

April 22, 2020

ADM Brett P. Giroir, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue SW
Room 715-G
Washington, DC 20201

Re: Federal authorization for dentists to conduct point of care testing for COVID-19

Dear Dr. Giroir:

The undersigned organizations respectfully ask your office to use its discretionary authority during public health emergencies to extend federal authorization for licensed dentists to conduct Food and Drug Administration (FDA) authorized point-of-care testing for novel coronavirus (COVID-19).¹ This authorization is critical in light of the FDA's decision to allow clinical laboratories and commercial manufacturers to put COVID-19 diagnostic tests on the market prior to receiving FDA approval.²

Dentists are doing their part to help mitigate the spread of COVID-19. Dentists are now mainly performing only urgent and emergency dental procedures for patients who would otherwise seek care in hospital emergency departments. Dentists are also screening every visitor and patient for COVID-19 symptoms, as recommended by Centers for Disease Control and Prevention (CDC), and referring symptomatic patients for appropriate medical care.

According to the Occupational Safety and Health Administration (OSHA), dental personnel have a very high risk of exposure to infected but asymptomatic patients.³ Questions also remain about whether individuals who have recovered from a COVID-19 infection are susceptible to reinfection. Front end testing is therefore key to protecting dental patients, staff, and the communities in which they live and serve.

In many states, licensed dentists can already conduct COVID-19 point of care testing within their scope of practice. As with all clinicians, a Certificate of Waiver from the Centers for Medicare and Medicaid Services (CMS) is needed,⁴ and some states may have additional requirements.

Unfortunately, there is a nationwide shortage of COVID-19 testing kits in the United States. To address the shortage, the FDA authorized clinical laboratories and commercial manufacturers to put COVID-19 diagnostic tests on the market prior to receiving FDA approval. Though well intentioned, many health professionals are questioning whether these unregulated gray market tests are reliable. A false negative for an infected but asymptomatic could prove harmful, and possibly deadly, to patients and providers both.

We recognize that COVID-19 testing kits are currently scarce—and agree that they should be available when and where they are most needed (e.g., hospital emergency departments, etc.). It is worth noting, however, that there is an opportunity to alleviate the testing burden on hospital emergency departments—by testing the more than 27 million people who visit a dentist every year, but not a physician.⁵ Every one of those dental encounters is an opportunity to screen patients for COVID-19.

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Given the very high risk of COVID-19 exposure in dental settings—and the value of keeping uninfected dental patients away from hospital emergency rooms—we urge you to use your discretionary authority to extend federal authorization for licensed dentists to conduct FDA-authorized point-of-care testing for COVID-19. Doing so will reduce the need for dental patients to seek out other testing sites, except for appropriate medical referrals when indicated.

Thank you for considering our request. We applaud your leadership on this issue and hope the COVID-19 pandemic will soon be under control. If you have any questions, please contact Mr. Robert J. Burns at the American Dental Association. Bob can be reached at 202-789-5176 or burnsr@ada.org.

Sincerely,

American Dental Association
Academy of General Dentistry
American Academy of Dental Group Practice
American Academy of Oral and Maxillofacial Pathology
American Academy of Oral and Maxillofacial Radiology
American Academy of Pediatric Dentistry
American Academy of Periodontology
American Association of Endodontists
American Association of Oral and Maxillofacial Surgeons
American Association of Women Dentists
American College of Prosthodontists
American Dental Education Association
American Society of Dentist Anesthesiologists
American Student Dental Association

¹ 42 U.S.C. 247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures.

² 85 FR 13169 (March 6, 2020).

³ U.S. Department of Labor, Occupational Safety and Health Administration, Guidance on Preparing Workplaces for COVID-19 (2020).

⁴ 42 U.S.C. 263a. Certification of laboratories.

⁵ American Dental Association, Screening for Chronic Diseases in the Dental Office (2020).