratory pathogen panels, testing was positive, coinfection with COVID-19 was unlikely. As mentioned above, there should be improved international surveillance of infectious diseases that is coordinated between the U.S. Departments of State and Health and Human Services (HHS), as well as the World Health Organization (WHO), and other countries that maintain equivalent departments so that up-to-date information on infectious diseases can be shared in a timely manner. Information sharing regarding potentially new infectious agents and latest recommended techniques and technologies to combat these diseases should be a priority.

We recommend that hospital systems also be included in your list of partners that work together to identify barriers to earlier identification of cases given their important role of developing staff protocols and procedures that impact clinical care.

Recommendation 2.3: The Departments of Health and Human Services, Homeland Security, and Transportation should coordinate to improve access to passenger contact information by appropriate public health officials to inform public health responses to infectious diseases (such as measles and COVID-19), with necessary privacy protections in place. CDC should, in coordination with state, tribal, and local health officials, review and improve the systems used to communicate such information to states and localities.

The CDC should work with state health officials and private industry (such as Apple, Google, and other technology and telecommunications leaders), to improve individualized communication to residents as well as contact tracing. We recognize this has individual privacy implications, but it would be worthwhile to explore this area further if those concerns can be resolved. There is clearly a wealth of relevant data that could be used that could help combat COVID-19 and other infectious diseases that constitute public health crises.

Recommendation 2.4: Congress should pass the Public Health Data Systems Modernization Act, included in the Lower Health Care Costs Act, to modernize our nation's biosurveillance systems.

Clearly, this nation needs to modernize its public health data collection. Given the technology that is currently available, it is incomprehensible why this data is not publicly available in close to real-time. ACEP suggests looking to the private sector or other public partners to achieve some of these goals. As you noted in your white paper, decision-makers turned to the Johns Hopkins University's COVID-19 dashboard to get information about the number of tests, reported cases, deaths, and recovered individuals.

In emergency management, we believe in "best practices." Instead of reinventing or creating a government product, there should be more willingness to use what is available through other means.

Recommendation 3.1: Utilize existing authorities to build public-private partnerships, such as vendor managed inventory contracts with manufacturers and distributors, to create excess medical supplies managed by private sector partners that could be needed for the next pandemic or public health emergency. Additionally, the Strategic National Stockpile could contract with manufacturers to maintain manufacturing capability for certain products, such as N95 masks or other personal protective equipment, to rapidly manufacture supplies needed for a future pandemic.

Current cost reduction practices in health care such as just-in-time supply chain and inventory management create a first level of vulnerability for individual staff and facilities. Significant consideration should be given to whether federal, state, or local resources will be designated to provide financial incentives to hospitals and other health care facilities that maintain critical PPE stockpiles. Hospitals that have the storage capacity, the central supply tracking capability to rotate the pandemic PPE through their regular PPE supply, and the personnel required to manage these systems should be able to apply for federal incentives. In exchange for this annual monetary supplement, the hospitals would agree to house and maintain the materiel. The federal financing would also be tied to supply oversight requirements, such as temperature control, rotation time requirement, etc., for the PPE and other material.

Industry consolidation has led to a small number of suppliers, sometimes just one, which creates a second level of vulnerability when multiple facilities, and even states, compete for the same inventory or that supplier themselves faces a disruption. We recognize fair and reasonable reimbursement should be afforded to manufacturers who produce critical supplies and we suggest new financial mechanisms (tax breaks, government subsidies, grants, etc.) be put in place to

incentivize companies to invest in excess manufacturing capacity that is vital to health surge capabilities and the production of essential emergency medications, which are also needed on a daily basis but often have low profit margins.

However, it is vital that any conversations regarding altered manufacturing processes begin with an emphasis, if not mandate, on domestic production of PPE, ventilators, normal saline, medicines (all medicines; not just antidotes and certain antivirals), and any other products deemed necessary for the nation's emergency preparedness. This also needs to include the manufacturing of specific materials needed to make the supplies, such as the filter material for masks. The goal should be domestic utilization of this manufacturing capability on a daily basis so the business model remains viable and production capabilities remain consistent. This will also make it easier to surge production when necessary as the production lines will already be available.

Recommendation 3.2: States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.

