



STATE OF IOWA

IOWA DENTAL BOARD

KIM REYNOLDS, GOVERNOR
ADAM GREGG, LT. GOVERNOR

JILL STUECKER
EXECUTIVE DIRECTOR

IOWA DENTAL BOARD MEETING AGENDA

April 24, 2020

The mission of the Iowa Dental Board is to ensure that all Iowans receive professional, competent, and safe dental care of the highest quality.

Meeting Location: The open session portion of this meeting will held via Cisco Webex. Board offices are not currently open due to COVID-19. To access the meeting, see details below:

Click here to [join the Webex meeting](#)

Meeting ID: 625 329 484

Password: eJvfS5RTm64 (35837578 from phones)

Call Line for Phone Access: 408-418-9388 (Access code: 625 329 484)

Board Members: *Will McBride, D.D.S.; Monica Foley, D.D.S.; Michael Davidson, D.D.S; Lisa Holst, D.D.S.; Gregory Ceraso, D.D.S.; Mary Kelly, R.D.H.; Nancy Slach, R.D.H.; Lori Elmitt, Public Member; Bruce Thorsen, Public Member*

BOARD MEETING:

OPEN SESSION: 8:30 AM

- I. CALL MEETING TO ORDER – ROLL CALL**
- II. OPPORTUNITY FOR PUBLIC COMMENT**
- III. OTHER BUSINESS**
 - a. Discussion on Re-Opening of Dental Offices
 - b. Discussion on AGD and ADA Letter Regarding COVID-19 Testing in Dental Offices
 - c. Discussion and Report from Dental Hygiene Committee
 - d. Discussion on Options for Dental and Dental Hygiene Students Unable to Take the Required Clinical Exam for Licensure

- e. Discussion of Request to Reduce Continuing Education Hours for 2020 Renewal Period

IV. ADJOURN

NEXT REGULARLY-SCHEDULED MEETING: JUNE 5, 2020

Please Note: At the discretion of the Board Chair, agenda items may be taken out of order to accommodate scheduling requests of Board members, presenters or attendees or to facilitate meeting efficiency.

If you require the assistance of auxiliary aids or services to participate in or attend the meeting because of a disability, please call the office of the Board at 515-281-5157.

147.34 Examinations.

1. Each board shall by rule prescribe the examination or examinations required for licensure for the profession and the manner in which an applicant shall complete the examination process. A board may develop and administer the examination, may designate a national, uniform, or other examination as the prescribed examination, or may contract for such services. Dentists shall pass an examination approved by a majority of the dentist members of the dental board.

2. When a board administers an examination, the board shall provide adequate public notice of the time and place of the examination to allow candidates to comply with the provisions of this subtitle. Administration of examinations, including location, frequency, and reexamination, may be determined by the board.

3. Applicants who fail the examination once shall be allowed to take the examination at the next authorized time. Thereafter, applicants shall be allowed to take the examination at the discretion of the board. An applicant who has failed an examination may request in writing information from the board concerning the examination grade and subject areas or questions which the applicant failed to answer correctly, except that if the board prescribes a national or uniform examination, the board shall only be required to provide the examination grade and such other information concerning the applicant's examination results which are available to the board.

[C97, §2576, 2582, 2589, 2597; S13, §2575-a29, -a37, 2576, 2582, 2583-a, -i, -k, 2589-a, 2600-c, -d; SS15, §2589-a; C24, 27, 31, 35, 39, §2471, 2567, 2572, 2573; C46, 50, 54, 58, 62, 66, §147.34, 153.3, 153.8, 153.9; C71, 73, §147.34, 153.2, 153.6, 153.8; C75, 77, 79, 81, §147.34]

94 Acts, ch 1132, §17; 96 Acts, ch 1036, §14; 98 Acts, ch 1053, §12; 2007 Acts, ch 10, §45; 2008 Acts, ch 1088, §21

Referred to in §153.21, 155.3, 156.4



560 W. Lake St. 312.440.4300
Sixth Floor Fax: 312.440.0559
Chicago, IL USA Toll-free: 888.243.3368
60661-6600 agd.org

April 15, 2020

Dear Governors and State Dental and Health Boards,

The Academy of General Dentistry (AGD) is engaged in developing guidance for its members in preparation of reopening dental practices to non-urgent care once executive order restrictions are lifted. We are committed to working with all stakeholders to plan a strategic, science-based approach to patient delivery in the days to come. Dentistry has a strong record of leading in infection control, as it did during the HIV/AIDS crisis.

Until there is a vaccine for COVID-19, dental practices will need to continue to focus on identifying non-contagious patients and non-urgent procedures for the safety of patients and staff. State legislators, federal agencies, and regulators will be important partners in assuring that any interim or final state regulations do not create unnecessary barriers and that regulatory agencies work in partnership with dental practices.

