

June 26, 2020

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education, Labor,  
and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

Dear Chairman Alexander:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the white paper “Preparing for the Next Pandemic.” While the country continues to face myriad challenges during the ongoing COVID-19 pandemic, we commend the effort to ensure America is better prepared for future pandemics.

As detailed further below, the AMA has recommendations in several key areas that it believes are crucial to combating the COVID-19 pandemic and would be essential in being better prepared for the next pandemic. These areas include:

- Creating better coordination across federal and state governments and streamlining pandemic response logistics;
- Improving diagnostic testing infrastructure, organization, and regulation;
- Ensuring accelerated vaccine and therapeutic development is guided by evidence and protects the health of subjects and patients;
- Enhancing state and federal stockpiles and improving the system for acquisition and distribution of medically necessary supplies;
- Creating and maintaining a comprehensive, well-coordinated, and culturally sensitive data collection strategy;
- Ensuring digital contact tracing efforts are built around privacy and transparency to promote trust;
- Expanding access and coverage to telehealth services; and
- Protecting physicians and other healthcare professionals on the front line of pandemic response from increased liability arising from situations outside of their control.

In developing strategies to combat future pandemics, we urge Congress to consider how the COVID-19 pandemic has had a profound and disproportionate effect on minoritized and marginalized communities. While the data remains incomplete, the data that have emerged on the racial and ethnic patterns of the COVID-19 pandemic show that the virus has clearly disproportionately affected Black and Latinx, American Indian/Alaska Native—particularly in the Navajo Nation—Asian-American, and Pacific Islander communities. The latest data from the [COVID Racial Tracker](#) shows that while Black Americans account for 13 percent of the U.S. population, they account for 24 percent of the deaths where race is

known: this means Black people are dying at a rate nearly two times higher than their population share. Policy solutions aimed at preparing for the next pandemic must have an acute focus on protecting underserved areas and marginalized communities. This must include a comprehensive and well-coordinated data collection strategy, that takes into account sensitivities when collecting demographic information from historically marginalized populations. In addition to better collection information about which communities face the highest burden of disease, any future plan for addressing a pandemic must prioritize promptly providing culturally appropriate public health information to minoritized populations through appropriate channels and ensuring access to testing and telehealth services for underserved areas in order to identify pandemic spread and assist those communities in gaining access to health care services while maintaining physical distancing.

### **CLEARLY IDENTIFY RESPONSIBILITIES AT THE FEDERAL, STATE AND LOCAL LEVELS AND SOLVE LOGISTICAL CHALLENGES IN THE MEDICAL SUPPLY CHAIN**

One of the significant challenges of the current pandemic remains the lack of clearly delineated roles and responsibilities with respect to the public health emergency response within federal departments and agencies. Also presenting a significant issue is the lack of coordination between individual states and the federal government, as well as a lack of understanding what role each was to play in the response. As Congress considers how best to deal with future public health emergencies, the AMA offers the following recommendations to help provide clarity and ensure coordination so that public officials may more quickly and efficiently respond to an impending public health crisis:

A national strategy for response coordination must be in place that clearly outlines the roles and responsibilities of both federal and state governments.

Early in the COVID-19 pandemic, there was a clear lack of coordination between federal and state governments, with neither seeming to clearly understand what their roles and responsibilities were in responding to this pandemic. States were looking to the federal government for leadership and assistance, while the federal government was expecting states to lead their own response. This lack of clarity hinders the ability of each to respond quickly and effectively to the needs of the general public. The AMA strongly recommends a mandate that requires creation of a national strategy for response coordination, clearly delineating the roles of federal and state governments in public health emergencies, so that each can properly prepare and move quickly the next time we face a public health crisis.

The needs of physicians and patients in all practice settings must be considered to ensure continuity of care for patients and continued viability of non-hospital practices.

When responding to an emerging global health threat, it goes without saying that we must urgently respond to and prioritize the needs of front line providers helping to mitigate the impacts of public health emergencies. While these needs understandably take precedence in the midst of a crisis, we also must continue to consider the impacts of public health emergencies on non-hospital providers and patients needing management of chronic conditions. Non-emergent medical services were rightly halted at the beginning of the COVID-19 pandemic, but we need to be better prepared in a future epidemic to address the needs of non-hospital providers and patients with chronic conditions who have to make in-person visits to a physician's office or other health care setting. However, we must be better prepared to help these practices and patients navigate uncertain times where access to physician practices may be temporarily suspended. **The AMA recommends that both legislators and regulators consider the needs of non-hospital practices and patients when implementing new policies for pandemic**

**response.** This may include financial assistance considerations, acquisition and distribution of PPE, and other important considerations discussed in the recommendations below.

Logistical planning for public health emergency response must have a permanent home within the federal government.

As the federal government engaged in acquisition and distribution of critical medical supplies, such as PPE and ventilators, it became clear that expertise in supply chain management and logistics would play a critical role in the federal response to the COVID-19 pandemic. **The AMA recommends that responsibility for coordination of these activities become part of a permanent role within the federal government, instead of part of a temporary task force where lessons learned are potentially lost after the end of the public health emergency.** If responsibility for pandemic response supply chain and logistics rests with FEMA, the AMA recommends creation of a permanent/formalized bridge to HHS to ensure coordination of the two agencies during times of need.

Interagency coordination should be improved by creation of permanent roles responsible for coordination between the major departments and agencies responding to public health emergencies.

Response to a public health emergency is delayed when there are not clearly defined roles dedicated to response. The AMA recommends that each agency with a role to play in public health emergency response have dedicated individuals or units that will be responsible for interagency coordination. These individuals or units should be permanently tasked with this responsibility so that they are able to respond rapidly to emerging threats. These roles should not be created on a temporary basis, or as part of a task force that is rapidly disbanded when the threat subsides.

Ensure federal, state, and local governmental entities have readily available points of contact to assist in identifying available PPE and infection control products.

**Throughout the current COVID-19 pandemic, access to PPE has presented tremendous challenges to providers in all care settings.** Many health care facilities have been unsure where to turn to find out information about available suppliers of PPE and infection control products. This has become even more problematic for non-hospital practices, as they begin to resume elective services and procedures. **The AMA recommends that federal, state, and local entities managing pandemic response maintain readily available points of contact for questions about PPE and infection control supplies and logistics.** Information about points of contact who can assist with questions must be made publicly available. Alternatively, the AMA recommends consideration of partnerships with clearinghouses that could provide assistance with sourcing and vetting of available PPE and matching supply with demand.

Provide greater transparency around the supply chain and distribution of medically necessary supplies including test kits, PPE and ventilators.

As you are aware, the intense global demand for test kits and testing supplies has significantly impacted access to tests at many locations where those tests are critical to the treatment of seriously ill patients. While we appreciate the federal government's efforts to procure needed supplies, both domestically and abroad, there has been very little transparency about those supplies provided to laboratories in need. **The AMA strongly recommends new requirements for transparency and clarity in the testing supply chain, including what is in shortage, what is available, when additional supplies may be expected, and quantities that may be expected so that laboratories can develop strategies to best deal with**

**available supplies.** This responsibility should be clearly delineated by Congress and ultimately housed in a single federal entity that is responsible for gathering all information on the supply chain and delivering that information to relevant stakeholders at the state and local levels.