Fundamentally, ACEP believes the scope of the emergency situation should dictate how the Strategic National Stockpile (SNS) distributes supplies. COVID-19 is a national (and international) health crisis and, in this setting, we think the most effective way to disseminate these supplies is through direct federal oversight that provides a coordinated, centralized distribution network. During a pandemic, it is inefficient and ineffective to have hospital systems, other health care providers, states, and the federal government in competition for these already limited supplies. Otherwise, the entities/governments with the greatest resources will obtain all, or a majority, of the PPE and other vital equipment even though the spread of the virus is not contained by arbitrary state or local jurisdictional boundaries. While creating this type of competitive marketplace may be good for business interests, it is not in the best interest of public health and safety. The point of the Strategic "National" Stockpile is for its use across the nation.

We recognize that a larger scale, protracted event, such as after Hurricane Katrina as well as COVID-19, may result in heterogeneous occurrences and demands. In order to streamline requests for, and dissemination of, SNS materials, it may become necessary for cities and states to submit their requirements to a regional medical coordination center, which likely will have better and more current information and contacts regarding shortages and location-specific concerns. However, it is imperative that there be transparency in what is available in the SNS, where those resources are distributed, and realistic timelines of when those materials will arrive.

Although it is reasonable to keep SNS cache locations secret, their general regional locations should be disclosed. This will enable local disaster planners to estimate how much access they will have, and how quickly, to supplies in the event of a disaster that interrupts transportation routes (e.g., an earthquake that damages bridges in and out of San Francisco).

States should be responsible for monitoring the type, capabilities, and total number of existing hospitals operating within their borders and communicating this information as needed to the federal government. This will help ensure supply distribution plans can be appropriately tailored to the "needs on the ground" and not rely upon potentially outdated data.

Recommendation 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.

This issue has led to a notable amount of contention and animosity between different hospital services (emergency department vs. inpatient ward vs. critical care units), health care staff, and hospital administrators, as well as health care personnel and the CDC. Multiple incidents occurred in which health care staff were not allowed by hospital administrators to utilize personally acquired PPE that the hospital was conserving or could not supply. Furthermore, across the country, various levels of "airborne" vs. "droplet" precautions, protective measures, and cleaning protocols were utilized, sometimes because of the lack of PPE to conform to contemporary guidelines.

ACEP also found it quite disturbing that the CDC's recommendations regarding PPE were lower for emergency physicians and other frontline personnel than its own established requirements for what CDC lab workers wear when dealing with the same agent. This went unnoticed by the general public, but it did not by those who have worked in the high-risk infectious disease world.

Furthermore, we need to have a public discourse about what constitutes sufficient supplies at various health care facilities. Many hospitals and other health care entities are claiming they have "sufficient" stockpiles of PPE, but that is only because they have changed their protocols and require emergency physicians (and others) to utilize a single mask, or other PPE, for an entire shift (or longer) when that mask is designated as a one-time-use product. This very issue was highlighted at the Senate Homeland Security and Governmental Affairs Committee hearing on June 9, 2020, when it was revealed that the Federal Emergency Management Agency (FEMA) was basing its analysis that it would have a sufficient stockpile of PPE in the fall on the assumption that frontline health care workers would be reusing their N95 masks and surgical gowns. This, of course, significantly increases the risk of contamination and possible infection.

We also need to acknowledge we cannot simply stockpile our way to resilience. The nation is too large for a single, static stockpile to accommodate demand. Instead, the "stockpile" must include a Defense Department-like plan to immediately ramp up manufacturing at many times baseline when an outbreak starts. The SNS should have rotating supplies with key regional assets to reduce stockpile deterioration and supply expiration. Additionally, this country needs better medical PPE that is designed for increased safety when donning and doffing this equipment in high-threat environments. The PPE used in medicine today is still basically repurposed from industrial settings, which do not have the same threat of live agents. We need to completely rethink how PPE is designed for safety, comfort, and sustainability; the single use paradigm for medical PPE is not effective from a cost, waste, space, and surge perspective. Given these shortcomings in our PPE supplies, strong consideration should be given to transition to half (or full) face respirators instead of surgical and N95 masks and there should be greater emphasis on appropriate, reusable supplies, such as cloth gowns, elastomeric respirators, etc., which are not as quickly exhausted as disposable supplies.

Recommendation 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.

We need a much more transparent, rational, and consistent plan for how SNS assets and other medical countermeasures are allocated. The plans to assess needs and distribute newly developed tests, treatments, or vaccines should include environments both inside and outside the hospital setting for essential health care personnel (e.g., using PPE on public transportation traveling to-and-from work). Special analysis must also be paid to how the redistribution of finite health resources could lead to unintended consequences for patient care (e.g., hydroxychloroquine ran out for patients with lupus during COVID-19).