Authorizing licensed dentists to obtain and administer FDA-approved and emergency use authorization point-of-care COVID-19 tests is critical to allowing resumption of dental care for noninfectious patients. The AGD has asked the U.S. Department of Health and Human Services (DHHS) to issue guidance under the Public Readiness and Emergency Preparedness Act granting this, as it has for pharmacists. Challenges with CLIA requirements and scope of practice issues must be rectified to allow testing for pharmacists as well as dentists without undue administrative burdens.

The AGD is requesting that state dental boards proactively review their dental practice acts to determine whether administering diagnostic (molecular) and/or a serological COVID-19 tests are currently permissible within the scope of practice and, if necessary, to make changes to ensure that it is permissible. Working with CDC, NIOSH, NIH, FDA, and OSHA, AGD leadership will add valuable insight into best practices to ensure a safe environment for providers, staff, and patients. Once the DHHS issues guidance, the dental board will then be in a position to provide clear direction to licensees.

The AGD requests states consider broadening the scope of their prescription drug monitoring programs (PDMPs) database to include results of COVID-19 tests performed at pharmacies. If patients consented for results to be included in the database and accessed only by treating providers, it would be a mechanism for dentists to obtain the patient's status and would support point-of-care testing. Whatever the method or location of testing, health care providers must be able to obtain access to the database containing patient results in order to determine the infected and/or immune status at time of treatment. AGD awaits CDC guidance in the testing arena to best utilize scientific evidence in the safe treatment of patients.

Thank you very much for your consideration. As states work to effectively combat the COVID-19 pandemic, the AGD is ready to assist in any way we can. If you have questions or would like to discuss further, please contact AGD Government Relations Manager, Michael Toner at michael.toner@agd.org.

Sincerely,

A handwritten signature in black ink that reads 'Connie L. White, DDS, FAGD'.

Connie L. White, DDS, FAGD

AGD President

April 17, 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: Guidance authorizing dentists to administer COVID-19 tests

Dear Dr. Giroir:

On behalf of our 163,000 members, we respectfully ask your office to issue federal recognition that licensed dentists may administer point of service tests authorized by the Food and Drug Administration (FDA) for novel coronavirus (COVID-19) under their existing scope of practice. Doing so would allow dentists to qualify as “covered persons” under the Public Readiness and Emergency Preparedness Act (PREP Act), which may extend protection from liability associated with the administration or use of FDA-authorized COVID-19 tests.

Dentistry is essential to the public’s health. Enabling dentists to test patients prior to dental treatment will help lower the “very high exposure risk” of dental personnel in contracting COVID-19 when treating infected but asymptomatic patients.¹ It would add a layer of safety for both dental personnel and the patients they treat. This is important not only now—when most dentists are performing only urgent and emergency dental procedures—but also as the nation cautiously reopens.

Moreover, front-end testing would enable dental offices to optimize their personal protective equipment (PPE). Optimizing the use of PPE is particularly important now, when PPE is scarce in all health care settings, including emergency departments.

For these reasons, we urge you to issue federal recognition for dentists to administer FDA-authorized COVID-19 diagnostic tests as soon as possible. We recognize that these testing kits are currently scarce. However, approving dentists to administer these tests now will expand the nation’s medical surge capacity, optimize the use of PPE in health care settings, and create a safer environment for treating dental patients who would otherwise seek care in overburdened emergency departments.

It is worth noting that every year more than 27 million people visit a dentist, but not a physician.² Federal guidance for dentists to administer FDA-authorized COVID-19 tests would help make every encounter an opportunity to test those individuals.

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 202-789-5176 or burnsr@ada.org.

Adm. Brett Giroir, M.D.
April 17, 2020
Page 2

Sincerely,

/s/

Chad P. Gehani, D.D.S.
President

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

CPG:KTO:rjb

¹ U.S. Department of Labor, Occupational Safety and Health Administration, Guidance on Preparing Workplaces for COVID-19 (2020).

² American Dental Association, Screening for Chronic Diseases in the Dental Office, 2020.

Important Information on the Use of Serological (Antibody) Tests for COVID-19 - Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) recommends that health care providers continue to use serological tests intended to detect antibodies to SARS-CoV-2 to help identify people who may have been exposed to the SARS-CoV-2 virus or have recovered from the COVID-19 infection. Health care providers should also be aware of the limitations of these tests and the risks to patients and the community if the test results are used as the sole basis to diagnose COVID-19.

The FDA is not aware of an antibody test that has been validated for diagnosis of SARS-CoV-2 infection. While the FDA remains open to receiving submissions for these tests for such uses, based on the underlying scientific principles of antibody tests, the FDA does not expect that an antibody test can be shown to definitively diagnose or exclude SARS-CoV-2 infection.