## **IMPROVE DIAGNOSTIC TESTING INFRASTRUCTURE, ORGANIZATION AND REGULATION**

Development and deployment of diagnostic tests for COVID-19 has provided physicians, hospitals, health systems, laboratories, researchers, and others many challenges over the course of the current pandemic. Despite obvious signs that SARS-CoV-2 would make its way to the United States, we appeared to, in many instances, be caught flat-footed and unprepared to deal with the significant demand for diagnostic tests.

The AMA has worked diligently with federal regulators, state officials, hospitals, physicians, and other health care providers to ensure access to diagnostic tests for SARS-CoV-2 throughout the course of the current pandemic. We have found that testing has faced numerous roadblocks, including regulatory barriers, overwhelming global demand for testing supplies causing significant shortages and supply chain strain, lack of clear national strategy for testing, questions regarding distribution of federally procured supplies, questions around test performance, and others. Many challenges remain in attempting to secure adequate testing to meet the needs of the current pandemic, but there are already a number of clear lessons that can be learned from the problems that have been encountered thus far.

Create clear regulatory oversight plans aimed at bringing diagnostic tests to market with minimal regulatory burden in place.

While developing diagnostics for a novel pathogen is always challenging, federal regulators, including the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) must recognize that large, emerging threats will require significant flexibilities in order to attempt to mitigate the threat to the public health. In the early stages of the pandemic, requirements to use the CDC test kit, and later on the requirement of CDC confirmation of results slowed the ability to test a greater number of individuals with potential COVID-19 infections.<sup>1</sup> Likewise, early FDA policy that required that all tests must be authorized under Emergency Use Authorizations further slowed the process of getting tests to market. Academic centers and other hospital laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA) are well-positioned to develop diagnostic tests and should not be burdened with additional regulatory requirements to bring these tests to market during a public health emergency. **We recommend new requirements that CDC, FDA, and other relevant components of HHS issue guidance for diagnostic testing during a public health emergency that provides prospective clarity to test developers. It should also state how the agencies intend to enforce their authorities and grant marketing status to diagnostic tests during a pandemic.**

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<sup>1</sup> See Goodnough, Abby and Shear, Michael D. “The U.S.’s Slow Start to Coronavirus Testing: A Timeline.” NYTimes. Available at <https://www.nytimes.com/2020/03/28/us/coronavirus-testing-timeline.html>.

Provide greater clarity on how testing strategies are to be deployed.

Development and deployment of diagnostic tests has appeared to be hindered by a lack of national strategy and clarity on who is responsible for developing and deploying testing plans. From the beginning there was confusion about whether the Administration would be developing a national testing plan and managing supply procurement and distribution, or whether states would be required to develop their own plans and procure their own supplies and test kits. **The AMA strongly recommends that the federal government develop a national testing strategy, clearly delineating what role the federal government will play, where responsibility for testing issues will be housed within the federal government, and what role the states will play.** These roles and responsibilities must be explicitly defined to avoid confusion and scrambling in the midst of a rapidly escalating public health threat. The national testing strategy should also account for the needs of hospital laboratories, which play a critical role on the front lines in identifying patients with COVID-19, in addition to the needs of public health and commercial laboratories. Should Congress determine that the individual states have a role to play in developing their own testing strategies and plans for procurement of test kits and supplies, that must be clearly communicated and requirements for the states must be in place as soon as possible.

Ensure that payment and coverage for testing does not serve as a barrier to access.

When faced with a rapidly emerging public health threat, access to testing services is critical to help mitigate the spread of the disease and to triage and treat patients in hospitals and other facilities. A positive diagnosis can help to quickly isolate infectious patients and can ensure that infectious patients are properly placed in hospitals to avoid infecting others. Because diagnostic testing is so crucial to stopping the spread, it is critical that these tests be adequately paid to ensure laboratories can readily offer the test without incurring financial loss. Further, testing services should be fully covered without cost-sharing for patients, as cost should not serve as a barrier to this critical element of pandemic mitigation. This will be particularly important for minority and other disproportionately impacted communities, where costs can present more significant barriers to care. **The AMA recommends that Congress mandate coverage without cost sharing and adequate payment for diagnostic testing when faced with public health threats such as viral outbreaks.**

**VACCINE AND THERAPEUTIC DEVELOPMENT MUST BE GUIDED BY EVIDENCE AND PROTECT THE HEALTH OF SUBJECTS AND PATIENTS**

The AMA understands and supports the desire to quickly bring new therapies and vaccines to market to help mitigate the impacts of a pandemic. However, the desire for expediency does raise some corresponding concerns about the safety and efficacy of those products. **The AMA recommends that any decision to use a therapeutic or vaccine during a public health emergency continue to be evidence-based and must not subject patients to undue risks for the sake of expediency.** Where the potential for significant risk to patient health accompanies the use of the therapeutic or vaccine, that must be carefully weighed along with potential benefits. Use of a therapeutic or vaccine must not be the result of political pressure. We strongly encourage continued investment in development of vaccines and therapeutics for emerging public health threats; support clinical trials to establish safety and efficacy; and encourage the exploration of novel arrangements for resourcing these efforts, such as new public-private partnerships.

## **ENHANCE STATE AND FEDERAL STOCKPILES AND IMPROVE THE SYSTEM FOR ACQUISITION AND DISTRIBUTION OF MEDICALLY NECESSARY SUPPLIES**

Acquisition of appropriate personal protective equipment (PPE) for health care providers has been a significant and ongoing challenge for physicians in every health care setting during the COVID-19 pandemic.<sup>2</sup> Hospital and health system physicians on the front lines have for months been struggling with limited supplies of basic PPE, compromising their ability to adequately protect physicians, other health care providers, and patients. As we shift towards reopening non-hospital physician practices for elective visits and procedures, we face new demands on the PPE supply chain. While we appreciate the overwhelming global demand for these critical products and the strain on the supply chain this creates, below we offer some recommendations to help ease the burden on the National Strategic Stockpile, the distribution system, and help physicians, hospitals, and health systems address the problems that currently exist and better prepare for dealing with shortages of these critical supplies.

Improve system for acquisition and distribution of PPE and other infection control products and increase supply chain transparency to provide physicians, hospitals, and health systems insights into currently available supplies and methods of distribution.