The federal government may consider working with large, national retail businesses to help with logistics and distribution. The location of these retail outlets as distribution points for treatments and vaccine dissemination can supplement the community health care resources. Ideally, these locations would be selected with the input of local public health officials working in consultation with Disaster Medicine physicians.

Recommendation 3.5: Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.

Although multiple Administrations may be associated with the insufficient replenishing of the SNS, other factors contributed to the lack of necessary equipment as well, such as inventory that did not evolve over the past couple of decades (masks/respirators) and failures to provide sufficient oversight of federal contracts to manufacture ventilators. However, the current situation we find ourselves in is a major failure due to lack of planning and lack of adequate ongoing support for the SNS. Unfortunately, it is too easy to decrease support when all is well and no immediate threats are on the horizon. This has been true at the national and state levels and readiness has been further compromised at the local level by "just-in-time" inventory, leaving no room for surge requirement of supplies.

As noted previously, we are only now beginning to understand our supply chain vulnerabilities where much of our vital equipment is being manufactured outside of the United States in countries that can then deny us customary access when a surge arises. The SNS must be guaranteed adequate ongoing support with a more robust, evergreen inventory and domestic production. We must also fix the issue of ongoing shortages of common drugs during normal times. These are only exacerbated during times of increased national utilization when we run the risk of running out of routine drugs needed to support ventilated patients (paralytics and sedatives) and patients in need of palliative care (opioids and sedatives). To not have access to these agents in a time of need results in needless and unimaginable patient suffering.

Recommendation 3.6: Better leverage the support provided by FEMA and their emergency management experience and assets by improving a coordinated process between HHS and FEMA to more rapidly distribute supplies to states, health care providers, and other entities on the front lines, while utilizing HHS expertise with respect to public health and medical care and medical supplies.

We believe this was covered in our response to recommendation 3.2.

Recommendation 4.1: Get Americans back to their routine health care safely, and develop better plans for the future so that doctors and hospitals can continue to provide health care services and outpatient treatment during a pandemic.

Policymakers must make a conscious and concerted investment in revitalizing America's EDs, and these improvements should occur in both the process of emergency care and the physical facilities where ED staff provide care. This investment should upgrade the facilities needed for disaster care by building new areas needed to accommodate large groups of patients presenting for care at the same time. Simultaneously, this space would serve the critical needs of daily crises. Conceptually, this new space could wrap around the existing ED to create the new areas needed for reception, monitoring, and initial care.

This project should be a joint and mutual investment, funded and facilitated by federal, state, and local governments – and then carried out in conjunction with the many business, charity organizations, and individuals who want a new level of emergency preparedness in their community. If we wish to pour money into the community disaster systems, we should make sure it helps to rebuild a system of routine emergency medical care. After all, an effective disaster response system must be built on a foundation of effective day to day emergency care.

There are approximately 5,300 EDs currently in the country, servicing about 150 million patients per year for all forms of illness and injury. Virtually all of these EDs needs to be re-fitted for a new role in community surveillance and major incident medical care. These same EDs have been strained beyond the ability to provide timely care in most American metropolitan areas, due to a reduction in funding, closure of more than 1,000 hospitals and EDs, and a steady increase in the number of patients seeking care from the emergency system. Overcrowding of patients in the ED is a direct result of a lack of inpatient resources needed to care for high acuity patients who are boarding in the ED. When EDs are overcrowded and saturated, it leaves them unable to meet demands for day to day emergency care, much less a surge during a pandemic or other medical disaster.

A reinvestment program is needed in essentially all existing EDs. This would include the Level One Trauma Centers, which provide many critical care services to a regional group of patients. But this group of Trauma Centers cannot accommodate all the community needs, either on a day to day basis, or in the event of a major crisis. All hospitals are now responsible for developing plans to prepare for victims from any type of crisis – from trauma, to contagious disease, to radiation exposure or burn. With this background, it is critical to rebuild the country's emergency system to accommodate day to day, as well as disaster, medical needs.

The United States health system faced a similar need for capital investment after World War II when American communities were growing rapidly, health sciences had dramatically improved medical treatment, and this nation's leaders feared disasters on U.S. soil with the beginning of the Cold War. The federal government considered these needs and created an infrastructure funding program established by the Hill-Burton Act in 1946. We believe now is the time for consideration of another capital infusion to prepare this country's safety net health care facilities for the threats we face today.