Recommendations

The FDA recommends health care providers:

- Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
- Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
- Be aware that not all marketed serological tests have been evaluated by the FDA. The FDA's authorized tests, including serological tests, are listed on the Emergency Use Authorization (EUA) page (</medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>). Tests being offered under a policy outlined in the FDA's COVID-19 Diagnostic Policy Guidance (</regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency>) are listed on our FAQ page (</medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>). Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.

Background

Serological tests detect antibodies present in the blood when the body is responding to a specific infection, like COVID-19. They detect the body's immune response to the infection caused by the virus rather than detecting the virus itself. Experience with other viruses suggests that individuals whose blood contains antibodies associated with SARS-CoV-2 infection—provided

they are recovered and not currently infected with the virus—may be able to resume work and other daily activities in society. They may also be eligible to serve as potential donors of convalescent plasma.

In the early days of an infection, when the body's immune response is still building, antibodies may not be present in detectable levels. This limits the test's effectiveness for diagnosing COVID-19 and is why it should not be used as the sole basis to diagnose COVID-19. Currently authorized serological tests for SARS-CoV-2 measure IgM and/or IgG antibodies. Since IgM antibodies may not develop early, or at all, in infected patients, this type of antibody test is not used to rule out SARS-CoV-2 in an individual. Since IgG antibodies generally do not develop until later, this type of antibody test, even though it is more specific to SARS-CoV-2, is not used to rule-out SARS-CoV-2 infection in an individual. We also do not know how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after the infection has been cleared.

While antibody tests by themselves are of limited value in the immediate diagnosis of a patient where COVID-19 infection is suspected, using this type of test on many patients may help the medical community better understand how the immune response against the SARS-CoV-2 virus develops in patients over time and how many people may have been infected. While there is a lot of uncertainty with this new virus, it is also possible that, over time, broad use of antibody tests and clinical follow-up will provide the medical community with more information on whether or not and how long a person who has recovered from the virus is at lower risk of infection if they are exposed to the virus again.

Serological tests can play a critical role in the fight against COVID-19 by helping health care professionals identify individuals who may have been exposed to SARS-CoV-2 virus and may have developed an immune response. In the future, this may potentially be used to help determine, together with other clinical data, whether these individuals are less susceptible to infection.

Serological test results may also aid in determining who may qualify to donate blood that can be used to manufacture convalescent plasma ([/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19](#)) as a possible treatment for those who are seriously ill from COVID-19.

Under the FDA's March 16 policy for serological tests ([/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency](#)), the FDA provided regulatory flexibility for developers offering such tests without FDA review and without an EUA where they have notified FDA that they have validated their tests and provide disclaimers about the limitations of the tests with any results generated by their tests, as outlined in the policy. The FDA does not review the validation, or accuracy, data

for these tests unless an EUA is submitted. Test for which developers have provided a notification are listed on the FDA's COVID-19 Diagnostics FAQ page (</medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>).

Serological test developers may pursue an EUA by submitting information about their test, including their validation data, to the FDA for review. Tests that are issued an EUA (</medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>) are listed on the FDA's EUA web page.

FDA Actions

To help ensure that health care providers have access to accurate tests, the FDA is working with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) on a validation project (<https://federallabs.org/news/nci-brings-serological-test-validation-to-covid-19-fight>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) to help identify the most promising serological tests. This validation project is ongoing, and we hope to have additional information to share in the future.

The FDA will continue to keep health care providers and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

Some firms are falsely claiming that their serological tests are FDA approved or authorized, or falsely claiming that these tests can diagnose COVID-19. The FDA will take appropriate action against firms making false claims or marketing tests that are not accurate and reliable.

In addition, the FDA encourages health care providers to report any adverse events or suspected adverse events experienced with serological tests.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>).
- Device manufacturers and user facilities must comply with any applicable Medical Device Reporting (MDR) regulations (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>) should follow the reporting procedures established by their facilities.

- The sale of fraudulent COVID-19 products is a threat to the public health. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program (</safety/report-problem-fda/reporting-unlawful-sales-medical-products-internet>) or the Office of Criminal Investigations (<https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>). You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov (<mailto:FDA-COVID-19-Fraudulent-Products@fda.hhs.gov>)

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (</medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>). For specific questions about COVID-19 diagnostic development, contact CDRH-EUA-Templates@fda.hhs.gov (<mailto:CDRH-EUA-Templates@fda.hhs.gov>).

Additional resources:

- Serological/Antibody Tests (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology>) in FAQs on Diagnostic Testing for SAR-CoV-2