Throughout the early months of the COVID-19 pandemic in the United States, PPE, infection control products, and ventilators were in shockingly short supply, particularly in hot spots dealing with an exceptional case load. Procurement of PPE and other infection control products appeared to be a free-for-all, with the federal government claiming states were on their own to procure what they could, but the federal government also attempting to purchase large quantities of PPE and other items to distribute. The AMA has been made aware that there was significant confusion as to where to acquire PPE, who was managing procurement (federal officials, state officials, individual facilities), how much PPE was available, and when more may be made available. Claims of federal requisition of items purchased by states are widely known and made it virtually impossible for states or individual hospitals to acquire needed supplies. This confusion put hospitals, physician's offices, and health care workers on the front lines in an impossible situation where they did not have critical information necessary to plan for usage of PPE and other medically necessary supplies. **The AMA recommends creation of a clear and transparent plan for acquisition and distribution of PPE and other needed supplies, with clear delineation of federal and state roles and requiring supply chain information be made available to physicians, hospitals, and health systems during public health emergencies.**

Increase funding and modernize planning for the strategic national stockpile, create contingency plans and provide federal guidance on what supplies should be stockpiled and should be provided to states and local entities.

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<sup>2</sup> See Mehrota et al., "Personal Protective Equipment Shortages During COVID-19 – Supply Chain-Related Causes and Mitigation Strategies," available at <https://jamanetwork.com/channels/health-forum/fullarticle/2766118>.

Funding for the strategic national stockpile has decreased precipitously since 2003.<sup>3</sup> Moreover, funding and stockpile planning were inadequate to meet the demands of a nationwide extended epidemic.<sup>4</sup> At the start of the epidemic, there were reportedly just 12 million N95 masks and 30 million surgical masks available in the national stockpile, an amount that would have been inadequate for any major viral outbreak.<sup>5</sup> The strategic national stockpile priorities should be reassessed with future pandemics in mind. In particular, the strategic national stockpile should contain enough supplies to help bridge the gap while production is ramped up on PPE, diagnostic testing equipment, ventilators, and other necessary supplies when the next pandemic hits. **Given that we have learned that global demand can quickly outpace supply of even simple items such as cotton testing swabs, the AMA recommends that new plans be put in place for federal, and possibly state, stockpiles of critical testing supplies.** In addition, in order to better prepare for unforeseen challenges and demands on supplies, the **AMA recommends requirements for the federal government to develop a contingency plan to best deal with supply shortages and supply chain issues impacting critical medical supplies during a pandemic, including ventilators, PPE, and testing supplies.** This may include recommendations on best recommended alternatives to supplies in shortage, plans to engage alternative manufacturers that may be able to produce said supplies, or plans on when and how best to invoke the Defense Production Act.

Moreover, given the crushing demand for PPE throughout the COVID-19 pandemic, we agree that federal, state, and local entities should all consider the merits of creating stockpiles of PPE, ventilators, and infection control products. **The AMA recommends the federal government work to provide guidance to states and local entities as to what those stockpiles should look like, and what should be included.** The federal government should provide transparency around what is included in the federal Strategic National Stockpile, and when the SNS will and will not be utilized.

CDC should provide clear guidance to health care providers, hospitals, and health systems on how to manage limited PPE, including guidance on how best to conserve PPE, guidelines for re-use, guidelines for sterilization/disinfecting, and alternatives when preferred PPE is not available.

While the CDC did eventually move toward providing this information during the current COVID-19 pandemic, the CDC should have permanent guidelines in place to address these critical issues. While COVID-19 was surging in hot spots such as New York City, providers in those locations did not have adequate guidance to instruct their use of PPE. The current COVID-19 pandemic should provide CDC, possibly in conjunction with the National Institute for Occupational Health and Safety, in developing permanent guidelines for PPE use.

Strong measures must be in place to restrict price gouging during a public health emergency and limit counterfeit PPE and infection control products from coming to market in the U.S.

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<sup>3</sup> Greenberg, Jon. "Federal pandemic money fell for years. Trump's budget didn't help." Politifact, March 30, 2020. Available at <https://www.politifact.com/article/2020/mar/30/federal-pandemic-money-fell-years-trumps-budgets-d/>; Torbati, Yeganeh and Arnsdorg, Isaac. "How Tea Party Budget Battles Left the National Emergency Medical Stockpile Unprepared for Coronavirus." Propublica April 3, 2020. Available at <https://www.propublica.org/article/us-emergency-medical-stockpile-funding-unprepared-coronavirus>.

<sup>4</sup> Palmer, Doug "U.S. Medical Stockpile Wasn't Built For This, former director says." Politico, April 8, 2020. Available at <https://www.politico.com/news/2020/04/08/national-stockpile-coronavirus-crisis-175619>.

<sup>5</sup> Levey, Noam M. et al. "A disaster foretold: Shortages of ventilators and other medical supplies have long been warned about." LA Times, March 20, 2020. Available at <https://www.latimes.com/politics/story/2020-03-20/disaster-foretold-shortages-ventilators-medical-supplies-warned-about>.

On May 23, President Trump signed an Executive Order prohibiting the hoarding of necessary medical supplies for the purpose of selling them above market value. While the AMA is not specifically aware of instances of hoarding, we are aware of numerous instances where entities were asked to pay prices significantly above normal sales prices for items in high demand, such as N95 masks. States report a willingness to pay \$300 million for only 50 million N95 masks. Other entities report N95 respirators selling for seven times the usual amount. **The AMA recommends that Congress establish permanent restrictions on hoarding and price gouging of necessary medical supplies during a public health emergency or disaster and provide for enforcement mechanisms against individuals or entities engaged in these activities.**

In addition, the AMA has heard from numerous members issues with the proliferation of bad actors looking to take advantage of a desperate market by selling counterfeit PPE. The AMA recommends creation of a system to validate vendors so that purchasing entities, whether they be state or local government, physician practices, hospitals or health systems can ensure that the products they are purchasing meet safety standards and are not counterfeit goods.

### **A COMPREHENSIVE, WELL-COORDINATED, AND CULTURALLY SENSITIVE DATA COLLECTION STRATEGY IS ESSENTIAL TO PANDEMIC PREPAREDNESS**

Syndromic surveillance by public health authorities is critical to pandemic response and ensuring coordination of medical resources across the country to leverage the greatest and most equitable level of care possible for all patients. Public health experts have emphasized to us the importance of prioritizing transmission of information to public health officials at the state and local levels since these officials urgently need data to make decisions for the general public. Absent such surveillance and other types of data collection at all levels of government, it is difficult to know where virus “hot-spots” are occurring, and where testing and other resources need to be focused. This information is also important to pandemic recovery: for example, it helps to inform policymakers as the country lifts restrictions on physical distancing and as businesses, schools, and governments reopen. Unfortunately, issues with accurate, consistent, and complete data have been a continuing concern throughout the current pandemic, including on the number of cases, testing results (e.g., the CDC and many states combined statistics on diagnostic tests and antibody tests), hospitalizations, and deaths.

#### Data collection requests must be streamlined and consistent.

Lack of coordination has proven a significant barrier to data collection: state data collection and sharing requirements are varied, which creates a bottleneck for health information technology (health IT) systems to quickly develop robust exchange systems. Additionally, a variety of entities attempted to create new systems for data collection early in the COVID-19 pandemic, whereas public health officials we spoke to emphasized the need to strengthen existing systems rather than invest in new ones. Some EHR vendors reported reluctance to create multiple connections to different public health agencies. Furthermore, we heard reports that in addition to complying with state and federal reporting laws, commercial labs have received duplicative reporting mandates from a variety of entities, including health information exchanges (HIEs), Governors’ offices, Medicaid plans, and government contractors.