We propose the federal government convene an expert panel to design the components of the "ED Major Incident Center" focusing on the following critical design components: approachable and responsive to communities and patients; information systems linked with a regional health care coordination center; major incidence preparedness elements; safe management of contaminated patients (or those exposed to hazardous substances); and links to all health care emergency system services within the community. The ED Major Incident Center will be the new heart of a community preparedness plan. It will serve as a community-based health management center, fully integrated with the overall health system and the community's emergency response system.

Recommendation 4.2: Ensure that the United States does not lose the gains made in telehealth.

As already noted, as more and more small and rural hospitals close, their EDs close too, leaving a gap in emergency care in a region. To fill these gaps, before the pandemic hit our nation, some emergency physicians were taking their own initiative to provide life-saving telehealth services. Different types of emergency care models have already been tested, from "direct-to-consumer" models to models that involve a hub that connects emergency physicians to EDs in remote locations or allows emergency physicians to provide consultations for specific clinical conditions. In general, studies have shown that physicians and patients are extremely satisfied with the care being provided through these models, and costs have decreased due to avoided ED visits and inpatient admissions.

There are established examples of high quality, cost-effective telehealth programs in the ED setting that allow greater access to an emergency physician in inner-city or rural EDs that would not usually be able to economically support that level of provider on a 24/7 basis, if at all.

Yet these emergency telehealth efforts were not widespread, both because of a lack of a consistent funding stream to support the provision of emergency telehealth services, and significant federal state and local legislative and regulatory hurdles that hinder the proliferation of emergency telehealth programs. During the COVID-19 crisis, CMS made two critical policy telehealth policy changes that impacted emergency medicine specifically – (1) allowing medical screening exams (MSEs), a requirement under the Emergency Medical Treatment and Labor Act (EMTALA), to be performed via telehealth; and (2) adding the ED evaluation and management (E/M) codes to the list of approved Medicare telehealth services. These policy changes have temporarily allowed some EDs to further invest in their existing telehealth programs and allowed others to initiate new programs to better serve their patients.

Being able to perform MSEs via telehealth over the course of the pandemic has helped protect emergency physicians and their patients from unnecessary exposure to the virus and helped preserve the limited supply of PPE. Furthermore, having the ED E/M codes on the approved list of Medicare telehealth services has given EDs an appropriate and consistent reimbursement mechanism to support their telehealth programs.

ACEP strongly believes that we cannot let the great strides we have made in the delivery of emergency telehealth services simply come to an abrupt end once the pandemic ends. To ensure that patients continue to get timely, personalized, highquality care, and that our nation's hospitals can maintain the capacity they need to provide emergency care at all times, we need to make sure that federal and state policies keep pace with clinical innovation. First, Congress should change the Medicare telehealth statute. Once the pandemic ends, CMS loses its ability to grant Medicare the telehealth flexibilities that allow any physician to provide services from any physical location. Congress can ensure patient access to telehealth after the pandemic by repealing the "originating site" requirement, which forces patients to travel to certain healthcare facilities to receive telehealth services instead of allowing them to receive medical attention from the convenience of their home. CMS has temporarily instituted this change because of COVID-19 and Congress should make it permanent.

All state Medicaid programs and health plans should follow Medicare's lead as well. Health plans and states should embrace telehealth with the same enthusiasm as Medicare and align their telehealth policies with Medicare's to ensure consistent regulation, licensure, billing, and coding for emergency telehealth services. Different billing rules and state regulations make reimbursement inconsistent and adds administrative challenges that hinder the sustainability of these new and vital telehealth programs.

Finally, CMS must permanently add the ED E/M codes to the list of approved Medicare telehealth services. That way, EDs could continue operating the telehealth programs that they have established during the pandemic.

To jump-start such a next step, Congress should enact S.2741, the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act. This vital legislation sets the stage for permanent reforms to telehealth that would advance care delivery, improve preparedness and capacity, and improve patient outcomes.

Recommendation 4.3: States need to maintain the capacity to trace contacts for emerging infectious diseases, and have programs in place to surge that capacity if necessary.

We need a consistent national contact tracing standard and system that can respond much more effectively than we did to COVID-19. Unless there is sustained funding for these programs to train personnel and maintain the systems in place to carry out this initiative, we risk losing this ability during the next public health emergency. Congress must consider all available resources to carry out this mission, including public-private partnerships and using access to research and innovation that academic institutions may provide.

Recommendation 4.4: Remove red tape and allow states to use Public Health Emergency Preparedness and Hospital Preparedness Program funds to respond to a public health emergency and report back to HHS on how they were used, rather than having to wait for written approval from Washington.

