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March 13, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

On behalf of the Board of Trustees of the American Medical Association and our physician and medical student members, I am writing to express the urgent need to work together to find solutions to the mounting problems the nation is facing with the novel coronavirus (COVID-19). The AMA is in an ongoing dialogue with various arms of the U.S. Department of Health and Human Services (HHS) and we want to continue to work with HHS on constructive solutions to the pandemic that the nation and the world are confronting. The AMA urges HHS and its agencies to be as creative and flexible as possible with regulatory barriers when identifying and crafting solutions. Furthermore, while HHS and its many agencies are posting a great deal of information about COVID-19, confusion still exists among the public and physicians. The AMA urges HHS to be as clear and transparent as possible with the information.

The AMA continues to hear deep concerns from physicians about their ability to test their patients for SARS-CoV-2. We are very pleased to see the Administration's increased focus on ensuring access to testing services and applaud the appointment of Assistant Secretary for Health, ADM Brett Giroir, to coordinate the Administration's work on this critical issue.

We appreciate that the Food and Drug Administration (FDA) has exercised increased flexibility in the issuance of the Emergency Use Authorizations (EUA) for laboratories developing tests for SARS-CoV-2 with the February 29th policy guidance. That said, the AMA urges FDA to consider what, if any, additional flexibilities they may be able to extend to help ensure an adequate number of SARS-CoV-2 tests are available. For example, if appropriate, we urge the agency to consider additional appropriate flexibilities in issuing EUAs for any in-vitro diagnostics that could help increase testing capacity.

The AMA also continues to hear that physicians are not adequately informed about where to turn for testing services. We urge FDA and/or the Centers for Disease Control and Prevention (CDC) to make public as much information as possible regarding access to SARS-CoV-2 testing services, potentially including the laboratories authorized to perform this testing. Providing this information could help to alleviate the confusion and concern among our physician members and the general public.

Furthermore, we are continuing to hear from physicians, as well as laboratories, that significant confusion remains with regards to testing protocol. We strongly urge HHS to provide further clarity around testing criteria and work with stakeholders, including state and local health departments, in these communities to eliminate misunderstandings around testing protocol and prioritization.

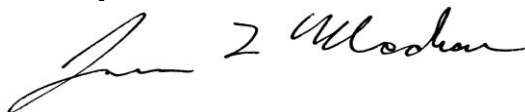
Physicians are also expressing concern about access to personal protective equipment (PPE). Many physicians are contacting their state and local health departments for PPE who in turn are sending them to their professional associations. We urge HHS to identify for physicians where they can turn to in their local areas to access needed PPE. If HHS anticipates that there will be a shortage of PPE, the AMA urges HHS to have a dialogue with the physician community sooner rather than later.

We know that the Centers for Medicare & Medicaid Services (CMS) is drafting program instruction/guidance implementing the new telehealth provision of H.R. 6074, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. The AMA has made a series of recommendations to CMS about the guidance. Again, the AMA urges HHS and CMS to be as flexible as possible when drafting the guidance. No one knows where this epidemic will head. Prior to its passage the AMA spoke to many congressional members and staff about the bill and understand that the intent was for CMS to have broad implementation authority.

The COVID-19 outbreak underscores the need for Medicare to provide better coverage for telephone visits with patients than is available currently. Physicians are deeply concerned about the possibility of the infection spreading from COVID-19 patients to healthy patients as well as health professionals and practice staff. Considering the COVID-19 risk to patients of Medicare age, as well as the potential of affecting the health care workforce needed to care for individuals with the highest risk, we support recommendations from the White House Coronavirus Task Force that patients stay at home even in communities with minimal-to-moderate COVID-19 impact, and we urge CMS to take this important step to expand coverage to these services.

The AMA recognizes as these issues get addressed others may emerge. We stand ready to work with you and your colleagues throughout HHS to address this latest and unprecedented public health threat. If you or your staff have any questions, please contact Margaret Garikes, the AMA's Vice President of Federal Affairs, at Margaret.Garikes@ama-assn.org or 202-789-7409.

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