Moreover, the lack of standardized data and real-time data across health IT systems are significant barriers to surveillance, leading to manual data reconciliation and normalization. The AMA is aware, for example, that some laboratory case reports are arriving at health departments missing key information necessary to inform our response to COVID-19. Specifically, the Council of State and Territorial

Epidemiologists (CSTE) noted during a [Health IT Advisory Committee on April 15, 2020](#) that some states, including those that have been the most highly impacted by COVID-19, report that “race and ethnicity [data] is missing 85% of the time [and] patient address is missing as much as 50% of the time.” To help rectify this gap in reporting, the AMA is developing guidance for physicians to help them identify the key demographic information that health departments need included on their patient’s lab orders. We were also pleased to see HHS issue [guidance](#) outlining what data must be reported to HHS by laboratories reporting COVID-19 test results. However, improvements must also be made to the current standards for lab reports themselves, as well as to the way electronic health records (EHRs) are configured to ensure health departments have complete data. Current lab order standards include fields for public health reporting data, but these fields can be left unpopulated when submitted. Additionally, EHRs may not be configured with the ability to auto-populate the data from lab orders entered by physicians. **We urge the federal government to encourage EHR vendors to support physicians and proactively work with medical practices to make sure their systems are properly configured and can leverage automation functions and capabilities.**

Race, ethnicity, and language data is needed to aid response.

It is extremely difficult to respond to a pandemic—including conducting effective contact tracing—with incomplete information. **The nation’s data collection strategy must ensure collection of information to help understand and anticipate the impact of pandemics on communities of color; indigenous people, those with Limited English Proficiency (LEP); LGBTQ+ individuals; and women.** The current pandemic has highlighted the importance of collecting, analyzing, and reporting data on patient race, ethnicity, and preferred spoken/written language related to testing, hospitalization, and mortality associated with COVID-19. To be clear, social and health inequities are long-standing and systemic disturbances to the wellness of many American communities are not unique to pandemics. For example, many communities of color experience higher rates of chronic diseases (asthma, diabetes, hypertension), lower access to health care, lack of paid sick leave, lack of or inadequate health insurance, and income disparities compared to non-Hispanic Whites.<sup>6</sup> Each of these inequities—individually and compounded—exacerbate the effects of a pandemic. COVID-19 is not the first pandemic to highlight these inequities; previous pandemics, including the H1N1 virus, have demonstrated the need for a holistic understanding of racial and ethnic implications prior to and during pandemic scenarios to maximize public health resources and advance equity in health care delivery.<sup>7</sup> Several epidemiologic studies and reviews reported higher rates of hospitalization in the U.S. from H1N1 among low-income individuals, those living in impoverished neighborhoods, and people of color and with diverse ethnic backgrounds.<sup>8</sup> Additionally, language barriers for LEP patients or community members may increase exposure to misinformation about the impact and nature of a pandemic.<sup>9</sup>

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<sup>6</sup> Thorpe, K.E. et al. 2017. “The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases.” Health Affairs Blog. Available at <https://www.healthaffairs.org/doi/10.1377/hblog20170817.061561/full/>

<sup>7</sup> Quinn, S.C. et al. 2011. “Racial Disparities in Exposure, Susceptibility, and Access to Health Care in the US H1N1 Influenza Pandemic.” *American Journal of Public Health*. 101(2): 285-293.

<sup>8</sup> Kumar, S. et al. 2012. “The Social Ecological Model as a Framework for Determinants of 2009 H1N1 Influenza Vaccine Uptake in the US.” *Health Education & Behavior*. 39(2):229-243.

<sup>9</sup> Kaplan, J. 2020. “Hospitals Have Left Many COVID-19 Patients Who Don’t Speak English Alone, Confused and Without Proper Care.” *ProPublica*. Available at <https://www.propublica.org/article/hospitals-have-left-many-covid19-patients-who-dont-speak-english-alone-confused-and-without-proper-care>.

It is also important to recognize the complexity of collecting data by race and ethnicity. For example, there are 573 federally-recognized Indian nations in the United States. Tribal members from each of these nations can differ ethnically, culturally, and linguistically, and can live on or off reservations and can access health services from the Indian Health Service, the U.S. Veteran's Administration, or through other public or private providers. Of the 42 million people who identify as Black or African American more than three million are immigrants, mostly from Africa or the Caribbean while the majority have lived in the United States for generations. Latinx population now represent about 20 percent of the U.S. population, and the majority self-identify as Mexican, Puerto Rican, or Cuban, which represent strikingly different cultures and histories. Inequities can affect segments within these populations differently because of variances in structural determinants of health and other conditions.<sup>10</sup>

Unfortunately, data emerging from states on the racial and ethnic patterns of the pandemic paint an alarming picture: COVID-19 is disproportionately impacting communities of color. In fact, a recent study found "excess risk of COVID-19 death at all ages among Non-Hispanic Blacks, Hispanics, Non-Hispanic American Indian or Alaskan Natives, and Non-Hispanic Asian Pacific Islanders as compared to Non-Hispanic Whites (NHW), with disparities particularly extreme at younger ages (25-54 years old)."<sup>11</sup> Specifically, Latinx people ages "35 to 44 have a coronavirus mortality rate nearly eight times higher than white people in that age group—and Black people in the same age range have a mortality rate nine times higher than white people."<sup>12</sup>

Data collection messaging must be clear, culturally sensitive, and appropriate for the intended audience.

**All the reasons above underscore the importance of an effective data collection strategy when planning for pandemic preparedness. The data collection strategy must be comprehensive, well-coordinated, and culturally sensitive, particularly when collecting potentially sensitive demographic information from historically marginalized populations.** For example, during the COVID-19 pandemic, Pennsylvania was an early adopter of technology used to collect information related to sexual orientation and gender identity (SOGI). The move was heralded by advocates as a positive step toward correcting a lack of SOGI data that could be used to better assess needs and allocate resources.<sup>13</sup> Unfortunately, the Pennsylvania Department of Health's executive deputy secretary reports that people are hesitant to answer questions about their SOGI; so far only about one in five people have volunteered to answer the questions, noting that "many people can feel uncomfortable sharing information with state workers."<sup>14</sup> The executive deputy secretary noted that the state's Department of Health is "working with

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<sup>10</sup> Rubin, Victor et al. "Counting a diverse nation: disaggregating data on race and ethnicity to advance a culture of health." PolicyLink. Available at [https://www.policylink.org/sites/default/files/Counting\\_a\\_Diverse\\_Nation\\_08\\_15\\_18.pdf](https://www.policylink.org/sites/default/files/Counting_a_Diverse_Nation_08_15_18.pdf).