ACEP agrees that this type of flexibility can be very useful during public health emergencies. Too often, critical time, effort, and initiative may be lost while navigating the bureaucratic approval process, provided there is appropriate oversight and accounting of the funds by HHS within a reasonable timeframe.

Recommendation 5.1: Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.

Since the enactment of the first "Pandemic and All-Hazards Preparedness Act" (PAHPA), ACEP has supported the role of the Assistant Secretary for Preparedness and Response (ASPR) within HHS for the very reason that this position was supposed to fill this responsibility, especially during a public health emergency. We would encourage Congress to reevaluate the ASPR position to ensure it is strengthened as a response agency, staffed with sufficient experts to manage the health care issues that arise at the federal level, and provided with a clear scope of authority. The role and responsibilities of the ASPR must not only be clearly delineated within the structure of a federal response but should also be communicated to the public and private industry as well to improve coordination in the context of a pandemic.

ACEP recommends a clearly defined mechanism be put in place for the public dissemination of important medical information during times of crisis and/or declared emergencies. Some statements have been made during the COVID-19 crisis that have been in conflict with official government policies or medical expertise regarding the pandemic and this has led to confusion and mistrust. It is vital during times of national emergencies that evidence-based, medically sound information be shared with the public in a manner that instills confidence in our nation's leaders, government, and health care system.

ACEP would further recommend an annual review of the agencies and programs that would be responsible during public health emergencies, similar to the National Defense Authorization Act (NDAA). This annual authorization and oversight activity by Congress would provide opportunities to review the current structure of the nation's public health response activities, review current and potential public health threats, and make adjustments to the nation's response strategy as appropriate.

Recommendation 5.2: A key lesson from Crimson Contagion and COVID-19 is that plans and systems cannot be improved upon if they are not practiced. More training is needed, as well as more opportunities to exercise plans and processes nationwide.

We agree that training for emergency scenarios is very helpful when responding to actual events and we would encourage Congress to provide additional resources for these activities. We would also suggest Congress dedicate funding to supplement Disaster Medical Assistance Teams (DMATs) that are comprised of medical professionals and para-professionals who can quickly be sent to provide expert patient care when local health systems become overwhelmed.

Some states, such as Texas, have also established what is essentially a state-based DMAT. Within the umbrella of the Texas Emergency Medical Task Force is an Infectious Disease Response Unit. That team is comprised of both prehospital and hospital personnel who can rapidly deploy to emerging and existing infectious disease threats. They have had great success in disaster deployments and the COVID-19 response.

Congress should consider not only funding these national and state response units, or in some instances to help states develop this capability, but also to establish funding for training programs in medicine such as Disaster Medicine fellowships and training sites across the nation. COVID-19 has shown the importance of Disaster Medicine as a subspecialty, especially in terms of preparing for, and helping to guide, the hospital's operational response to a major incident such as this pandemic.

Development of national systems to improve overall disaster medical expertise, capacity, and capabilities is also vital. The creation of the National Emerging Special Pathogen Training and Education Center (NETEC) and the Regional Disaster Health Response System (RDHRS) pilots has established a good foundation, but we need a robust network of at least 10 RDHRS sites as centers of excellence that fit into a regional and state set of plans that leverage expert capabilities to improve disaster care for all (much like the national trauma network does).

Finally, ACEP would strongly urge Congress to appropriate funds for the implementation of the "Military Injury Surgical Systems Integrated Operationally Nationwide to Achieve ZERO Preventable Deaths (MISSION ZERO) Act." This program has already been authorized and its purpose is to enable military trauma care teams to provide their services at civilian trauma centers. During times of national emergencies, this would allow for leveraging of military assets in crisis through these relationships.

Additional ACEP Recommendations

1. Racial Disparities: Across the country, communities of color are disproportionately being infected by, and dying from, COVID-19. While racial data for COVID-19 is still incomplete, race or ethnicity is known for around half of all cases and 90% of deaths. Based on information derived by the COVID Tracking Project, we know African-American deaths from COVID-19 in this country are nearly two times greater than would be expected based on their share of the population. In four states, the rate is three or more times greater. In 42 states and Washington, D.C., Hispanics/Latinos make up a greater share of confirmed cases than their share of the population. In eight states, it's more than four times greater. White deaths from COVID-19 are lower than their share of the population in 37 states and Washington, D.C. Focusing on these disparities is crucial for helping communities respond to the virus effectively. Robust tracking of granular demographic data relative to COVID-19 incidence, morbidity, and mortality is necessary to better understand the factors associated with the disproportionate impact of this disease on underserved racial and ethnic minority groups. Congress and the Administration should make it a priority to collect this data and make it accessible in order to foster research and analysis of this phenomenon.

