

July 1, 2020

The Honorable James E. Clyburn
Chairman
U.S. Capitol
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Steve Scalise
Ranking Member
U.S. Capitol
2105 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Clyburn and Ranking Member Scalise:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments to the U.S. House of Representatives Select Subcommittee on the Coronavirus Crisis. The AMA has serious and ongoing concerns about the availability of personal protective equipment (PPE) for both frontline health care providers who provide direct care to COVID-19 patients and physician practices re-opening their practices after extended closures. Through the course of the COVID-19 pandemic, we have seen serious issues in the acquisition and distribution of PPE, with little transparency provided around the supply chain and distribution strategies, a lack of clear national strategy for acquisition and distribution of this critical equipment, and confusion between federal, state and local officials. While it appears that domestic production has increased to help lessen the burden of PPE shortages felt by hospitals and health systems, we are still struggling to help ambulatory care sites locate PPE to protect physicians and staff as they move towards once again offering non-emergent, non-COVID care that has been put on hold for several weeks.

As we are still in the middle of a critical time in this global public health crisis, we still have many lessons still to learn about how to best manage critical resources. However, the AMA has identified some recommendations that may help mitigate PPE acquisition and distribution issues throughout the duration of the COVID-19 pandemic or may prove useful as our health care system creates plans for dealing with subsequent public health emergencies. These recommendations were also recently provided to the Chairman of the Senate Health, Education, Labor & Pensions Committee as part of his recent call for input on pandemic preparedness.

AMA Recommendations for Managing Critical PPE Resources During Public Health Emergencies

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 when 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 no 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 contacts 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 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 was also attempting to purchase large quantities of PPE and other items to distribute. The AMA is 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 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.

Funding for the strategic national stockpile has decreased precipitously since 2003.¹ Moreover, funding and stockpile planning were inadequate to meet the demands of a nationwide extended epidemic.² 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.³ 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 (SNS), 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,

¹ 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>.

² 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>.

³ 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>.

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possibly in conjunction with the National Institute for Occupational Health and Safety in developing permanent guidelines for PPE use.

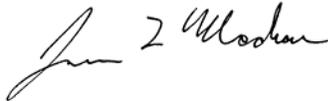
Strong measures must be in place to restrict price gouging during a public health emergency and limit counterfeit PPE and infection control products from coming to market in the U.S.

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 governments, physician practices, hospitals or health systems can ensure that the products they are purchasing meet safety standards and are not counterfeit goods.**

While many lessons have been learned through the first few months of the current COVID-19 pandemic, many more are likely to be learned as we continue to move through efforts to mitigate the spread of this deadly disease. We look forward to continuing to work with members of the Select Committee to address these critical issues and ensure the health and safety of our nation's health care workforce and their patients.

Sincerely,

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

James L. Madara, MD