<sup>11</sup> Basset, M.T. et al. "The unequal toll of COVID-19 mortality by age in the United States: Quantifying racial/ethnic disparities." *Harvard Center for Population and Development Studies Working Paper* Volume 19, Number 3. June 12, 2020. Available at [https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20\\_Basset-Chen-Krieger\\_COVID-19\\_plus\\_age\\_working-paper\\_0612\\_Vol-19\\_No-3\\_with-cover.pdf](https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20_Basset-Chen-Krieger_COVID-19_plus_age_working-paper_0612_Vol-19_No-3_with-cover.pdf).

<sup>12</sup> Barrón-López, Laura. "Rising coronavirus cases among Latinos alarm public health experts." *Politico*. June 18, 2020. Available at <https://www.politico.com/news/2020/06/18/rising-coronavirus-cases-among-latinos-alarm-public-health-experts-329248>.

<sup>13</sup> Amell, J. "Pennsylvania becomes trailblazer in LGBTQ data collection." *Philadelphia Gay News*. May 13, 2020. Available at <https://epgn.com/2020/05/13/pennsylvania-trailblazer-in-lgbtq-data-collection/>.

<sup>14</sup> Rayasam, R. "Covid messes with Texas." *Politico Nightly: Coronavirus Special Edition*. June 17, 2020. Available at <https://www.politico.com/newsletters/politico-nightly-coronavirus-special-edition/2020/06/17/covid-messes-with-texas-489559>.

the governor’s LGBTQ commission to better train health workers in asking the questions...so they don’t come across to the individuals as unexpected.”<sup>15</sup> Another example relates to considerations for immigrant and mixed-documentation status families. Heightened anti-immigrant rhetoric and policies, xenophobia, and unaddressed hate crimes may limit a patient’s desire to seek help or participate in contact tracing. It is not uncommon for immigrants or families of mixed-documentation status to not be forthcoming about household size, living accommodations, or working arrangements for fear of being reported to immigration authorities.<sup>16</sup>

Finally, we note the importance of explaining terms like “surveillance” when developing data collection strategies such as contact tracing. Contact tracing is a well-established practice in public health used to help track and trace the spread of disease among people. However, when officials discuss contact tracing and surveillance without careful consideration of how such terms will sound to a variety of populations, their efforts may be futile at best and harmful at worst. For example, the Minnesota Department of Public Safety Commissioner announced that law enforcement would begin “contact tracing” those arrested during protests in the aftermath of George Floyd’s murder in Minneapolis.<sup>17</sup> The Commissioner’s remarks reflected his desire to investigate the protestors’ platforms and associations, and social media quickly spread the Commissioner’s message, “tapping into fears that a tool intended to track cases of the coronavirus could be abused by police. Now, public health experts worry that [the Commissioner’s] misleading remarks could undermine both traditional and digital contact tracing efforts to stop the spread of Covid-19.”<sup>18</sup>

These are critical considerations for collection of information that some may deem “sensitive,” including SOGI, immigration status, race, ethnicity, and preferred language data. Patients should not be compelled by the health care system or the government to disclose racial or ethnic information (including immigration status or country of origin) against their will. Rather, **government officials and others undertaking syndromic surveillance and contact tracing must be thoughtful about the language they use when collecting information and prepared to explain in plain terms why the information is being collected and with whom it will be shared. We encourage officials to seek guidance from advocates and other professionals with expertise in best practices when strategizing around data collection from historically marginalized populations. Furthermore, we urge the federal government to collaborate with state, tribal and local public health authorities and clinical data registries where possible to minimize data burden collection for front-line clinicians caring for patients.**

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<sup>15</sup> Rayasam, R. “Covid messes with Texas.” *Politico Nightly: Coronavirus Special Edition*. June 17, 2020. Available at <https://www.politico.com/newsletters/politico-nightly-coronavirus-special-edition/2020/06/17/covid-messes-with-texas-489559>.

<sup>16</sup> American Medical Association. “COVID-19 FAQs: Health equity in a pandemic.” April 16, 2020. Available at <https://www.ama-assn.org/delivering-care/health-equity/covid-19-faqs-health-equity-pandemic>.

<sup>17</sup> Mullin, E. “Calling Police Investigations ‘Contact Tracing’ Could Block Efforts to Stop Covid-19.” OneZero. June 5, 2020. Available at <https://onezero.medium.com/calling-police-investigations-contact-tracing-could-block-efforts-to-stop-covid-19-349cdc27766e>.

<sup>18</sup> Mullin, E. “Calling Police Investigations ‘Contact Tracing’ Could Block Efforts to Stop Covid-19.” OneZero. June 5, 2020. Available at <https://onezero.medium.com/calling-police-investigations-contact-tracing-could-block-efforts-to-stop-covid-19-349cdc27766e>.

Effective pandemic response will require continued investment in public health infrastructure including surveillance and response.

The AMA believes that the enhancement of surveillance, response, and leadership capabilities of state and local public health agencies should be specifically targeted as among our nation's highest priorities. We recognize that increased funding is needed to preserve and modernize our nation's public health systems to prevent and respond to outbreaks and other public health crises.

States are facing dire revenue shortfalls from the COVID-19 pandemic and resulting economic downturn that threaten every aspect of state government operations. As states grapple with limited resources in the coming months and years, much of the success of state efforts to strengthen public health infrastructure will depend on federal investments. These investments are important in both amount and type.

State and local health agencies will need considerable support to maintain core public health activities: detecting and investigating cases, identifying underlying causes and etiologies, assessing the needs of vulnerable communities, communicating with the public, collecting data and developing comprehensive plans with stakeholders to enact actions for mitigation, preparedness, response, and recovery. Also important is the type of funding provided. The AMA supports flexible funding in public health for unexpected infectious diseases to improve timely response to emerging outbreaks and build public health infrastructure at the local level with attention to medically underserved areas. Existing block grant programs are often accompanied by rigid requirements on the use of the funds that are designated only for specific tasks related to a targeted condition or disease. States lack flexibility needed to redistribute resources to respond to changing circumstances. The siloed nature of public health grant funding also hampers states' ability to invest in basic infrastructure, particularly an adequate and well-trained workforce. These functions require sustained and broad-based funding that current programs often do not support.

**DIGITAL CONTACT TRACING EFFORTS REQUIRE ATTENTION TO PRIVACY AND TRANSPARENCY TO PROMOTE TRUST**

Throughout the pandemic, public and private entities have explored the use of tools such as smart phone apps and Bluetooth as a way collect, use, and disseminate public health surveillance data. These efforts are critical, but they have fallen short in addressing questions about how best to handle data both during collection and once the pandemic has subsided. A recent poll from The Washington Post and University of Maryland shows the American public has deep privacy concerns about using the tech-enabled COVID-19 tracking and tracing systems that could help limit the pandemic's deadly toll.<sup>19</sup> In short, people do not have confidence that their information will be handled appropriately by technology companies. There is growing awareness of how companies monetize individuals' health and other personal information. Social media platforms, Internet search engines, wearable fitness trackers, and applications (apps) to manage pregnancy and mental health all pool personal data, turning it into a valuable commodity. Individuals are also beginning to access their medical records using apps—an activity the AMA supports. However, apps that help individuals access their records can also market that information to data brokers that collect

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<sup>19</sup> Timberg, C. et al. "Most Americans are not willing or able to use an app tracking coronavirus infections. That's a problem for Big Tech's plan to slow the pandemic." *The Washington Post*. April 29, 2020. Available at <https://www.washingtonpost.com/technology/2020/04/29/most-americans-are-not-willing-or-able-use-an-app-tracking-coronavirus-infections-thats-problem-big-techs-plan-slow-pandemic/>.

large sets of data about patients and their families. Data mining by insurers and employers leads to the creation of health or “risk” scores, which can result in harmful profiling and discrimination.