2. Employment Rights and Benefits: Congress should establish these protections for health care personnel (full and parttime employees) who become injured/infected (including medical and disability insurance coverage) as well as persons under investigation and quarantined because of institutional and government recommendations and guidelines. There have been incidents where employers have denied pay/benefits because of the assertion that the exposure/infection could not be proven to have been work-related (e.g. acquired via community despite exposures that occurred at work). In order to achieve these goals, ACEP urges Congress to enact the "ER Hero and Patient Safety Act" (H.R. 6910).

3. <u>Liability Protections</u>: Emergency physicians are putting themselves at risk each day while facing tremendous challenges during the COVID-19 pandemic, including inadequate safety supplies, scarce or changing information on treatment protocols, insufficient testing, and a lack of other essential resources needed to combat this disease. Despite these obstacles, we continue to go above and beyond, doing everything possible to treat the sick and bring comfort to others, often without regard for our own wellbeing.

The very health care professionals and facilities that are so dedicated to preserving and protecting the health of the American public should not face unwarranted legal action for our efforts to respond to the COVID-19 crisis, often under challenging conditions and limited resources. Yet, we still face the threat of medical liability lawsuits, which may come long after public memory of our sacrifices is forgotten, for outcomes that were frequently beyond our control, given that the normal standard of care is impeded by limited capacity and access to needed medication, equipment, or other resources and supplies.

America's health care system cannot achieve maximum capacity and capability when we are asked to sacrifice so much while being simultaneously threatened with a future of numerous lawsuits based on this evolving pandemic. ACEP urges Congress to enact the "Coronavirus Provider Protection Act" (H.R. 7059). This bill provides liability protections for emergency physicians, other health care providers, and health care entities by: (1) shielding them from lawsuits during the emergency, as well as 60 days following the termination of the emergency declaration; (2) accounting for federal, state, or local guidance or recommendations in response to COVID-19; (3) safeguarding our treatment decisions that takes into account a lack of resources, including manpower, attributable to COVID-19; and (4) excluding harm as a result of gross negligence or willful misconduct.

4. <u>Insurance Status</u>: During a pandemic, when individual health is directly affected by population health, consideration must be made for how to handle the large number of uninsured and underinsured Americans. We need to ensure insurance status does not make an individual less likely to seek care or more likely to spread the infection.

5. Food Supply: COVID-19 has been a medical crisis, but it came near to, and still may, become a food crisis. A complete analysis of practices existing at processing plants, meat packing plants, etc., needs to be done. COVID-19 has ran rampant through this industry. Congress should examine what can make these work environments safer and how the spread of infectious diseases may be mitigated in this industry during future pandemics.

6. Cost-Sharing: We urge Congress and the Administration to require all health plans to waive cost-sharing (including copayments, coinsurance, *and* deductibles) for all testing and ED services related to COVID-19. Removing the fear of potential out-of-pocket costs will remove what could be a dangerous obstacle to patients seeking treatment and more widespread testing. Broader testing not only increases the likelihood that treatment can be provided early (when it has been found to be more effective), but it also helps ensure those with mild or even no symptoms to know they must now isolate themselves until they recover, limiting further spread in the community. As well, it provides public health officials with valuable information with which to track the virus's spread and identify areas where additional resources might be needed. It must be explicit that the insurer is solely and completely responsible for the full cost-sharing amount (copayment, coinsurance, *and* deductible) that the patient would have incurred otherwise.

Furthermore, insurers must not be allowed to retroactively deny claims or not cover cost-sharing if patients thought that they may have the disease but wound up not having it. Now more than ever, the Administration must enforce the federal prudent layperson standard (PLP) standard, which ensures a health insurance carrier must provide coverage for emergency services "if a prudent layperson acting reasonably would have believed that an emergency medical condition existed." This patient protection is especially vital with the spread of the deadly COVID-19 virus.

7. Protect Those Engaged in COVID-19 Response: Managing a response to large-scale mass casualty incidences (MCIs) and pandemics requires making difficult decisions that are in the best interest of the public health. These decisions can often be unpopular and controversial. However, it should never be acceptable that the lives of these public health officials or their families be threatened. Congress should consider making such threats a federal offense and provide appropriate support and protection for these officials.