Patients’ confidence in the privacy and security of their data has been shaken by repeated technology sector scandals and the wired economy’s default business model that quietly gathers intimate glimpses into private lives—often without patient knowledge, consent, or trust. As a result, patients may be less willing to share information with physicians for fear that technology companies and data brokers will have full authority over the use of their indelible health data. A 2019 [study](#) by Rock Health and Stanford’s Center for Digital Health shows people have become more reticent when it comes to sharing their health data. Out of all health care stakeholders, people were most willing to share their health data with physicians, but that sentiment has slipped since 2017. People were least willing to share their health data with technology companies whose business models and technical capabilities are reliant on it.

We must always strive to avoid putting patients in the untenable position of deciding whether to share relevant information with their physicians or public health authorities for fear that it will eventually be used against them by third parties. **Without clear guardrails for data use, public trust may crumble in the face of repeated privacy scandals and may undermine the potential for digital health to facilitate an era of more accessible, coordinated, and personalized care.** Rather than viewing guardrails around data use as an inhibitor to data exchange, guardrails help to build trust. They create rules of the road to promote individuals’ confidence in our institutions. Above all, patients must feel confident that their health information will remain private.

Critical privacy and transparency considerations must guide policy and implementation of digital contact tracing tools.

For this reason, the AMA created a set of [Privacy Principles](#) to guide Congress, the Administration, and industry stakeholders as they address growing concerns around data privacy. The AMA’s Privacy Principles provide guidance on what any federal privacy framework should include—namely (1) individual rights; (2) equity; (3) entity responsibility; (4) applicability; and (5) enforcement mechanisms. They also take into consideration that some data historically not considered “personal” may in fact be personally identifiable (e.g., IP addresses, advertising identifiers from mobile phones). Accordingly, the Privacy Principles’ use of the term “data” includes information that can be used to identify an individual, even if it is not descriptive on its face. The more assurances people have about how entities will use and exchange data, the more willing society will be to use technologies such as telehealth and public health contact tracing apps. **Specifically, we encourage incorporation of the following privacy protections in any digital technologies used in disease surveillance:**

- Individuals have the right to control how entities access, use, process, and disclose their data, including secondary (and beyond) uses. Accordingly, an entity must disclose to individuals exactly what data elements it is collecting and the purpose for its collection. Such information should not be used for a materially different purpose than those disclosed in the notice at the point of collection of such information. For example, an entity that collects location data to provide weather should not use that data for advertising. Entities should only collect the minimum amount of information needed for a particular purpose, in accordance with regulation and/or federal guidance. For example, a weather app may need general location data (e.g., zip code), but not precise location data (e.g., GPS coordinates). Entities should also make their de-identification processes and techniques publicly available.

- An entity should be required to disclose to an individual specifically with whom it is sharing the individual's data. In all circumstances, disclosures of an individual's data should be limited to that information necessary to fulfill the immediate and specific purpose of disclosure. Furthermore, employers and insurers should be barred from unconsented access to identifiable medical information to assure that knowledge of sensitive facts does not form the basis of adverse decisions against individuals, such as non-coverage of stigmatized health conditions. Individuals should also have the right to know whether their data will be used to develop and/or train machines or algorithms; moreover, the opportunity to participate in data collection for these purposes must be on an opt-in basis.
- Privacy protections should promote equity and justice. For example, individuals should be protected from discrimination, stigmatization, discriminatory profiling, and exploitation occurring during collection and processing of data, and resulting from use and sharing of data, with particular attention paid to underserved communities. Similarly, individuals should be protected from discrimination, stigmatization, profiling, and exploitation based on inferences drawn from a refusal to use or cessation of use of an app or digital health tool. Additionally, privacy policies should be written to promote understanding by individuals with elementary school levels of reading comprehension. Terms should be clearly defined and unambiguous. For example, statements such as, "We may share this data with our partners to improve quality" are vague and should not be permitted. Entities should also be prohibited from using health data to discriminate against individuals, including creation of "risk scores" that could hinder patients and their families from receiving health, disability, or life insurance; housing; employment; or access to other social services.

Importantly, these types of considerations do not prevent exchange of information for public health purposes, including between health care providers and public health authorities. Rather, they aim to prevent third parties like data brokers and technology developers from collecting and sharing information for purposes that they do not communicate to individuals. For example, an app might collect health information, saying it is for public health purposes, but then use that information also for advertising and risk scores. **It is critical that public health authorities and health care providers—not technology developers, data brokers, or information exchange platforms—be responsible for determining what information is necessary for public health purposes.**

Data segmentation functionality in technology promotes information sharing.

Relatedly, **we urge policymakers to consider in a new light the importance of technology that can segment and exchange data on a granular level.** Such capabilities would better enable data holders—whether they are clinicians, technology platforms, or HIEs—to share data critically needed by public health officials without sharing more of an individual's personal information than is necessary. The AMA is aware that some entities felt constrained in their ability to share information by perceived barriers related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We believe those barriers are not due to HIPAA but rather limitations in technology. Covered entities generally may share protected health information with public health authorities authorized by law to collect or receive such information to prevent or control disease and covered entities may rely on representations from a public health authority that the requested information is the minimum necessary. However, if a platform can only send information on an "all or nothing" basis, they may decide to send nothing. The solution here is not to change the law, but rather to change what we demand of our technology—that is, the ability to send pieces of information rather than an entire data set.

The need for data segmentation is important as data are increasingly generated outside of the clinical setting, and can help ease burden associated with using and disclosing multiple types of sensitive data such as substance use disorder, HIV or other sexually transmitted disease status, genetic information, minors' health information, and reproductive health information. While we recognize that segmentation efforts do not seem to have been prioritized by developers, such technology currently exists, as recognized by ONC's Draft Report to Congress (Draft Report) on reducing regulatory and administrative burden relating to the use of health IT and EHRs:

“[With respect to difficulty implementing Part 2 and integrating such information into EHRs,] HHS has recognized these implementation challenges and encourages the use of health IT to help clinicians appropriately share sensitive information while complying with legal requirements and respecting patient privacy preferences. For example, technical standards exist for electronically tagging health information to indicate privacy considerations, including legal requirements, within a patient record or summary of care document within the EHR, and SAMHSA supports ONC's Data Segmentation for Privacy initiative [DS4P] to support clinicians sharing of health information in accordance with patient choices. These tags on data elements, segments, or whole documents can then be used by automated access control solutions to prevent unauthorized access to patient data.”<sup>20</sup>

ONC recommended in its Draft Report that HHS monitor, test, and support development of technical standards for data tagging and segmentation. We wholeheartedly agree with this recommendation, and strongly urge Congress to demonstrate its commitment to greater interoperability and privacy protections by prioritizing data segmentation in development, testing, and policymaking. We note that while technology exists to tag and segregate data and software can help to electronically manage patient consent (e.g., Consent2Share), we have heard from physicians and health systems that such segregation functionality is costly to implement, and that open-source consent management software can be prohibitively expensive to incorporate into a customized EHR.

We urge Congress to recognize the pressing need for data segmentation to be made accessible and affordable. Such capabilities will not only enhance interoperability and improve care coordination and patient outcomes, but also will help in situations like pandemics where sharing of some information—but not the entire medical record—is critical to stopping the spread of disease. Furthermore, such data segmentation capabilities would help stakeholders navigate variability in state privacy laws. **Congress and HHS should reject the approach of legislating and regulating around these problems and instead focus on developing data segmentation standards and software, while ensuring that such technology is widely available and affordable.**

## **EXPAND ACCESS TO AND COVERAGE OF TELEHEALTH SERVICES**

The AMA agrees with the initial recommendation 4.2 that it is imperative for the United States to continue to expand access to and provide coverage for telehealth services. Telehealth services have emerged as a critical tool during the COVID-19 pandemic to provide care to patients while supporting

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<sup>20</sup> *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, available at <https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf>, p. 44.

physical distancing efforts and reducing the spread of **SARS-CoV-2 and other** infectious diseases by avoiding unnecessary outpatient visits.

The AMA continues to hear success stories from patients and physicians who see the expansion of telehealth as a positive step for health care delivery. Telehealth technologies allow health care providers to increase continuity of care, extend access beyond normal clinic hours, and help overcome clinician shortages, especially in rural and other underserved populations, which ultimately helps health systems and physician practices focus more on chronic disease management, enhance patient wellness, improve efficiency, provide higher quality of care, and increase patient satisfaction. It has also emerged as a critical tool during the COVID-19 pandemic because it helps support physical distancing efforts and reduce the spread of infectious diseases while still providing care to those who need it. For example, individuals with serious chronic medical conditions, such as diabetes, chronic lung disease, and moderate/severe asthma, are at a higher risk of experiencing serious complications from COVID-19 but still need regular contact with their health care provider.<sup>21, 22</sup> These individuals are benefiting from the ability to mitigate their risk of becoming infected from the virus, by avoiding traditional outpatient visits when possible, especially in crowded hospitals, and instead access telehealth services from the privacy and safety of their homes.

The expansion of telehealth services as a result of the pandemic is also positively impacting a wider swath of people who now have the ability to utilize telecommunication technology to access their providers without having to navigate accessing public transportation in densely populated urban communities, time off from work spent commuting to/from the appointment, or driving lengthy distances in rural areas to attend an outpatient office visit with a specialist. Physicians are touting the expansion of telehealth as a positive step for health care delivery due to increased provider/patient communication, greater provider/patient trust, and access to real-time information related to a patient's social determinants of health (i.e., a patient's physical living environment, economic stability, or food insecurity); which can lead to better health outcomes and reduced care costs

**The success of telehealth technology adoption during the COVID-19 public health emergency has made it abundantly clear that these technologies should be available to patients and covered by their medical plan after the public health emergency ends and available in the event of another pandemic.** Physicians and patients have seen the value of telehealth services and should not be forced to stop using these tools when the public health emergency ends.

As detailed below, the AMA strongly supports all efforts to increase, maintain, and expand patient's access to telehealth services and offers several recommendations below.

Permanently fix the geographic and site of service restrictions on audio-visual technologies and create equal access for all Medicare beneficiaries to all covered telehealth services.

Currently, under 1834(m) of the Social Security Act (SSA) (42 U.S.C. 1395m(m)), Medicare is prohibited from covering and paying for telehealth services delivered via two-way audio-visual technology unless it is provided at an eligible site in a rural area. The home is not considered an eligible originating site, except in a few instances where Congress has acted to authorize telehealth to the home for specific services. As a result, the 1834(m) restrictions essentially bar Medicare beneficiaries from using widely

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<sup>21</sup> <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html>

<sup>22</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/asthma.html>

available two-way audio-visual technologies to access covered telehealth services unless they live in a rural area, and, with a few exceptions, even those in rural areas must travel to an eligible health care site.

Two-way audio-visual services are the only communication modality that Medicare places such a prohibition on. Audio-only phone, remote patient monitoring, text and other communication technologies do not meet the definition of a telehealth technology and services furnished via these technologies are not subject to the 1834(m) geographic and originating site restrictions and go through regular Medicare coverage and payment processes. Moreover, the Medicare Fee for Service Program is the only program without a waiver for 1834(m) in place. Congress has already provided 1834(m) waiver authority to the Medicare Advantage (MA) plans, Capability Maturity Model Integration (CMMI), and for Medicare-Medicaid dual eligibles through Sec. 1116 waivers. This has resulted in a patchwork of coverage with inequitable access to telehealth services for beneficiaries based on their geographic location and what part of the Medicare program they are participating in. These arbitrary decisions have created an inequitable status quo where coverage and payment are inconsistent for different beneficiaries across Medicare.

In response to the COVID-19 pandemic, Congress gave CMS the ability to waive the geographic origination requirement for the duration of the COVID-19 pandemic, allowing patients to receive telehealth services anywhere, including in their homes. Prior to the pandemic, patients were previously unable to receive care from their homes and instead were required to travel to an originating site such as a clinic or hospital. As a result of CMS' waiver, Medicare beneficiaries have been able to access telehealth services broadly for the first time ever and have come to rely on them in difficult circumstances.

The AMA commends Congress for granting the Secretary of HHS temporary authority to waive the arbitrary geographic and site of service restrictions on audio-visual technologies in response to the coronavirus pandemic. The current waiver authority will terminate abruptly when the national public health emergency declaration for COVID-19 ends. **The AMA strongly recommends that Congress permanently fix the geographic and site of service restrictions on audio-visual technologies to allow Medicare to cover and pay for telehealth services to beneficiaries anywhere in the country and to any site, including to the home.**

Require ERISA plans to cover telehealth services during a declared public health emergency.

Telehealth has become a vital option for many during the COVID-19 pandemic and will continue to be a necessary option for patients and health care providers to reduce the number of patients who need to come into a health care facility or hospital during a future pandemic. However, the ability to access needed care through telemedicine will remain limited for many patients without a legislative mandate for health plans regulated by the Employee Retirement Income Security Act of 1974 (ERISA) to cover telehealth services.

Limited access and a lack of uniformity remain among plans governed by ERISA. This leaves physicians and other health care providers unsure of whom, and under what conditions, they are permitted to provide medical services via telehealth. For example, health plans frequently have separate telehealth networks that may not include physicians who normally provide in-person care. In this situation, physicians may not be given the option to continue seeing their patients via telehealth. In other instances, the plan's credentialing process to allow physicians to provide telehealth services is slow and cumbersome, leading to a long delay in much needed care. Moreover, some plans are requiring physicians to sign up with a specific telemedicine company to provide services or incentivizing or directing patients to a select telehealth provider for care, rather than the patient's normal physician. This has led to a disruption in

continuity of care and created additional anxiety and confusion for patients during an already stressful time.

Similar to the guidelines provided by Medicare, it is of the utmost importance that telehealth coverage is expanded to ERISA plans. **Congress should pass legislation requiring that services provided via telehealth be paid at the same rate as in-person services during a declared public health emergency, allowing for the use of expanded modalities for the provision of telehealth to include telephone visits in addition to common audio-video technology, and enabling physicians to offer telehealth services to new and established patients.** These changes will make it possible for ERISA plan patients to access the care they need without having to increase their risk of exposure by traveling to their physician's office or a hospital during the COVID-19 pandemic and future public health emergencies.

Congress should not create artificial barriers to telehealth by defining an established doctor-patient relationship inconsistently with the standard of care or creating unique and burdensome fraud and abuse requirements.

AMA policy, established in 2014, states that a valid physician-patient relationship may be established virtually face-to-face via real-time audio and video technology, if appropriate for the service being furnished. It also allows for the relationship to be established in a variety of other ways such as meeting standards of care set by a major specialty society. All 50 states and the territories allow a physician-patient relationship to be established virtually or through other means. The exact parameters vary by states, however, many state laws are based on an AMA model law. **Congress should not impose a one-size-fits-all requirement on services furnished via telehealth technology that are in direct conflict with standards of care and that do not exist for other technologies.**

**Congress should also refrain from imposing new and discriminatory restrictions on the use of audio-visual communications technologies.** All the normal Medicare coverage and payment and fraud and abuse authorities apply to telehealth services just as they do any other Medicare covered service. Additional restrictions do not currently apply under the MA, CMMI, Sec. 1116 waiver authorities, the existing Medicare telehealth coverage authority or other technologies such as phone, text or remote patient monitoring.

Gains made in access to telehealth will be greatly hampered if unique and arbitrary barriers are erected around the use of telehealth services. Such barriers will have dramatic and negative impact on patients seeking care, particularly during the current COVID-19 pandemic and in any future pandemic where patients need access to care without visiting a crowded health care facility.

States must continue to play a central role in licensing physicians.

State medical boards play a pivotal role in protecting the safety of patients through physician licensure, regulations and disciplinary action. At the start of the COVID-19 pandemic, there was some concern that state licensing requirements would limit physicians' ability to quickly move into those areas hardest hit by COVID-19 and meet the workforce demands on the ground and via telehealth. In response to this concern, the states acted quickly to temporarily allow physicians to practice across state lines by waiving licensure or creating a streamlined licensure or registration processes in response to the COVID-19 emergency.

AMA opposes proposals to change which state is responsible for overseeing the physician from the state where the patient is located to the state where the physician is located. This changes what state practice and scope laws apply to the care rendered and raises serious enforcement issues as states do not have interstate policing authority and cannot investigate crimes that happen in another state. This is inconsistent with AMA policy.

**Instead, AMA believes efforts should be made to increase membership in the Interstate Medical Licensure Compact (IMLC), a one stop-shop for providers who are in good standing with their state medical boards to seek a license to practice in multiple jurisdictions in an expedited process.** This maintains state-based licensure and the ability of state medical boards to protect the safety of patients, while allowing for greater sharing of information between states and expediting the licensure process for physicians who want to move states or practice in more than one jurisdiction.

Congress should act to further expand broadband infrastructure and access to telehealth services to reduce health disparities.

AMA applauds recent action by Congress and FCC to fund and create the Connected Care Pilot and the COVID-19 Telehealth Program. These grant programs help providers purchase necessary services and equipment in order to provide telehealth services to underserved populations and in areas that have been hit especially hard by the COVID-19 pandemic. Efforts like these are essential to ensure patients can maintain needed access to health care regardless of where they are and allow for physicians to provide care without asking vulnerable patient populations to come into a crowded setting.

AMA strongly supports bipartisan calls to expand broadband infrastructure to address inequities, including improving access to health care via telehealth. Congress should continue to build upon these programs to ensure equitable access to broadband and telehealth services for all patients and communities.

## **LIABILITY PROTECTIONS FOR PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS DURING A DECLARED PUBLIC HEALTH EMERGENCY**

The COVID-19 pandemic created a public health emergency that is rapidly altering the provision of health care services across the country based on guidance and recommendations from federal, state, and local government directives. During this unprecedented national health emergency, physicians and other health care professionals have been putting themselves at risk every day while facing shortages of medical supplies and safety equipment, and making critical medical decisions based on changing directives and guidance at the federal, state, and local levels. These physicians and other health care professionals are now facing the threat of years of costly litigation due to the extraordinary circumstances. Although necessary, these measures have raised serious concerns about the potential liability of physicians and other health care professionals who are responding to the pandemic and continue to provide high-quality patient care while adhering to such guidance and recommendations. Examples of increased liability risk facing physicians and other health care professionals include the following:

- Suspension or cancelation of elective in-person visits and replacing them with virtual visits;
- Providing treatments or care outside their general practice areas and for which they may not have the most up-to-date knowledge;

- Coming out of retirement to alleviate workforce shortages related to the growing health crisis caused by the COVID-19 pandemic;
- Inadequate supplies of safety equipment that could result in the transmission of the virus from patient to physician and then to additional patients, or directly from one patient to another;
- Shortages of equipment, such as ventilators, that can force facilities and physicians to ration care;
- Inadequate testing that could lead to delayed or inaccurate diagnosis; and
- Delays in treatment for patients with conditions other than COVID-19.

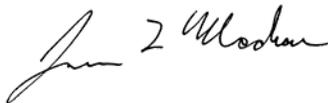
In these and other scenarios, physicians and other health care professionals face the threat of costly and emotionally draining medical liability lawsuits due to circumstances that are beyond their control. These lawsuits may come months or even years after the public health emergency is over.

Many of the same issues affecting physicians and other health care professionals during the COVID-19 issues could repeat themselves in a future pandemic or other public health emergency. **Therefore, we recommend that Congress provide targeted liability protection for physicians and other health care professionals, and the facilities in which they practice, during a declared public health emergency.** Specifically, these liability protections should cover physicians and other health care professionals, and the facilities in which they practice, who provide care in good faith during a public health emergency (plus a reasonable time, such as 60 days, after an emergency declaration ends), and not in situations of gross negligence or willful misconduct.

Physicians and other health care professionals have provided truly heroic efforts during the COVID-19 pandemic and will be called on to do so in future public health emergencies. Congress should ensure they can do their job in the face of extremely difficult circumstances and protect the lives of Americans without fear of future unwarranted lawsuits.

The AMA appreciates the opportunity to provide recommendations on how to improve public health preparedness for the next pandemic and we look forward to working with Congress and other stakeholders on this important work.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD