

MEETING OF THE VIRGINIA BOARD OF DENTISTRY BOARD BUSINESS MEETING

Perimeter Center, 9960 Mayland Drive, Second Floor Conferencing Center, Henrico, VA 23233

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March 4, 2020

Ms. Sandra Reen Executive Director Virginia Board of Dentistry 9960 Mayland Drive, Suite 300 Henrico, VA 23233-1463

Dear Ms. Reen and Board Members,

On behalf of the Virginia Society of Oral & Maxillofacial Surgeons (VSOMS), I would like to address concerns regarding the *Overview of Regulatory Advisory Panel regarding Sedation Regulations*, which was discussed at the February 28, 2020 Board of Dentistry Regulatory-Legislative Committee meeting. We specifically have serious concerns with the following recommendation, stated on pages 61-62 of the meeting materials: "The Committee stated concerns about dentists utilizing a laryngoscope stating that, as a dentist, they have limited training and practice and there was a concern that if utilized the dentist would cause more damage. They stated it was more reasonable for a dentist to utilize CPR and call 911 and let an EMT who has more experience and practice to utilize a laryngoscope. Therefore, it was recommended to review this requirement within the regulations."

It is not an overstatement to say that the VSOMS is alarmed about the possibility of the laryngoscope being removed as a requirement for practitioners administering deep sedation/general anesthesia. One of the most critical skill sets (estimated to be as high as 90% of anesthetic complications) is our ability to manage the airway. Airway patency, especially when there is not a secure airway being established, is of supreme importance.

The majority of deep sedation/general anesthesia administered in the Commonwealth is performed by either oral and maxillofacial surgeons or dental anesthesiologists, both of whom receive extensive training and comfort in intubation techniques. In fact, we often place either endotracheal tubes (which require the use of a laryngoscope) or laryngeal masks (LMA) electively for the provision of protected airway anesthesia in our clinics and offices. It would be legally precarious and clinically reprehensible for an OMS or dental anesthesiologist (or any practitioner performing deep sedation/general anesthesia) NOT to place an advanced airway in an airway emergency. Without laryngoscopes, foreign bodies being used in the daily practice of dentistry could find their way into the airway and the trachea, causing a life-threatening situation. Therefore, a provider who is not trained to properly use a laryngoscope is not qualified to perform anesthesia.

Again, I appreciate your consideration of the VSOMS position to keep anesthesia safe for all citizens treated in Virginia. Safety is ALWAYS our first priority. Please feel free to contact VSOMS if you need additional information or have any questions. Thank you in advance for your consideration.

Respectfully,

Dipa J. Patel, DDS President TIME & PLACE: This meeting of the Virginia Board of Dentistry was called to order at

9:03 am, on December 13, 2019 at the Perimeter Center, 9960 Mayland

Drive, in Board Room 4, Henrico, Virginia 23233.

President August A. Petticolas Jr., D.D.S., President

MEMBERS PRESENT: Sandra J. Catchings, D.D.S., Vice President

Nathaniel C. Bryant, D.D.S., Secretary

Patricia B. Bonwell, R.D.H., PhD

Jamiah Dawson, D.D.S.
Perry E. Jones, D.D.S.
Mike Nguyen, D.D.S
Tammy C. Ridout, R.D.H.
James D. Watkins, D.D.S.

STAFF PRESENT: Sandra K. Reen, Executive Director

David Brown, D.C., DHP Director

Barbara Allison-Bryan, MD, DHP Chief Deputy Director

Elaine J. Yeatts, Senior Policy Analyst

Jamie C. Sacksteder, Deputy Executive Director

Kathryn E. Brooks, Executive Assistant

COUNSEL PRESENT: James E. Rutkowski, Assistant Attorney General

ESTABLISHMENT OF

A QUORUM:

With nine members of the Board present, a quorum was established.

Ms. Reen read the emergency evacuation procedures.

PUBLIC COMMENT: Dr. Petticolas explained the parameters for public comment and opened

the public comment period.

Misty Mesimer, RDH (Germanna Community College - GCC) addressed her petition for rulemaking to amend the definition of "Dental Assistant I" to require certification in infection control procedures and in radiation health and safety. She said the Dental Assisting National Board (DANB) currently offers the National Entry Level Dental Assistant (NELDA) examination and the proposed certification. She stated GCC's dental assisting program is accredited and includes a minimum of 11 hours of study on microbiology, modes of disease transmission, infection control protocols, aseptic technique, sterilization and disinfection, and personal

protection. Ms. Mesimer urged the Board to ensure dental assistants meet a minimum standard of competency in infection control and radiation exposure to protect dental patients.

Heather Fonda, CDA_(Germanna Community College) spoke in support of the petition to require dental assistants to be certified in infection control and radiology by completing the NELDA examination before they are allowed to practice in Virginia.

APPROVAL OF MINUTES:

Dr. Petticolas asked if there were any corrections to the three sets of draft minute. Hearing none, Dr. Catchings moved to approve the minutes as presented for the two Formal Hearings held on September 12, 2019 and the Board Business Meeting held on September 13, 2019. The motion was seconded and passed.

DEPARTMENT OF HEALTH PROFESSIONS REPORTS:

Dr. Brown addressed the success of the Department's October 7, 2019 Board Member Training, which received an overall rating by attendees of 4.5 stars out of a possible 5. He also stated his continuing commitment to providing training for board members and agency staff. He then talked about the changes in the composition of the General Assembly and noted the changes include the addition of a second dentist. He said the major issues to be addressed in the 2020 Session include gun control, voting rights and the biennial budget. He added that the Department has only one bill in the upcoming Session. He also noted his appreciation for having several health professionals serving in the General Assembly.

Dr. Allison-Bryan explained the importance of security and said board members should "expect the check" when entering the Perimeter Center as agencies in the building implement recommended security measures. She said the board members' temporary badges allow entrance to the building and second floor. She added that members who enter the building without their temporary badge must sign in with security. She reinforced the importance of every person swiping his or her badge when entering the building from the west side parking lot. She said "panic buttons" will be provided soon to alert security personnel of any emergency that occurs during a meeting.

LIAISON AND COMMITTEE REPORTS:

Dr. Watkins gave the following reports:

• The Southern Regional Testing Agency has decided to continue

- giving dental and dental hygiene exams and exam booklets are being updated for 2020.
- The **Board of Health Professions** received information about legislation passed in Michigan that eliminates health profession boards and establishes an umbrella agency to address cases. Dr. Brown confirmed this is a national trend and said Idaho is proposing legislation to deregulate health professions.
- The draft **Exam Committee** minutes are in the agenda package for review; no action is needed today.

Dr. Bryant reported on his participation in the **Commission on Dental Accreditation**'s site visit to the Dental Hygiene Program at Germanna Community College; explaining he could not provide specific information due to a confidentiality agreement. He said the results of the review would be evident in a matter of months. In response to Dr. Catchings's question, he said GCC offers a dental assistant program and a dental hygiene program.

Dr. Petticolas and Dr. Catchings reported on the **AADB's 136th Annual Conference.** Dr. Catchings said the conference was a disappointment due to the manner in which the organization conducted business. She described the questionable voting process for officers; noting one candidate was an attorney who represents clients in lawsuits against board of dentistry. She added that she was told the AADB would be contacting Ms. Reen about excluding Virginia board members from future meetings if the state level membership isn't paid.

Dr. Petticolas agreed with Dr. Catchings comments then explained his experience of staying an extra day to attend a meeting AADB scheduled with the testing agencies. He said this meeting was advertised as being open then suddenly it was closed and he wasn't allowed to observe. He added that the public session that followed was very brief with no disclosure on the discussion in the closed meeting. He said the only value of this organization is the ability to network with members of other state dental boards. He recommended postponing a decision on continued membership until the next meeting is announced.

Discussion of the AADB included the following. Dr. Watkins noted that another value of the AADB is that it has representatives on many of the ADA's commissions. Dr. Brown added that dentistry is the only health

profession that does not have a functional national organization. He stressed the importance of a continued presence to know what is happening in this organization and questioned the possibility of creating a vibrant organization in the future. Ms. Reen explained the AADB's two levels of membership, noting that the state level membership does not provide a voice in the organization; only individual members who are present at the meetings have voting privileges. She added that individual membership is open to any current or former board member.

Ms. Ridout said the **Regulatory-Legislative Committee** discussed the definition of dentistry then formed a subcommittee to propose language for the definition to include A1C testing. She stated the Committee will meet on February 28, 2020.

Dr. Dawson thanked the Board for asking her to participate in the **VCU Digital Dentistry Symposium** and referenced her summary of events included in the agenda.

LEGISLATION AND REGULATION:

Ms. Yeatts noted that the General Assembly convenes the second Wednesday in January. She then updated information in the Regulatory Action Chart, indicating the emergency regulation for obtaining a waiver for e-prescribing went into effect on December 2, 2019. She added that the comment period for the final regulation is open from December 23, 2019 through January 22, 2020. She then addressed the following subjects:

Blanchard Petition for Rulemaking: Ms. Yeatts explained the petitioner's request is to remove the requirement that a dentist be physically in the office to supervise dental hygiene services which would require elimination of the provisions for in-direct supervision. She reported that the Regulatory-Legislative Committee reviewed the petition and recommended that the Board take no action. Dr. Catchings moved to accept the Committee's recommendation to take no action. The motion was seconded passed.

Practice by Public Health Dental Hygienists under Remote

<u>Supervision</u>: Ms. Yeatts advised that these regulations are identical to the emergency regulations for remote supervision of dental hygienists practicing in the Virginia Department of Health and in the Department of Behavioral Health and Developmental Services. She reported no

comments were received on this action. Dr. Watkins moved to accept the regulations as proposed. The motion was seconded and passed.

Change in Renewal Schedule: Ms. Yeatts reviewed the proposed regulations for changing the renewal schedule to birth months, noting that this draft is an amendment from the original proposal. She reviewed the comments received both in favor and opposed and noted that no one appeared at the public hearing held on October 18th. Due to the length of time this action was under review, she recommended changing the year the renewal schedule will change from the year 2020 to 2021 throughout the proposal. Dr. Catchings moved to adopt the proposal as amended. The motion was seconded. Ms. Ridout questioned changing the year in the dental hygienist and dental assistant regulations. Ms. Yeatts and Ms. Reen agreed the proposal should be 2021. At Dr. Petticolas's request, Ms. Reen explained that currently, all renewals are processed in February and March and the proposed change will reduce the number of licensees affected when mail is lost in the postal system or delayed due to production issues. Dr. Catchings suggested that in the future consideration be given to enabling licensees to print their license renewals. Dr. Petticolas called for a vote on the pending motion to change the renewal schedule. The motion passed.

Returned Check Fee: Ms. Yeatts reported the Office of the Comptroller advised DHP to increase this fee from \$35 to \$50 to comply with the Virginia Debt Collection Act, which is most recent statutory requirement. Dr. Watkins moved to amend the regulation as proposed. The motion was seconded and passed.

<u>Consideration of Guidance Documents</u>: After requesting that these guidance documents be addressed in one motion, Ms. Yeatts briefly explained the proposed changes to:

- 60-3, Periodic Office Inspections for Administration of Sedation and Anesthesia, noting that the blue highlighted sections are still under discussion and only the yellow highlighted sections should be included in the motion.
- 60-4, Questions and Answers about Sedation, the changes highlighted in yellow reflect current regulatory language.
- 60-17, Policy on Recovery of Disciplinary Costs, the changes highlighted in yellow update the costs.

• 60-23, Policy on Teledentistry, needs to be readopted without any changes.

Dr. Catchings moved to adopt these documents as presented. The motion was seconded and passed.

Ms. Yeatts said the Virginia Dental Hygienist Association had concerns about Guidance Document 60-13, **Practice of a Dental Hygienist under Remote Supervision**. She presented an updated draft with new language addressing the settings that qualify as a dental practice physically located in Virginia to include the places that remote supervision can be practiced. Dr. Bonwell moved to accept all the proposed changes, including the changes made after the Regulatory-Legislative Committee met. The motion was seconded and passed.

Dr. Petticolas took a moment to formally introduce Dr. Nguyen and thank him for accepting the request to serve, to which Dr. Nguyen replied that he felt honored and privileged to do so.

BOARD DISCUSSION/ ACTION:

Dr. Petticolas asked for discussion of the comments received.

Ms. Ridout moved to assign the petition to change the definition of the term "dental assistant I" to the Regulatory-Legislative Committee for discussion. The motion was seconded and passed.

Dr. Petticolas stated that the comments addressing remote supervision were addressed in Guidance Document 60-13 and the comment from SRTA was received as information. He then asked how the comment and material received from AAOMS should be addressed. Dr. Catchings moved to refer the comment to the Regulatory-Legislative Committee. The motion was seconded and passed.

Dr. Petticolas called for discussion of the **Clinical Competency Examination Requirements**. Dr. Watkins reported staff is gathering information on the definition of the term "clinical" so the Exam Committee can expand the regulatory requirements for an acceptable clinical competency exam.

Dr. Petticolas asked staff to establish a Regulatory Advisory Panel to discuss digital dentistry. Dr. Dawson agreed to serve as Chair and Dr. Nguyen agreed to serve as a member. Ms. Reen said experts on this

topic will be included, and noted that the VCU School of Dentistry will be contacted to contribute to the discussion.

DEPUTY EXECUTIVE DIRECTOR'S REPORT:

Ms. Sacksteder reviewed the **Disciplinary Board Report** on case activity from January 1, 2019 through November 30, 2019; giving an overview of the actions taken and a breakdown of the cases closed with violations. Dr. Petticolas asked about the number of cases closed with unlicensed activity violations and how these numbers compared to 2018 and 2017 case activities. Ms. Sacksteder replied she did not make note of those cases when preparing the report on 2019 actions and said she would provide this information in a future report.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Reen said one of the duties of staff is to facilitate consistency across Board members in reviewing cases for probable cause. She passed out a photograph of a patient's mouth, which she asked the Board to discuss. She said a calibration exercise was attempted previously and that exercise entailed having each board member review and do a probable cause sheet on the same case. She said that exercise did not achieve the needed discussion so she thought focusing on a photo might be a good option to try. Dr. Petticolas asked the members to describe what they see in the photo. Discussion followed about the information needed to make a decision. To facilitate further discussion, Dr. Petticolas asked the Board to assume the photo shows a crown with an open margin. Following further discussion of what stage in the treatment process the photo was taken and the possible causes for the darkened area, Dr. Petticolas asked for discussion of the darkened area as an open margin assuming the crown was place three months ago by a dentist and the photo was taken by a subsequent dentist. There was general but cautious agreement that, if the darkened area was a defect in a crown, correction was needed and the defect would be considered a violation of the acceptable standard of care. Dr. Petticolas posed a second scenario wherein the patient left the dental practice with this crown in place; then returned to the dentist in 2 weeks because of pain in the area of the crown; and the dentist said nothing was amiss. Ms. Reen asked for discussion of the appropriate sanction in this scenario. During the discussion, Dr. Allison-Bryan said the Board's sanction reference points could help decide sanctions and described the Board of Medicine's process for case review and addressing uniformity in sanctions. Ms. Sacksteder said the purpose of the exercise is to foster critical thinking skills and that more information can be requested if it is needed to make

a determination. Following further discussion, it was generally agreed more information was needed to reach a consensus on the appropriate sanction.

Ms. Reen asked for suggestions for future calibration exercises. There was consensus that a written case summary would be better than a photograph or a full case. Ms. Sacksteder requested more detailed explanations of the findings in a case in layman's terms to support development of notices. Dr. Petticolas concluded the exercise by thanking everyone for their participation and noting there will be more of these exercise in the future.

	these exercise in the future.			
ADJOURNMENT:	With all business concluded, the Board adjourned at 11:39 AM.			
Augustus A. Petticola	s Jr., D.D.S., President	Sandra K. Reen, Executive Director		
 Date		Date		

REPORT: SOUTHERN REGIONAL TESTING AGENCY FOR MARCH, 2020 MEETING

The Board of Directors of SRTA has telephone conference calls each month to conduct the business of the agency. Most of the information during our calls deals with contacts that are being made with different states who may be interested in accepting the SRTA exam either in its present format or as a non-patient exam. Oklahoma, Georgia, South Dakota and Louisiana have contacted SRTA to obtain information. SRTA has contracted for a booth/exhibit at the American Student Dental Association meeting being held in St. Louis this month (March,2020). The officers of the agency have been the main contacts for such communications and remain diligent in attempts to promote the agency.

I will be one of the examiners giving the dental licensure exam at the dental school at West Virginia University in Morgantown on March 5-7, 2020. There are to be 17 dental candidates for the exam there. On March 27-29, 2020 the exam will be administered at the University of Tennessee dental school for 41 dental candidates.

I serve on the SRTA dental exam committee and this committee has updated its candidate and examiner manuals for 2020; and this committee continues to fine tune its non-patient exam criteria.

I also serve on the SRTA Nominating committee for 2020-2021.

Respectfully submitted: Dr. James D. Watkins March 13, 2020

Board of Health Professions Meeting: February 27, 2020

Meeting was called to order at 10:05am by the Vice-Chair Dr. Herb Stewart (chair was caught up in traffic and will arrive ASAP).

Director, Dr. Brown, reported on the progress of medical marijuana oils in the state and that the first site with a full permit to grow marijuana is up and running in Bristol, Va. Four other sites are geographically located throughout the state. Also, there were some bills recently passed that pertain to cannabinol (CBD) oils made from hemp.

Chair, Dr. Jones, arrived at 10:15am and continued with the meeting.

Mrs. Elaine Yeatts gave her Legislative and Regulatory report that addressed status of bills that were presented by or of interest to DHP.

Executive Director, Dr. Carter, presented the BHP Revenues and Expenditures report for July 1, 2019 to January 31, 2020 (55.7% of budget spent). Dr. Carter also presented the Agency statistics/performance report, which showed the Clearance rate (81%: Board of Dentistry), Age of pending caseload (24%: Board of Dentistry) and the Time to disposition (83%: Board of Dentistry) of all of the Boards of the DHP.

Her report showed that the Board of Dentistry currently has 14,911 licensees. She also states that the revision/update of the BHP Mission Statement has been placed on hold for now.

Some discussion was held about a proposal that had been presented about having the terms of the officers for this Board to be for two years instead of one; but the final outcome was to leave terms as one year.

Healthcare Workforce Data Center update was given by Dr. Carter and Dr. Shobo.

The next full meeting of the BHP will be on Wednesday, May 27, 2020.

Meeting adjourned at 1:20pm by Chair, Dr. Jones Respectfully submitted by Dr. James D. Watkins

TIME & PLACE: The meeting of the Examination Committee ("Committee") was called

to order at 9:05 a.m., on January 31, 2020, at the Department of Health Professions, 9960 Mayland Drive, Second Floor Conference

Center, Board Room 3, Henrico, Virginia 23233.

PRESIDING: James D. Watkins, D.D.S., Chair

COMMITTEE Nathaniel C. Bryant, D.D.S.

MEMBERS Patricia B. Bonwell, RDH, PhD

PRESENT:

COMMITTEE Jamiah Dawson, D.D.S. MEMBERS ABSENT: Perry E. Jones, D.D.S.

BOARD MEMBERS Augustus A. Petticolas, Jr., D.D.S., Board President **PRESENT:**

STAFF PRESENT: Sandra K. Reen, Executive Director

Jamie C. Sacksteder, Deputy Executive Director

Kathryn Brooks, Executive Assistant

COUNSEL PRESENT: James E. Rutkowski, Assistant Attorney General

ESTABLISHMENT OF With three members of the Committee present, a quorum was established.

Ms. Sacksteder read the emergency evacuation procedures.

PUBLIC COMMENT: Written comment received from Perry E Jones, DDS, recommended

using the New Hampshire Board of Dentistry's definition of the term

"clinical" in addressing acceptable clinical examinations.

APPROVAL OF Dr. Watkins asked if there were corrections to the posted minutes.

MINUTES: Hearing none, Dr. Bonwell moved to accept the minutes from

November 22, 2020 as presented. The motion was seconded and

passed.

COMPENSATORY SCORING:

Ms. Sacksteder began the discussion of acceptable clinical exams by reviewing her research findings on scoring practices. She read the respective definitions for compensatory scoring used by CRDTS and WREB. She then presented proposed regulatory language on

examination requirements which would deny acceptance of compensatory scoring, set the passing score at 80% and specify the components that must be tested and passed. She also recommended consideration of when the revised regulation should take effect and of including provisions for applicants who may have already taken an exam that doesn't meet the new requirements. Discussion followed on these topics:

- Requiring a minimum passing score of 80% or 75% as the standard for acceptance of clinical examinations. It was agreed by consensus to recommend to the Board setting 75% as the minimum standard.
- The respective scoring policies of CRDTS and WREB, which include **compensatory scoring**, were reviewed. Compensatory scoring, as used by these testing agencies, means the grade for parts of the exam are determined by reviewing the scores given by each examiner then manipulating the examiner scores to compensate for a low score to arrive at the final score for that part of the exam. The consensus was to recommend to the Board that it not accept examination results where the passing grade received was calculated using compensatory scoring for parts of the exam.

MEMBERSHIP IN TESTING AGENCIES:

Ms. Reen explained that the Board was a founding member of SRTA and is currently a member. She said SRTA administered the dental and dental hygiene clinical exams at the VCU School of Dentistry until three years ago when CITA became the examining agency. In response to questions, Ms. Reen explained the Board was previously advised by Board Counsel it could be a member of one testing agency but not be a member of more testing agencies due to the potential for conflicts occurring as a result of the interests of competing testing agencies. She asked if the Board should consider being a member of CITA rather than SRTA. Discussion followed about whether the Board needed to be a member of any testing agency; SRTA being the first agency working to provide a non-patient examination; concern about the ability to verify the required parts were passed without the use of compensatory scoring; continuing membership in ADEX: the expectation for the graduating candidate to be competent in all areas tested, which ensures standards have been met; and accepting test

results based on compensatory scoring for applicants applying by credentials.

Dr. Watkins asked for discussion on being a member of a testing agency or opting out of membership to any testing agency. Forgoing membership in a testing agency was proposed. Then membership in CITA was proposed. The harm that might result if Virginia withdraws from SRTA was questioned. Ms. Reen explained that the Board does not provide any direct funding for SRTA; SRTA is funded by its examination fees; and, since SRTA has not examined at VCU for 2 or more years, it does not get very much money from Virginia exam candidates. Dr. Watkins proposed recommending that the Board not be a member of any agency. Ms. Reen explained that, if the Board is not a member of any testing agency, then members of the Board could be prevented from examining by state statutes. Dr. Watkins asked Mr. Rutkowski to research the implications for board members serving as examiners if the Board is not a member of a testing agency then he asked what action should be taken if the Board must maintain membership with an agency in order for the board members to examine. Dr. Bonwell moved to recommend becoming members of CITA, and ending membership with SRTA. The motion was seconded and passed.

PATIENT VS. NON-PATIENT REQUIREMENT FOR EXAMS BY STATE: Ms. Sacksteder reviewed a map published by ADEA showing the increasing number of states that have alternate pathways towards licensure. She also reviewed a chart showing states' provisions for patient based or non-patient based clinical examination requirements. She said she did not find any state that had provisions for accepting non-patient clinical examinations. She stated only a few states expressly require a live-patient portion and most states only address the exams they accept. She added there appears to be a general assumption that a clinical examination includes testing with a live patient. Ms. Reen said this information supports defining the term "clinical" in regulations to include both live-patient and patient-less exams as the Board addresses acceptance of patient-less exams.

Ms. Reen agreed to research information provided by Dr. Bryant about attesting to the validity of the ADEX exam.

CLINICAL	Ms. Sacksteder reviewed the terms that include the word "clinical" in
DEFINITIONS:	the Board's regulations; read two proposed definitions; and reviewed
	language used by a few other state boards and the definition in

the Board's regulations; read two proposed definitions; and reviewed language used by a few other state boards and the definition in Mosby's Dental Dictionary. It was stated that the first proposed definition includes both live-patient and manikins. Mr. Rutkowski added that the definition submitted by Dr. Jones may be problematic. Ms. Reen suggested defining the terms "clinical" and "clinical examination." Dr. Bonwell moved to recommend adoption of the first proposed definition as written for "clinical examination" and to use the new Hampshire definition as the broader approach for the

definition of "clinical". The motion was seconded. Following

discussion, the motion passed.

LAWSUITS
REGARDING EXAM
REQUIREMENTS:

Ms. Sacksteder reported the only lawsuit she discovered in her research was with the Hawaii Board, which resulted in the state no longer administering their own exam. She added that now Hawaii only

administers the ADEX examination.

EXAM CYCLES: Ms. Sacksteder affirmed that all exam cycles were based on a calendar

year.

NEXT MEETING: The Committee will submit its recommendations and receive findings

from Board Counsel at the March 13, 2020 Board meeting.

ADJOURNMENT: With all business concluded, the meeting was adjourned at 11:27 p.m.

James D. Watkins, D.D.S., Chair	Sandra K. Reen, Executive Director
 Date	Date

Agenda Item: Regulatory Actions - Chart of Regulatory Actions As of March 2, 2020

		Action / Stage Information
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Waiver for e-prescribing [Action 5382]
	o. Bondod y	Emergency/NOIRA - Register Date: 12/23/19 NOIRA comment closed: 1/22/20 Board to adopt proposed regulations: 3/13/20
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Amendment to restriction on advertising dental specialties [Action 4920]
		Proposed - At Governor's Office for 168 days
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Administration of sedation and anesthesia [Action 5056]
		Proposed - At Governor's Office for 161 days
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Technical correction [Action 5198]
		Fast-Track - At Governor's Office for 105 days
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Handling fee/returned check [Action 5451]
		Fast-Track - At Secretary's Office for 47 days
[18 VAC 60 - 21]	Regulations Governing the Practice of Dentistry	Change in renewal schedule [Action 4975]
		Final - At Secretary's Office for 58 days
[18 VAC 60 - 25]	Regulations Governing the Practice of Dental Hygiene	Protocols for remote supervision of VDH and DBHDS dental hygienists [Action 5323]
		Proposed - At Secretary's Office for 13 days
[18 VAC 60 - 30]	Regulations Governing the Practice of Dental Assistants	Education and training for dental assistants II [Action 4916]
TO THE PARTY OF TH		Proposed - Register Date: 1/20/20 Comment period closes: 3/20/20

Report of the 2020 General Assembly

HB 115 Health care providers, certain; programs to address career fatigue and wellness, civil immunity.

Chief patron: Hope

Summary as introduced:

Programs to address career fatigue and wellness in certain health care providers; civil immunity. Expands civil immunity for health care professionals serving as members of or consultants to entities that function primarily to review, evaluate, or make recommendations related to health care services to include health care professionals serving as members of or consultants to entities that function primarily to address issues related to career fatigue and wellness in health care professionals licensed to practice medicine or osteopathic medicine or licensed as a physician assistant. The bill also clarifies that, absent evidence indicating a reasonable probability that a health care professional who is a participant in a professional program to address issues related to career fatigue or wellness is not competent to continue in practice or is a danger to himself, his patients, or the public, participation in such a professional program does not trigger the requirement that the health care professional be reported to the Department of Health Professions. The bill contains an emergency clause.

EMERGENCY

HB 165 Teledentistry; definition, establishes requirements for the practice of teledentistry, etc.

Chief patron: Hope

Summary as passed House:

Teledentistry. Defines "teledentistry," establishes requirements for the practice of teledentistry and the taking of dental scans for use in teledentistry by dental scan technicians, and clarifies requirements related to the use of digital work orders for dental appliances in the practice of teledentistry.

HB 299 Fluoride varnish; possession and administration by medical assistants, etc.

Chief patron: Sickles

Summary as passed House:

Medical assistants; administration of fluoride varnish. Allows an authorized agent of a doctor of medicine, osteopathic medicine, or dentistry to possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

HB 347 Commonwealth's medical cannabis program; SHHR to convene work group to review & make recommendation.

Chief patron: Davis

Summary as passed House:

Tetrahydrocannabinol products; permits to process and dispense cannabidiol oil and THC-A oil. Directs the Secretary of Health and Human Resources to convene a work group to review the Commonwealth's medical cannabis program and issues of critical importance to the medical cannabis industry and patients, including expansion of the medical cannabis program and the medical use of cannabis flowers, and to report its findings and recommendations, including any legislative recommendations, to the Governor, the Attorney General, and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than October 1, 2020.

HB 471 Health professionals; unprofessional conduct, reporting.

Chief patron: Collins

Summary as passed House:

Health professionals; unprofessional conduct; reporting. Requires the chief executive officer and the chief of staff of every hospital or other health care institution in the Commonwealth, the director of every licensed home health or hospice organization, the director of every accredited home health organization exempt from licensure, the administrator of every licensed assisted living facility, and the administrator of every provider licensed by the Department of Behavioral Health and Developmental Services in the Commonwealth to report to the Department of Health Professions any information of which he may become aware in his professional capacity that indicates a reasonable belief that a health care provider is in need of treatment or has been admitted as a patient for treatment of substance abuse or psychiatric illness that may render the health professional a danger to himself, the public or his patients, or that he determines,

following review and any necessary investigation or consultation with the appropriate internal boards or committees authorized to impose disciplinary action on a health professional, indicates that there is a reasonable probability that such health professional may have engaged in unethical, fraudulent, or unprofessional conduct. Current law requires information to be reported if the information indicates, after reasonable investigation and consultation with the appropriate internal boards or committees authorized to impose disciplinary action on a health professional, a reasonable probability that such health professional may have engaged in unethical, fraudulent, or unprofessional conduct.

HB 648 Prescription Monitoring Program; information disclosed to Emergency Department Information.

Chief patron: Hurst

Summary as introduced:

Prescription Monitoring Program; information disclosed to the Emergency Department Information Exchange; redisclosure. Provides for the mutual exchange of information between the Prescription Monitoring Program and the Emergency Department Information Exchange and clarifies that nothing shall prohibit the redisclosure of confidential information from the Prescription Monitoring Program or any data or reports produced by the Prescription Monitoring Program disclosed to the Emergency Department Information Exchange to a prescriber in an electronic report generated by the Emergency Department Information Exchange so long as the electronic report complies with relevant federal law and regulations governing privacy of health information.

HB 967 Military service members and veterans; expediting the issuance of credentials to spouses.

Chief patron: Willett

Summary as passed House:

Professions and occupations; expediting the issuance of credentials to spouses of military service members. Provides for the expedited issuance of credentials to the spouses of military service members who are (i) ordered to federal active duty under Title 10 of the United States Code or (ii) veterans who have left active-duty service within one year of the submission of an application to a board if the spouse accompanies the service member to the Commonwealth or an adjoining state or the District of Columbia. Under current law, the expedited review is provided more generally for active-duty members of the military who are the subject of a military transfer

to the Commonwealth. The bill also authorizes a regulatory board within the Department of Professional and Occupational Regulation or the Department of Health Professions or any other board in Title 54.1 (Professions and Occupations) to waive any requirement relating to experience if the board determines that the documentation provided by the applicant supports such waiver. The bill incorporates HB 930.

HB 1059 Certified registered nurse anesthetists; prescriptive authority.

Chief patron: Adams, D.M.

Summary as passed House:

Certified registered nurse anesthetists; prescriptive authority. Authorizes certified registered nurse anesthetists to prescribe Schedule II through Schedule VI controlled substances and devices to a patient requiring anesthesia, as part of the periprocedural care of the patient, provided that such prescribing is in accordance with requirements for practice by certified registered nurse anesthetists and is done under the supervision of a doctor of medicine, osteopathy, podiatry, or dentistry.

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m HB}$ 1328 Offender medical and mental health information and records; exchange of information to facility.

Chief patron: Watts

Summary as passed House:

Exchange of offender medical and mental health information and records. Provides that a health care provider who has been notified that a person to whom he has provided services within the last two years is committed to a local or regional correctional facility shall, upon request by the local or regional correctional facility, disclose to the local or regional correctional facility where the person is committed any information necessary to ensure the continuity of care of the person committed. The bill also provides protection from civil liability for such health care provider, absent bad faith or malicious intent.

HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Chief patron: Sickles

Summary as passed House:

Pharmacists; prescribing, dispensing, and administration of controlled substances. Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, and to convene a workgroup to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

SB 122 Teledentistry; definition, establishes requirements for the practice of teledentistry, etc.

Chief patron: Barker

Summary as passed Senate:

Teledentistry. Defines "teledentistry," establishes requirements for the practice of teledentistry and the taking of dental scans for use in teledentistry by dental scan technicians, and clarifies requirements related to the use of digital work orders for dental appliances in the practice of teledentistry. The bill incorporates SB 210 and SB 884.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-2700, 54.1-2711, and 54.1-2719 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 27 of Title 54.1 a section numbered 54.1-2708.5, relating to teledentistry.

Approved

[H 165]

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2700, 54.1-2711, and 54.1-2719 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 27 of Title 54.1 a section numbered 54.1-2708.5 as follows:

§ 54.1-2700. Definitions.

 As used in this chapter, unless the context requires a different meaning:

"Appliance" means a permanent or removable device used in a plan of dental care, including crowns, fillings, bridges, braces, dentures, orthodontic aligners, and sleep apnea devices.

"Board" means the Board of Dentistry.

"Dental hygiene" means duties related to patient assessment and the rendering of educational, preventive, and therapeutic dental services specified in regulations of the Board and not otherwise restricted to the practice of dentistry.

"Dental hygienist" means a person who is licensed by the Board to practice dental hygiene.

"Dentist" means a person who has been awarded a degree in and is licensed by the Board to practice dentistry.

"Dentistry" means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical, or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent, and associated structures and their impact on the human body.

"Digital scan" means digital technology that creates a computer-generated replica of the hard and

soft tissues of the oral cavity using enhanced digital photography.

"Digital scan technician" means a person who has completed a training program approved by the Board to take digital scans of intraoral and extraoral hard and soft tissues for use in teledentistry.

"Digital work order" means the digital equivalent of a written dental laboratory work order used in

30 the construction or repair of an appliance.

"License" means the document issued to an applicant upon completion of requirements for admission to practice dentistry or dental hygiene in the Commonwealth or upon registration for renewal of license to continue the practice of dentistry or dental hygiene in the Commonwealth.

"License to practice dentistry" means any license to practice dentistry issued by the Board.

"Maxillofacial" means pertaining to the jaws and face, particularly with reference to specialized surgery of this region.

"Oral and maxillofacial surgeon" means a person who has successfully completed an oral and maxillofacial residency program, approved by the Commission on Dental Accreditation of the American Dental Association, and who holds a valid license from the Board.

"Store-and-forward technologies" means the technologies that allow for the electronic transmission of dental and health information, including images, photographs, documents, and health histories, through a secure communication system.

"Teledentistry" means the delivery of dentistry between a patient and a dentist who holds a license to practice dentistry issued by the Board through the use of telehealth systems and electronic technologies or media, including interactive, two-way audio or video.

§ 54.1-2708.5. Digital scans for use in the practice of dentistry; practice of digital scan technicians.

A. No person other than a dentist, dental hygienist, dental assistant I, dental assistant II, digital scan technician, or other person under the direction of a dentist shall obtain dental scans for use in the practice of dentistry.

B. A digital scan technician who obtains dental scans for use in the practice of teledentistry shall work under the direction of a dentist who is (i) licensed by the Board to practice dentistry in the Commonwealth, (ii) accessible and available for communication and consultation with the digital scan technician at all times during the patient interaction, and (iii) responsible for ensuring that the digital scan technician has a program of training approved by the Board for such purpose. All protocols and procedures for the performance of digital scans by digital scan technicians and evidence that a digital scan technician has complied with the training requirements of the Board shall be made available to the

Board upon request.

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116 117 § 54.1-2711. Practice of dentistry.

A. Any person shall be deemed to be practicing dentistry who (i) uses the words dentist, or dental surgeon, the letters D.D.S., D.M.D., or any letters or title in connection with his name, which in any way represents him as engaged in the practice of dentistry; (ii) holds himself out, advertises, or permits to be advertised that he can or will perform dental operations of any kind; (iii) diagnoses, treats, or professes to diagnose or treat any of the diseases or lesions of the oral cavity, its contents, or contiguous structures, or (iv) extracts teeth, corrects malpositions of the teeth or jaws, takes or causes to be taken digital scans or impressions for the fabrication of appliances or dental prosthesis, supplies or repairs artificial teeth as substitutes for natural teeth, or places in the mouth and adjusts such substitutes. Taking impressions for mouth guards that may be self-fabricated or obtained over-the-counter does not constitute the practice of dentistry.

B. No person shall practice dentistry unless a bona fide dentist-patient relationship is established in person or through teledentistry. A bona fide dentist-patient relationship shall exist if the dentist has (i) obtained or caused to be obtained a health and dental history of the patient; (ii) performed or caused to be performed an appropriate examination of the patient, either physically, through use of instrumentation and diagnostic equipment through which digital scans, photographs, images, and dental records are able to be transmitted electronically, or through use of face-to-face interactive two-way real-time communications services or store-and-forward technologies; (iii) provided information to the patient about the services to be performed; and (iv) initiated additional diagnostic tests or referrals as needed. In cases in which a dentist is providing teledentistry, the examination required by clause (ii) shall not be required if the patient has been examined in person by a dentist licensed by the Board within the six months prior to the initiation of teledentistry and the patient's dental records of such

examination have been reviewed by the dentist providing teledentistry.

C. No person shall deliver dental services through teledentistry unless he holds a license to practice dentistry in the Commonwealth issued by the Board and has established written or electronic protocols for the practice of teledentistry that include (i) methods to ensure that patients are fully informed about services provided through the use of teledentistry, including obtaining informed consent; (ii) safeguards to ensure compliance with all state and federal laws and regulations related to the privacy of health information; (iii) documentation of all dental services provided to a patient through teledentistry, including the full name, address, telephone number, and Virginia license number of the dentist providing such dental services; (iv) procedures for providing in-person services or for the referral of patients requiring dental services that cannot be provided by teledentistry to another dentist licensed to practice dentistry in the Commonwealth who actually practices dentistry in an area of the Commonwealth the patient can readily access; (v) provisions for the use of appropriate encryption when transmitting patient health information via teledentistry; and (vi) any other provisions required by the Board. A dentist who delivers dental services using teledentistry shall, upon request of the patient, provide health records to the patient or a dentist of record in a timely manner in accordance with § 32.1-127.1:03 and any other applicable federal or state laws or regulations. All patients receiving dental services through teledentistry shall have the right to speak or communicate with the dentist providing such services upon

D. Dental services delivered through use of teledentistry shall (i) be consistent with the standard of care as set forth in § 8.01-581.20, including when the standard of care requires the use of diagnostic testing or performance of a physical examination, and (ii) comply with the requirements of this chapter

and the regulations of the Board.

E. In cases in which teledentistry is provided to a patient who has a dentist of record but has not had a dental wellness examination in the six months prior to the initiation of teledentistry, the dentist providing teledentistry shall recommend that the patient schedule a dental wellness examination. If a patient to whom teledentistry is provided does not have a dentist of record, the dentist shall provide or cause to be provided to the patient options for referrals for obtaining a dental wellness examination.

F. No dentist shall be supervised within the scope of the practice of dentistry by any person who is

not a licensed dentist.

§ 54.1-2719. Persons engaged in construction and repair of appliances.

A. Licensed dentists may employ or engage the services of any person, firm, or corporation to construct or repair an appliance, extraorally, prosthetic dentures, bridges, or other replacements for a part of a tooth, a tooth, or teeth in accordance with a written or digital work order. Any appliance constructed or repaired by a person, firm, or corporation pursuant to this section shall be evaluated and reviewed by the licensed dentist who submitted the written or digital work order, or a licensed dentist in the same dental practice. A person, firm, or corporation so employed or engaged shall not be considered to be practicing dentistry. No such person, firm, or corporation shall perform any direct dental service for a patient, but they may assist a dentist in the selection of shades for the matching of prosthetic devices when the dentist sends the patient to them with a written or digital work order.

B. Any licensed dentist who employs the services of any person, firm, or corporation not working in a dental office under his the dentist's direct supervision to construct or repair, an appliance extraorally, prosthetic dentures, bridges, replacements, or orthodontic appliances for a part of a tooth, a tooth, or teeth, shall furnish such person, firm, or corporation with a written or digital work order on forms prescribed by the Board, which shall, at minimum, contain: (i) the name and address of the person, firm, or corporation; (ii) the patient's name or initials or an identification number; (iii) the date the work order was written; (iv) a description of the work to be done, including diagrams, if necessary; (v) specification of the type and quality of materials to be used; and (vi) the signature and address of the dentist.

The person, firm, or corporation shall retain the original written work order or an electronic copy of a digital work order, and the dentist shall retain a duplicate of the written work order or an electronic

copy of a digital work order, for three years.

C. If the person, firm, or corporation receiving receives a written or digital work order from a licensed dentist engages a subcontractor to perform services relative to the work order, a written disclosure and subwork order shall be furnished to the dentist on forms prescribed by the Board, which shall, at minimum, contain: (i) the name and address of the person, firm, or corporation and subcontractor; (ii) a number identifying the subwork order with the original work order; (iii) the date the any subwork order was written; (iv) a description of the work to be done and the work to be done by the subcontractor, including diagrams or digital files, if necessary; (v) a specification of the type and quality of materials to be used; and (vi) the signature of the person issuing the disclosure and subwork order.

The subcontractor shall retain the subwork order, and the issuer shall retain a duplicate of the subwork order, which shall be attached to the work order received from the licensed dentist, for three years.

D. No person, firm, or corporation engaged in the construction or repair of appliances shall refuse to allow the Board or its agents to inspect the files of work orders or subwork orders during ordinary business hours.

The provisions of this section shall not apply to a work order for the construction, reproduction, or repair, extraorally, of prosthetic dentures, bridges, or other replacements for a part of a tooth, a tooth, or teeth, done by a person, firm or corporation pursuant to a written work order received from a licensed dentist who is residing and practicing in another state.

Agenda Item: Petition for rulemaking

Included in your agenda package are:

A copy of a petition from Misty Mesimer on behalf of the Va. Dental Hygiene Program Directors' Consortium

Copy of comments on the petition

Copies of applicable sections of regulation

Staff note:

The Regulatory/Legislative Committee reviewed the petition, the comments, and applicable sections of law and regulation and recommended that additional information be gathered relating to disciplinary cases involving infection control.

Board action:

- 1) Accept the petitioner's request and initiate rulemaking, or
- 2) Deny the petitioner's request for stated reasons, or
- 3) Decide to not initiate rulemaking but continue to obtain information on potential harm to the public



COMMONWEALTH OF VIRGINIA Board of Dentistry

9960 Mayland Drive, Suite 300 Richmond, Virginia 23233-1463

(804) 367-4538 (Tel) (804) 527-4428 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.

Please provide the information requested below. (Print	or Type)	
Petitioner's full name (Last, First, Middle initial, Suffix,) Mesimer, Misty, L on behalf of the Virginia Dental Hygiene	e Program Directors' Consortium	
Street Address 2130 Germanna Hwy, P.O. Box 1430	Area Code and Telephone I 540-423-9823	Number
City Locust Grove	State Virginia	Zip Code 22508
Email Address (optional) mmesimer@germanna.edu	Fax (optional) 540-423-9827	

Respond to the following questions:

- 1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.
- 2.
- 18 VAC 60-30-10. Definitions.

"Dental Assistant I" means any unlicensed person under the direction of a dentist or a dental hygienist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely an administrative, secretarial, or clerical capacity.

3. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

The Virginia Dental Hygiene Program Directors' Consortium who also includes program directors for American Dental Association Commission on Dental Accreditation approved dental assisting programs recommends the amending 18 VAC 60-30-10. Definitions. Dental

"Dental assistant I" means any unlicensed person certified in infection control procedures and radiation health and safety recognized by the Dental Assisting National Board (DANB) or the National Entry Level Dental Assistant (NELDA) under the direction of a dentist or a dental hygienist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely an administrative, secretarial, or clerical capacity.

The primary purpose of the Virginia Board of Dentistry is to protect the public. Dental practices must have strict infection control practices in order to protect patients and employees. Breaches in infection control techniques jeopardize the safety of patients and the community. In Oklahoma, an aseptic breach by an oral surgeons office resulted in exposure to more than 7000 patients. In New Jersey, there is documentation of a patient death. In both California and Georgia, there are cases of pediatric patients developing infections in the bone as a result of pulpotomy procedures where instruments were not correctly processed. All dental professionals have a responsibility to societal trust, nonmaleficence, and beneficence.

Historically, dental assistants have received on the job training, putting the responsibility of infection control training on the dentist. Establishing a requirement for calibrated training and certification would ensure that all assistants have received the same information. In reality, dental practitioners are not the people in the office responsible for infection control processes and procedures. The CDC reports that majority of dental offices have no written protocol, exposure control plans, or a designated infection control coordinator.

Frequent breaches in asepsis is a result from not following transportation requirements, not wearing correct personal protective equipment, incorrect instrument packaging and reprocessing practices, inadequate sterilization testing procedures, and incorrect waterline maintenance.

We urge the Board to require minimum credentials for the safety of the citizens in the Commonwealth. The recommended credentials are successful completion of the Infection Control Examination and Radiation Health and Safety portions of the Dental Assisting National Board Examination or the National Entry Level Dental Assistant examination. This will not only benefit patients by improving safety. It will improve the quality of oral health care delivered in Virginia. Dentists will be able to focus on the art and science of dentistry, treating their patients, and growing their practices. They will be able to delegate with confidence the most important task related to patient care — SAFETY. There is absolutely no reason why Virginia should wait for one case of morbidity or mortality to occur before taking action. We urge you be proactive, not reactive.

3.	State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.
§ 5	54.1-2400. General powers and duties of health regulatory boards. see general powers and duties of health regulatory boards shall be:
	To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate ensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to gage in the regulated professions.
	To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise juired by law, examinations shall be administered in writing or shall be a demonstration of manual skills.
3. par	To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the ticular profession or professions regulated by such board.

Christian Waterman, RDH, BSDH, BS 7702 Merrick Road Richmond, VA 23294

12/23/19

Virginia Board of Dentistry 9960 Mayland Drive, Ste 300 Richmond, VA 23233-1463

Dear Honorable Board Members,

My name is Christian Waterman, RDH. I graduated from Virginia Tech with a BA in Psychology in 2014. I graduated from Virginia Commonwealth University School of Dentistry Dental Hygiene program in 2018. I have been working as a full-time clinical dental hygienist at Virginia Family Dentistry for the past 1.5 years. I held the position of Virginia Dental Hygiene Association (VDHA) Component 2-Greater Richmond Chair last year. I currently hold the position of VDHA Vice President. This testimony is in regards to 18 VAC 60-30-10 Definitions. I write in support of regulation of Dental Assistant I and II's to have educational requirements to comply standards of Infection Control as defined by the Centers for Disease Control and Prevention guidelines for preventing the transmission of infectious disease. I have attached current VDHA policies that provide support for change in regulation of dental assistants to the end of this document.

On-the-job training alone does not ensure there is an understanding of current standards and practices within infection control prior to the potential dental assistant starting to practice or be involved with live patients. I believe it is a high risk to allow a potential dental assistant to be involved or practice on patients prior to having a form of infection control education. A potential dental assistant may learn a given infection control standard at some point during on-the-job training, but the dental assistant has a higher likelihood of violating this standard if he or she is assisting prior to learning or demonstrating an understanding of the standard. This places patients at a higher risk of exposure to an infectious disease. Dentists and dental hygienists are typically using all allotted time for treating patients without having to teach at the same time. Of course dentists and dental hygienists can easily teach and provide rational for the clinical actions they are preforming at a given time, but I do not believe all the standards can be taught through one given action or over a reasonable amount of time while treating patients. On-the-job training requires more dentist-dental assistant interaction and takes away from potential dentist/dental hygienistpatient interaction. Dentists and dental hygienists are also placed at a higher risk. If a potential dental assistant, while participating in on-the-job training, does not have educational requirements to comply standards of Infection Control as defined by the Centers for Disease Control and Prevention guidelines for preventing the transmission of infectious disease and violates an infection control standard, exposing a patient, who is responsible? My thought is the dentist or dental hygienist will be held responsible for not ensuring the potential dental assistant had knowledge or understanding of the infection control standard prior to actively assisting. If the potential dental assistant claims the dentist or dental hygienist never informed him or her of the infection control standard that was violated, how would the dentist or dental hygienist prove otherwise?

Again, I support regulation of Dental Assistant I and II's to have educational requirements to comply with standards of Infection Control as defined by the Centers for Disease Control and Prevention guidelines for preventing the transmission of infectious disease. I appreciate the Board of Dentistry's past and current dedication and efforts to ensure patient and professional safety in the field of dentistry. If the Board of Dentistry has any questions or concerns, please feel free to contact me through email at watermanrdh@gmail.com.

Respectfully,

Christian Waterman, RDH, BSDH, BS VDHA Vice President

R 4-05

STANDARD PRECAUTIONS

The Virginia Dental Hygienists' Association advocates the utilization of universal infection and exposure control precautions, and maximum work site safety and training to protect the health and safety of both practitioner and patient.

R-4-97

INFECTIOUS DISEASE TRANSMISSION GUIDELINES

The Virginia Dental Hygienists Association supports the Centers for Disease Control and Prevention's (CDC) guidelines for preventing the transmission of infectious disease.

Heather Fonda, CDA 14279 Deertrack Trail Culpeper, VA. 22701

December 22, 2019

Virginia Board of Dentistry 9960 Mayland Drive, Suite 300 Richmond, VA. 23233-1463

Dear Honorable Board Members,

My name is Heather Fonda and I am writing in support of the proposed regulation change (petition 313) requiring dental assistants to be infection control and radiology certified through DANB or NELDA before they are allowed to practice in the Commonwealth of Virginia. Having graduated from an accredited dental assisting program as a CDA in December of 2018, I am well aware that dentistry, like other medical fields, has its potential for health altering hazards. My education and subsequent DANB certifications have provided me with the knowledge I need to protect my patients, myself, my team, and my community from injury and communicable disease. An on-the-job trained dental assistant without certifications, however, will likely have no idea what air borne or blood borne pathogens are, what standard precautions are, or even that there is a difference between disinfection and sterilization; all of which are paramount knowledge in the avoidance of maleficence. Patients and people, in general, have immense societal trust in their healthcare providers; dentists and their team members included. Let's not ever let anyone down! Allowing substandard practice is unacceptable. I ask you to please see the validity and criticality in this proposed change. The patients and dentists in the Commonwealth of Virginia deserve competent certified dental assistants.

Thank you for reading my testimony and for your consideration of this very important issue.

Should you need to contact me for further comment I can be reached via the following means: (Cell) 703-966-2977 (Email) heatherfonda@yahoo.com

Very respectfully,

Heather Fonda



Dental Assisting National Board, Inc.

Measuring Dental Assisting Excellence®

Board of Directors

Chair Michael Conte, D.M.D., M.P.H.

Vice Chair Denise Romero, CDA, COA, RDA, M.A.

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Constance J. Reed, CDA, EFDA, B.S.

Executive Director
Cynthia C. Durley, M.Ed.,
MBA

December 25, 2019

Virginia Board of Dentistry
Attention: Sandra Reen, Executive Director
9960 Mayland Drive, Suite 300
Richmond, 23233
sandra.reen@dhp.virginia.gov

Dear Distinguished Members of the Virginia Board of Dentistry:

I am writing on behalf of the Dental Assisting National Board, Inc. (DANB) in connection with the petition filed on Virginia's Regulatory Town Hall Website on November 5, 2019, titled "Certification for dental assistants."

The petition asks the Virginia Board of Dentistry to amend its rules to require that dental assistants be "certified in infection control procedures and radiation health and safety recognized by the Dental Assisting National Board or the National Entry Level Dental Assistant."

It is our understanding that the petitioner is referring to DANB's Infection Control (ICE®) Exam and Radiation Health and Safety (RHS®) Exam, along with DANB's NELDA® certification.

As you may know, DANB is recognized by the American Dental Association (ADA) as the national certification board for dental assistants. DANB administers the nationally recognized Certified Dental Assistant™ (CDA®) certification program and four other certification programs for dental assistants, including the National Entry Level Dental Assistant (NELDA®) certification. DANB exams are recognized or required to qualify to perform dental assisting duties in 38 states, the District of Columbia, the Department of Veterans Affairs and the U.S. Air Force. Successful performance on DANB's RHS exam is currently recognized in Virginia as meeting the exam requirements for one pathway to qualify to perform radiography procedures.

DANB is a nonprofit organization whose mission is to promote the public good by providing credentialing services to the dental community. In accordance with that mission, DANB is fully supportive of all efforts to ensure that those who provide dental assisting services to the public are competent and qualified to do so. As such, DANB supports the current petition and encourages the Virginia Board of Dentistry to reduce the risk of infection or injury to dental patients and dental team members by requiring that dental assistants demonstrate competence in areas of knowledge that are critical to patient safety through successful performance on high-quality standardized assessments, developed in accordance with best practices, such as DANB's RHS and ICE exams.

To assist the Virginia Board of Dentistry in considering this petition, DANB is providing the following information about the exams and certification that are referenced in the petition:

Virginia Board of Dentistry December 25, 2019 Page 2

About DANB Exams

DANB's CDA and Certified Orthodontic Assistant (COA®) certification programs are nationally accredited by the National Commission for Certifying Agencies (NCCA) and internationally accredited by the International Accreditation Service (IAS) to the ISO 17024 standard for organizations that certify personnel. These national and international accreditations encompass evaluation of DANB's CDA certification component exams, which include the RHS and ICE exams.

DANB exams are administered at more than 250 proctored, secure computerized testing sites nationwide (through Pearson VUE), including eight in Virginia. Pearson VUE testing centers use standardized, rigorous security and proctoring procedures, ensuring that each candidate has a reasonably similar testing experience and protecting the integrity of exam results by minimizing opportunities for dishonest test-taking behavior.

DANB's Infection Control (ICE) Exam

DANB's ICE exam assesses a dental assistant's knowledge-based competence in dental infection control practices and is a component of the National Entry Level Dental Assistant (NELDA®), Certified Dental Assistant™ (CDA®) and Certified Orthodontic Assistant (COA®) certification programs. There are no eligibility requirements to take the ICE exam, when it is taken as a standalone exam. The ICE exam is a 75-minute, 100-question multiple choice test addressing the following content areas:

- I. Standard Precautions and the Prevention of Disease Transmission (20%)
- II. Prevention of Cross-contamination during Procedures (34%)
- III. Instrument/Device Processing (26%)
- IV. Occupational Safety/Administrative Protocols (20%)

A more detailed content outline for the ICE exam and suggested references for study are provided as Attachment 1.

DANB's Radiation Health and Safety (RHS) Exam

DANB's RHS exam assesses a dental assistant's knowledge-based competence in radiographic safety and technique and is a component of the National Entry Level Dental Assistant (NELDA®) and Certified Dental Assistant™ (CDA®) certification programs. There are no eligibility requirements to take the RHS exam, when it is taken as a standalone exam. The RHS Exam is a 75-minute, 100-question multiple choice test addressing the following content areas:

- I. Expose and Evaluate (26%)
- II. Quality Assurance and Radiology Regulations (21%)
- III. Radiation Safety for Patients and Operators (31%)
- IV. Infection Control (22%)

A more detailed content outline for the RHS exam and suggested references for study are provided as Attachment 2.

National Entry Level Dental Assistant (NELDA) Certification

DANB's NELDA certification provides entry-level dental assistants—those not yet qualified for DANB's Certified Dental Assistant (CDA) certification—with the opportunity to demonstrate mastery of foundational concepts and of knowledge critical to patient health and safety. NELDA certification consists of three component exams: DANB's ICE and RHS Exams, detailed on the preceding page, and the Anatomy, Morphology and Physiology (AMP) Exam.

There are no requirements to take each of the NELDA component exams, but to earn NELDA certification, candidates must meet the requirements of one of four eligibility pathways. All NELDA certifications require the applicant to hold a DANB-accepted hands-on CPR, BLS or ACLS card.

Education Pathways

Pathway I: Graduate of a DANB-accepted dental assisting program for NELDA certification (located within a post-secondary institution that is accredited by an organization recognized by the U.S. Department of Education) AND high school graduation or equivalent

Pathway II: Graduate of a U.S. Department of Labor Job Corps dental assisting program

Pathway III: Graduate of a DANB-accepted dental assisting program for NELDA certification offered within a high school that is recognized in the U.S. education system; this dental assisting program must encompass at least one semester of dental assisting curriculum (not a survey of all health occupations) AND high school graduation or equivalent

Work Experience Pathway

Pathway IV: A minimum of 300 hours and up to 3,000 hours of work experience as a dental assistant accrued over a period of at least two months and no more than three years AND high school graduation or equivalent

DANB's NELDA certification can be held for up to four years, after which NELDA certificants are encouraged to earn CDA certification. Additional information about the NELDA, certification, including renewal requirements, can be found in Attachment 3.

An Additional Note of Clarification About the Term "Certification"

"Certification" is a voluntary process by which a non-governmental entity grants a time-limited recognition and use of a credential to an individual after verifying that he or she has met predetermined and standardized criteria. *Typically, certification programs include education and/or experience requirements and passing a certification exam* built from a weighted exam outline based on the results of a formal job analysis. Only those who meet all certification requirements (including periodic renewal requirements) are authorized to use a specific certification mark, such as CDA or NELDA. For example, a person named Sue Smith who has earned DANB's NELDA certification is authorized to hold herself out as "Sue Smith, NELDA."

Although, like certification exams, DANB's ICE and RHS exam blueprints are developed based on the results of a formal job analysis, they are not certifications. Rather, they are two of three component exams that make up DANB's CDA certification and DANB's NELDA certification. A

Virginia Board of Dentistry December 25, 2019 Page 4

person who passes the ICE or RHS exam as a standalone exam earns a certificate of knowledge-based competence but is not "certified."

One feature that distinguishes an exam leading to a certificate of knowledge-based competence, like the standalone ICE and RHS exams, from a certification is that the ICE and RHS exams do not have eligibility prerequisites. In addition, passing either or both of these exams does not result in the individual being awarded a certification mark (that is, a person may not call herself "Sue Smith, RHS") as one would receive upon earning a professional certification like DANB's CDA or NELDA certifications (e.g., "Sue Smith, CDA" or "Sue Smith, NELDA"). Furthermore, unlike certifications, the certificates earned by passing the individual RHS or ICE exams do not expire and are not subject to renewal.

Though the petition under consideration uses the word "certification" to refer to DANB's ICE and RHS exams, it would be more accurate to avoid referring to these exams as "certifications" in any future rulemaking proposal that might mention these exams. If there are any questions about using these terms accurately, I will be happy to provide more information.

If the Virginia Board of Dentistry would like any additional information about DANB's ICE and RHS component exams or NELDA certification program, please don't hesitate to contact me at klandsberg@danb.org or 1-800-367-3262, ext. 431. I will be happy to provide any information that may be useful for the Board's discussion in advance of the Board's March 13, 2020 meeting.

Thank you for your consideration.

Sincerely,

Katherine Landsberg

Director, Government Relations

Cc: Cynthia C. Durley, M.Ed., MBA, DANB Executive Director Johnna Gueorguieva, Ph.D., DANB Chief Credentialing and Research Officer



Infection Control (ICE®)

Exam Blueprint and Suggested References

The ICE® exam is a component of the National Entry Level Dental Assistant (NELDA®), Certified Dental Assistant™ (CDA®) and Certified Orthodontic Assistant (COA®) certification programs.

NELDA component exams

Anatomy, Morphology and Physiology (AMP)
Radiation Health and Safety (RHS®)
Infection Control (ICE)

CDA component exams

General Chairside Assisting (GC)
Radiation Health and Safety (RHS)
Infection Control (ICE)

COA component exams

Orthodontic Assisting (OA)
Infection Control (ICE)

Effective 01/01/2018

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ICE

Exam Blueprint Overview

ICE Exam Weighting by Sub-Content Area

- I. Standard Precautions and the Prevention of Disease Transmission (20%)
- II. Prevention of Cross-contamination during Procedures (34%)
- III. Instrument/Device Processing (26%)
- IV. Occupational Safety/Administrative Protocols (20%)

ICE Exam Administration

Number of Questions: 100

Time for Exam: 75 minutes

• Tutorial Time: 5 minutes

• Comment Time: 5 minutes

DANB uses computer adaptive testing (CAT) to present questions to candidates. Each candidate starts with a question at or around the pass point. If the candidate gets a question correct, the next question will be slightly harder. If the question is incorrectly answered, the next question will be slightly easier. Question selection takes into account the content of the question, as each candidate is presented with the same percentage of questions from each domain on the exam outline. Using this method of testing, DANB can more accurately pinpoint a candidate's ability level. The average candidate will get around 50% of the questions correct and around 50% of the questions incorrect. The candidate's score is based on the difficulty of the questions that were answered correctly.

ICE Exam Blueprint

DANB exams are created using the exam blueprint, which is annually reviewed by subject matter experts. The blueprint is developed through a rigorous content validation study (CVS) and validated by DANB certificants using a job analysis survey. A CVS is conducted every five to seven years to ensure the blueprint is consistent with current clinical practices. DANB's Board of Directors approves all updates to DANB exam blueprints.

This exam references the following (see p. 6 for full citations for these references):

- Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings-2003
- Centers for Disease Control and Prevention. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care
- Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens (BBP) standard
- OSHA Hazard Communication standard

Sub-Content Area I: Standard Precautions and the Prevention of Disease Transmission (20%)

- A. Recognize infection diseases and their relationship to patient and occupational risk.
 - 1. Modes of disease transmission.
 - 2. Needs for immunization against infectious diseases (e.g., hepatitis, B, influenza).
- B. Demonstrate understanding of how to review a medical history to prevent adverse reactions during dental care (e.g., adverse reactions to latex or vinyl).
- C. Demonstrate understanding of proper hand hygiene as performed before, during and after oral surgery and intraoral procedures, including but not limited:
 - 1. Products (e.g., anti-microbial, anti-bacterial, alcohol rub).
 - 2. Skin/nail care.
 - 3. Techniques (e.g., length of time, sequencing).
 - 4. Select appropriate hand hygiene protocol.
- D. Describe how to protect the patient and operator by using personal protective equipment (PPE)
 - Selection and sequence of placing, removing and disposal of PPE according to the procedures(s) and areas, including but not limited to:
 - Instruments/device processing.
 - b. Laboratory.
 - c. Oral surgery.

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- d. Radiology.
- e. Treatment room.
- 2. Dispose of or launder contaminated clothing according to the OSHA Bloodborne Pathogens standard.
- E. Demonstrate understanding of how to protect the patient and operator through the reduction or aerosol, droplets and spatter, including but not limited to:
 - 1. Barrier techniques.
 - 2. Dental dams.
 - 3. Evacuation techniques.
 - 4. Patient eyewear.
 - 5. Pre-procedural mouth rinses.

Sub-Content Area II: Prevent Cross-contamination during Procedures (34%)

- A. Identify modes of disease transmission.
- B. Demonstrate understanding of how to maintain aseptic conditions to prevent cross-contamination for procedures and services.
 - Clean and disinfect for breakdown and setup of clinical treatment areas, the laboratory, and equipment.
 - a. Prepare and use chemical disinfection for breakdown and setup.
 - b. Protect the patient and operator using barrier techniques.
 - c. Prepare tray setups (e.g., single-use devices [SUD], single unite dosing, aseptic retrieval).
 - d. Maintain and monitor dental unit water lines.
 - e. Clean and maintain evacuation lines and traps.
 - 2. Clean and disinfect radiological areas and equipment to protect the patient and operator.
 - 3. Use aseptic techniques for acquiring and processing conventional and digital radiographic images.
 - 4. Select proper methods of disinfection for impressions and dental appliances.
 - 5. Dispose of biohazardous and other waste according to federal regulations.

Sub-Content Area III: Instrument/Device Processing (26%)

- A. Demonstrate understanding of processing reusable dental instruments and devices.
 - 1. Transport contaminated instruments/devices to prevent cross-contamination.
 - 2. Use work flow patterns to avoid cross-contamination of instruments/devices and supplies.
 - 3. Clean and maintain dental instruments/devices and supplies prior to sterilization
 - 4. Prepare and sue chemical agents for cleaning instruments/devices instructions.
 - 5. Prepare dental instruments/devices and supplies for sterilization.
 - 6. Select the system for sterilization.
 - 7. Select the system for sterilization monitoring (e.g., biological monitoring, chemical integrators).
 - 8. Package and label instruments/devices for sterilization.
 - 9. Load and unload the sterilizer.
 - 10. Store and maintain integrity of sterile instruments/devices and supplies.
- B. Demonstrate understanding of how to monitor and maintain processing equipment and sterilizers (e.g., ultrasonic cleaner, autoclave).
 - 1. Interpret sterilization monitoring devices, errors and results.
 - 2. Respond to equipment malfunctions.

Sub-Content Area IV: Occupational Safety/Administrative Protocols (20%)

- A. Demonstrate understanding of occupational safety standards and guideline for personnel.
 - 1. OSHA Bloodborne Pathogens standard as it applies to, but not limited to:
 - a. Engineering and work practice controls.
 - b. Needle and sharps safety.
 - c. Record keeping and training.
 - d. Sharps exposure and post-exposure protocol (e.g., first aid procedures).

Attachment 1

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- 2. OSHA Hazard Communication standard as it applies to, but not limited to:
 - a. Chemical exposure/hazard (e.g., amalgam, nitrous oxide, laser) and first aid.
 - b. Engineering and work practice controls.
 - c. Safety data sheets (SDS).
 - d. Secondary containers.
- 3. CDC Guidelines for Infection Control in Dental Health-Care Settings 2003.
- 4. CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care, 2016.
- 5. Federal regulations (e.g., EPDA, FDA).
- B. Demonstrate understanding of how to maintain and document programs/policies for infection control and safety, including but not limited to:
 - 1. Exposure control plan.
 - 2. Infection control breaches.
 - 3. Quality assurance (quality improvement).
 - 4. Sterilization logs/records.
 - 5. Training records.

ICE Exam Suggested References

DANB exam committees use the following textbooks and reference materials to develop this exam. This list does not include all the available textbooks and materials for studying for this exam; these are simply the resources that exam committee subject matter experts determined as providing the most upto-date information needed to meet or surpass a determined level of competency for this exam. Any one reference will likely not include all the material required to study to take the exam.

This list is intended to help prepare for this exam. It is not intended to be an endorsement of any of the publications listed. You should prepare for DANB certification and component exams using as many different study materials as possible.

Textbook References

- 1. Bird, Doni L., and Debbie S. Robinson. *Essentials of Dental Assisting*. 5th ed. St. Louis, MO: Elsevier/Saunders, 2013.
- 2. Bird, Doni L., and Debbie S. Robinson. *Modern Dental Assisting*. 10th and 11th ed. St. Louis, MO: Elsevier/Saunders, 2012 and 2015.
- 3. Miller, Chris and Charles J. Palenik. Infection Control and Management of Hazardous Materials for the Dental Team. 5th ed. Mosby, 2013.
- 4. Molinari, John and Jennifer Harte. Cottone's Practical Infection Control in Dentistry. 3rd ed. Lippincott, 2010
- 5. Phinney, Donna J., and Judy H. Halstead. *Dental Assisting: A Comprehensive Approach*. 3rd and 4th ed. Clifton Park, NY: Delmar, 2008 and 2013.

Organizational References

- 1. The Organization for Safety and Asepsis (OSAP). www.osap.org.
 - From Policy to Practice: OSAP's Guide to the Guidelines
 - OSAP's OSHA & CDC Guidelines: Interact Training System
- 2. The American Dental Assistants Association (ADAA). www.dentalassistant.org
 - Infection Control in the Dental Office: A Review for a National Infection Control Exam (Course #0906)
 - Guidelines for Infection Control in Dental Health Care Settings (Course #1305)
- 3. The DALE Foundation. www.dalefoundation.org.
 - DANB ICE Review
 - DANB ICE Practice Test
 - Glossary of Dental Terms
 - CDEA module: Understanding CDC's Summary of Infection Prevention Practice in Dental Settings: Basic Expectations for Safe Care

(list continues next page)

Attachment 1

DANB Comments, 12/25/2019

- 4. Centers for Disease Control and Prevention (CDC). www.cdc.gov
 - Guidelines for Infection Control in Dental Health-Care Settings 2003 (MMWR, Vol. 52, RR 17)
 - Centers for Disease Control and Prevention. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health; 2016
 - Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis (MMWR, Vol. 50, RR 11)
- 5. U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). www.osha.gov.
 - Hazard Communication Guidelines for Compliance (Publication 3111)
 - Hazard Communication Standard (Code of Federal Regulations #29, Part 1910)
 - Bloodborne Pathogens Standard (1910.1030)



Dental Assisting National Board, Inc.

Measuring Dental Assisting Excellence®

State Regulations

Each state's dental board implements regulations and establishes rules for delegating legally allowable duties to dental assistants. Passing one or more of the DANB component exams or earning DANB certification only conveys authority to perform these duties in those states that recognize these exams or this certification as meeting state dental assisting requirements. This information is at www.danb.org.



Radiation Health and Safety (RHS®)

Exam Outline and Suggested References

The RHS[®] exam is a component of the National Entry Level Dental Assistant (NELDA[®]) and Certified Dental Assistant[™] (CDA[®]) certification programs.

NELDA component exams

Anatomy, Morphology and Physiology (AMP)

Radiation Health and Safety (RHS)

Infection Control (ICE®)

CDA component exams

Radiation Health and Safety (RHS)

Infection Control (ICE)

General Chairside Assisting (GC)

Effective 01/01/2018

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RHS

Exam Outline Overview

RHS Exam Weighting by Domain

- I. Expose and Evaluate (26%)
- II. Quality Assurance and Radiology Regulations (21%)
- III. Radiation Safety for Patients and Operators (31%)
- IV. Infection Control (22%)

RHS Exam Administration

Number of Questions: 100

• Time for Exam: 75 minutes

• Tutorial Time: 5 minutes

• Comment Time: 5 minutes

DANB uses computer adaptive testing (CAT) to present questions to candidates. Each candidate starts with a question at or around the pass point. If the candidate gets a question correct, the next question will be slightly harder. If the question is incorrectly answered, the next question will be slightly easier. Question selection takes into account the content of the question, as each candidate is presented with the same percentage of questions from each domain on the exam outline. Using this method of testing, DANB can more accurately pinpoint a candidate's ability level. The average candidate will get around 50% of the questions correct and around 50% of the questions incorrect. The candidate's score is based on the difficulty of the questions that were answered correctly.

RHS Exam Outline

DANB exams are created using the exam outline, which is annually reviewed by subject matter experts (e.g., Certified Dental AssistantTM [CDA®] certificants and dentists). The outline is developed using a Content Validation Study (CVS), which includes a job analysis survey where practicing CDA certificants are surveyed about how often tasks are performed and how important competent performance of tasks is to the health and safety of the public. This study is conducted every five to seven years to ensure the outline is consistent with current clinical practices. DANB's Board of Directors approves all updates to DANB exam outlines. The RHS exam measures a candidate's knowledge of national radiographic imaging practices.

NOTE: DANB uses "image receptor" to refer to conventional film or sensors used for digital imaging.

Domain I: Expose and Evaluate (26%)

A. Assessment and Preparation

- 1. Describe patient preparation for radiographic exposures (e.g., inspect the patient's head and neck for removable appliances and foreign objects).
- 2. Select radiographic technique.
 - a. Describe use and purpose of intraoral and extraoral radiographic images, including but not limited to:
 - periapical.
 - ii. bitewing.
 - iii. occlusal.
 - iv. panoramic.
 - v. cephalometric and other extraoral views.
 - b. Select radiographic survey to examine or view conditions, teeth or landmarks.
 - c. Describe technique modifications based on anatomical variations.
- 3. Select equipment for radiographic technique.
 - a. Describe purpose or advantage of accessories.
 - b. Select image receptor size.
 - c. Describe purpose and advantage of double (dual) film packets.

Attachment 2 DANB Comments, 12/25/2019

B. Acquire

- 1. Describe how to acquire radiographic images using various techniques.
 - a. Define radiographic exposure concepts.
 - b. Intraoral
 - i. Define factors that influence quality of the radiographic image.
 - ii. Compare paralleling and bisecting angle techniques (e.g., advantages, disadvantages).
 - iii. Describe the parts and functions of radiographic film packets and digital image receptors.

c. Extraoral

- i. Identify function and maintenance of film cassettes and intensifying screens.
- ii. Describe exposure technique (i.e., patient positioning).
 - a) Panoramic radiography.
 - b) Cephalometric radiography.
- iii. Demonstrate basic understanding of CBCT (cone-beam computed tomography).
- 2. Demonstrate basic knowledge of digital radiography.
 - a. Advantages/disadvantages.
 - b. Handling errors.
 - c. Image receptors.
- 3. Demonstrate basic knowledge of conventional film processing.
 - a. Functions of processing solutions.
 - b. Process exposed intra- and extraoral films using automatic processors.
 - c. Procedures for processing films.

C. Evaluate

- 1. Evaluate radiographic images for diagnostic value.
 - a. Describe features of a diagnostically acceptable radiographic image.
 - b. Identify and describe how to correct errors related to acquiring intraoral radiographic images.
 - c. Identify and correct radiographic processing errors.
 - d. Identify and describe how to correct improper film handling errors.
 - e. Identify and describe how to correct errors related to acquiring panoramic radiographic images.
- 2. Mount and label radiographic images.
 - a. Describe how to mount radiographic images using facial (buccal and labial) view.
 - Identify anatomical landmarks that aid in mounting.

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- ii. Match tooth views to tooth mount windows.
- iii. Demonstrate understanding of radiographic image viewing techniques.
- b. Identify anatomical structures, dental materials and patient information observed on radiographic images (e.g., differentiating between radiolucent and radiopaque areas).

D. Patient Management

- 1. Describe techniques for patient management before, during and after radiographic exposure (e.g., patients with special needs).
- 2. Describe techniques for patients with a severe gag reflex.

Domain II: Quality Assurance and Radiology Regulations (21%)

A. Quality Assurance

- 1. Evaluate film storage areas.
- 2. Identify and describe how to correct errors related to improperly storing radiographic film.
- 3. Describe how to prepare, maintain and replenish automatic processor solutions.
- 4. Identify conditions required for film processing.
- 5. Describe how to implement quality assurance procedures.

B. Radiology Regulations

- 1. Describe how to prepare radiographic images for legal requirements, viewing, duplication and transfer.
- 2. Describe how to store chemical agents used in dental radiography procedures according to regulatory agencies, in compliance with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard.
- 3. Describe how to dispose of chemical agents and other materials used in dental radiography procedures.

Domain III: Radiation Safety for Patients and Operators (31%)

- A. Identify current American Dental Association (ADA) guidelines for patient selection and limiting radiation exposure.
- B. Apply the principles of radiation protection and hazards in the operation of radiographic equipment.

Attachment 2

DANB Comments, 12/25/2019

- 1. Factors affecting x-ray production (e.g., kVp, mA, exposure time).
- 2. X-radiation characteristics.
- 3. X-ray machine factors that influence radiation safety (e.g., filtration, shielding, collimation, PID [cone] length).
- 4. X-radiation physics.
 - a. Primary radiation.
 - b. Scatter (secondary) radiation.
- 5. Protocol for suspected x-ray machine malfunctions.

C. Demonstrate knowledge of patient safety measures to provide protection from x-radiation.

- 1. Major causes of unnecessary x-radiation exposure.
- 2. X-radiation biology:
 - a. short- and long-term effects of x-radiation on cells and tissues.
 - b. concepts of x-radiation dose and effective dose.
- 3. Reduce x-radiation exposure to patients (ALARA).
- D. Address patient radiation concerns (e.g., informed consent, patient refusal).
- E. Identify operator safety measures to provide protection from x-radiation.
 - 1. Sources of x-radiation to operators/other staff while exposing image receptors.
 - 2. Safety measures to reduce operator x-radiation exposure.
 - 3. X-radiation physics and biology pertaining to operator exposure.
- F. Describe techniques for monitoring individual x-radiation exposure.
 - 1. ALARA principle as related to operator safety.
 - 2. Function of a personal monitoring device.

Domain IV: Infection Control (22%)

A. Standard Precautions for Equipment

- Demonstrate understanding of infection control techniques used to minimize crosscontamination during radiographic procedures according to ADA, Centers for Disease Control and Prevention (CDC) and OSHA guidelines for conventional and digital radiography.
- 2. Demonstrate understanding of barriers used to minimize cross-contamination during radiographic procedures according to ADA, CDC and OSHA guidelines for conventional and digital radiography.

Attachment 2 DANB Comments, 12/25/2019

B. Standard Precautions for Patients and Operators

- 1. Demonstrate understanding of infection control for radiographic procedures according to ADA, CDC and OSHA guidelines for conventional and digital radiography.
- 2. Describe infection control techniques used during radiographic processing, following ADA, CDC and OSHA guidelines.

RHS Exam Suggested References

DANB exam committees use the following textbooks and reference materials to develop this exam. This list does not include all the available textbooks and materials for studying for this exam; these are simply the resources that exam committee subject matter experts have determined provide the most up-to-date information needed to meet or surpass a determined level of competency for this exam. Any one reference will likely not include all the material required to study to take and pass the exam.

This list is intended to help prepare for this exam. It is not intended to be an endorsement of any of the publications listed. You should prepare for DANB certification and component exams using as many different study materials as possible.

Textbook References

- 1. Bird, Doni L., and Debbie S. Robinson. *Essentials of Dental Assisting*. 5th ed. St. Louis, MO: Elsevier/Saunders, 2013.
- 2. Bird, Doni L., and Debbie S. Robinson. *Modern Dental Assisting*. 11th and 12th ed. St. Louis, MO: Elsevier/Saunders, 2015 and 2017.
- 3. Ianucci, Joen M., and Laura J. Howerton. *Dental Radiography Principles and Techniques* (with CD-ROM). 5th ed. St. Louis, MO: Elsevier/Saunders, 2017.
- 4. Johnson, Orlen N., and Evelyn M. Thomson. *Essentials of Dental Radiography for Dental Assistants and Hygienists*. 9th ed. Upper Saddle River, NJ: Pearson Education, 2012.
- 5. Miller, Chris H. *Infection Control and Management of Hazardous Materials for the Dental Team*. 5th and 6th ed. St. Louis, MO: Elsevier/Mosby, 2014 and 2018.
- 6. Phinney, Donna J., and Judy H. Halstead. *Dental Assisting: A Comprehensive Approach*. 5th ed. Clifton Park, NY: Delmar Cengage Learning, 2013.

Organizational References

- 1. Centers for Disease Control and Prevention (CDC). www.cdc.gov.
 - Guidelines for Infection Control in Dental Health-Care Settings 2003 (MMWR, Vol. 52, RR 17)
 - Centers for Disease Control and Prevention. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health; 2016
- 2. U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). www.osha.gov.
 - Hazard Communication Standard (Code of Federal Regulations #29, Part 1910)
 - Bloodborne Pathogens Standard (1910.1030)
- 3. American Dental Assistants Association (ADAA). www.dentalassistant.org.
 - An Introduction to Basic Concepts in Dental Radiography (Course #715)

Attachment 2

DANB Comments, 12/25/2019

- 4. The DALE Foundation. www.dalefoundation.org.
 - DANB RHS Review
 - Conventional Dental Radiography Review
 - DANB RHS Practice Test
 - Glossary of Dental Terms



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State Regulations

Each state's dental board implements regulations and establishes rules for delegating legally allowable duties to dental assistants. Passing one or more of the DANB component exams or earning DANB certification only conveys authority to perform these duties in those states that recognize these exams or this certification as meeting state dental assisting requirements. This information is available at www.danb.org.

NELDA®

National Entry Level Dental Assistant Certification Program Overview

DANB has developed a certification program for entry-level dental assistants — the National Entry Level Dental Assistant (NELDA) certification program. The NELDA certification program is an additional rung on the dental assisting career ladder, with eligibility pathways for individuals who do not yet qualify to earn DANB's Certified Dental Assistant™ (CDA®) certification.

NELDA Component Exams

A candidate must pass the three NELDA component exams within a three-year period to be eligible for NELDA certification. Exam questions are multiple-choice.

- Radiation Health and Safety (RHS®) 100 questions
- Infection Control (ICE®) 100 questions
- Anatomy, Morphology and Physiology (AMP) 105 questions

Candidates may take the three component exams in one administration (the NELDA exam) or may take each exam separately, in any order. Candidates also have the option of taking the RHS and ICE exams together in a combined administration.



Eligibility Requirements

There are no eligibility requirements to take the RHS, ICE and AMP exams. However, a candidate must meet eligibility requirements to earn NELDA certification after passing the three exams.

All eligibility pathways to earn certification require candidates to hold a current DANB-accepted, hands-on CPR, BLS or ACLS card.

Education Pathways

Graduate of a DANB-accepted dental assisting program for NELDA certification (located within a post-secondary institution that is accredited by an organization recognized by the U.S. Department of Education) AND high school graduation or equivalent

Pathway II: Graduate of a U.S. Department of Labor Job Corps dental assisting program

Pathway III: Graduate of a DANB-accepted dental assisting program for NELDA certification offered within a high school that is recognized in the U.S. education system; this dental assisting program must encompass at least one semester of dental assisting curriculum (not a survey of all health occupations) AND high school graduation or equivalent

Work Experience Pathway

Pathway IV: A minimum of 300 hours and up to 3,000 hours of work experience as a dental assistant accrued over a period of at least two months and no more than three years AND high school graduation or equivalent

Renewal Requirements

- NELDA certificants may annually renew the certification for up to four years
- To renew, certificants must
 - Earn 6 continuing dental education credits annually, in clinical topics, of which one must be in the OSHA Bloodborne Pathogens standard and two must be in infection control
 - Hold current a DANB-accepted, hands-on CPR, BLS or ACLS card
 - Answer Background Information Questions
 - Submit the annual NELDA renewal fee (currently \$50)

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Attachment 3

157.8 NELDA Overview (12/19)

Attachment 3

DANB Comments, 12/25/2019

After four years, to maintain DANB certification, an individual who holds NELDA certification must earn one of DANB's other national certifications— CDA, Certified Orthodontic Assistant (COA®), Certified Preventive Functions Dental Assistant (CPFDA®), or Certified Restorative Functions Dental Assistant (CRFDA®)

NELDA certificants may use the "NELDA" certification mark on a résumé, on a business card, on a website, in a book or publication, and in other print and electronic media. A certificant may also display the mark on a nametag or uniform worn during the rendering or promoting of services and on a wall plaque present at the place where he or she renders or promotes the services. Former NELDA certificants who do not renew their certification are no longer authorized to represent that they hold NELDA certification and may not use the certification mark "NELDA" following their names or represent themselves to the public as being a NELDA certificant, in any manner. Emeritus status is not available for NELDA certificants.

Background, Program Development and Launch

DANB's initiation of a certification program for entry-level dental assistants was influenced by several factors:

- Each state defines its own regulations and requirements for dental assistants, and in most states, there are no eligibility requirements to work as an entry-level dental assistant; however, entry-level assistants may be entrusted with tasks that affect patient health and safety, such as radiography and instrument sterilization
- In a 2011 DANB survey, state dental boards and state dental associations expressed a need for a valid and reliable way to measure knowledge-based competence of dental assistants who have completed some type of dental assisting education but who do not yet meet the eligibility requirements to qualify for competence testing through DANB's CDA certification program

In considering the structure and content of a competence measurement solution for entry-level dental assistants, DANB reviewed:

- The lists of duties that each state allows entry-level dental assistants to perform
- Oral healthcare concepts that the Commission on Dental Accreditation (CODA) considers to be "foundational" in dental assisting education

DANB's NELDA certification program includes component exams in the fundamental areas of dental radiation health and safety; infection control; and anatomy, morphology and physiology. The first two areas are critical to patient safety, and the third assesses knowledge of basic concepts that serve as a strong foundation required to perform most other dental assisting duties. States differ greatly in which chairside functions are allowed to be performed by entry-level dental assistants; consequently, DANB's Board of Directors has determined that specific knowledge-based competencies associated with chairside functions will continue to be tested by DANB's higher-level certification programs: CDA, COA, CPFDA, and CRFDA.

In June 2013, DANB invited representatives from select communities of interest to a forum about the proposed NELDA certification program. In August 2013, DANB solicited additional feedback from relevant stakeholder groups. DANB's Board reviewed the stakeholder feedback at its January 2014 meeting, and DANB launched the NELDA certification program in April 2015.

About DANB

DANB is recognized by the American Dental Association as the national certification board for dental assistants. DANB's mission is to promote the public good by providing credentialing services to the dental community. For those dental assistants who meet the eligibility and exam requirements, DANB certifications include the National Entry Level Dental Assistant (NELDA®), Certified Dental Assistant (CDA®), Certified Orthodontic Assistant (COA®), Certified Preventive Functions Dental Assistant (CPFDA®) and Certified Restorative Functions Dental Assistant (CRFDA®). In addition to these national certifications, DANB offers certificates of knowledge-based competency in Radiation Health and Safety (RHS®); Infection Control (ICE®); Coronal Polish (CP); Sealants (SE); Topical Anesthetic (TA); Topical Fluoride (TF); Anatomy, Morphology and Physiology (AMP); Impressions (IM); Temporaries (TMP); and Isolation (IS).

DANB's CDA and COA certification programs are accredited by the National Commission for Certifying Agencies and are also accredited by the International Accreditation Service (IAS) to the ISO 17024 Standard for personnel certification. Currently, there are more than 37,000 DANB certificants nationwide, and DANB certifications and certificates of knowledge-based competence are recognized or required in 38 states, the District of Columbia, the U.S. Air Force and the Department of Veterans Affairs. Passing DANB's exams demonstrates a dental assistant's competence in areas that are important to the health and safety of oral healthcare workers and patients alike.

Virginia.gov

Agencies | Governor



Department of Health Professions

Board

Board of Dentistry

Chapter

Regulations Governing the Practice of Dental Assistants [18 VAC 60 - 30]

29 comments

All good comments for this forum

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Commenter: Hannah Tatum

12/4/19 2:13 pm

I agree with this petition

I believe it is important for all dental assistants to have their radiation and health safety and their infection control. That way the dental assistants are aware of their surroundings and know how to protect themselves and others.

CommentiD: 77034

Commenter: Ashanty Ogborn, Dental Assisting Student

12/4/19 2:14 pm

I agree

Infection control is important enough to require certification. It's not just enough to know to wash your hands between patients and to wear a mask. We need to know how infection is transmitted and what needs to be done to prevent it. It's also important to know the effects of radiation and how to minimize it's exposure. Knowing that the staff at any dental (or medical) office is certified in infection control and radiation health and safety would give any patient peace of mind.

CommentID: 77035

Commenter: Monique Redcross

12/4/19 2:20 pm

| Agree!!!

Me knowing what I know now from taking the Dental Assisting course being if I were a patient I would want any assistant working on me to be certified or to at least have the knowledge of both Infectious Control and Radiation Health Safety. I want to be able to walk into a office and now that I am safe because I am putting my life in someone else hands. So by me feeling this way I know my patients feel the same as well. They deserve the fairness and respect that I would want as a patient. So I agree.

CommentID: 77036

Commenter: Kimberly Little ,ECPI University

12/10/19 3:44 pm

All Dental Assistants should be certified in Infection Control ,this law should be pass.

CommentID: 77744

Commenter: Kim Richardson, ECPI University

12/10/19 6:33 pm

Infection Control and Radiation Health Safety

It is a disservice to dental assistants and more importantly to the public, to have uneducated assistants that are ignorant to the dangers they are a part of each and every day as they provide care to the patient. The Infection Control certification and Radiation Health Safety certification through DANB is a very logical approach to a solution. I believe that if the public were truly aware of the critical nature of this issue, they would have grave concern when seeking dental treatment. The organisms we deal with in today's world of healthcare in general are far more infectious and life threatening than those of the "good old days". I believe that our approach to this should no longer be one that was appropriate for the "good old days".

CommentID: 77803

Commenter: Delia Phelps

12/10/19 8:52 pm

Certification for dental assistant infection control.

I agree with this petition

CommentID: 77831

Commenter: Rebekah Marrero Ortiz

12/10/19 9:23 pm

I agree

I agree

CommentID: 77840

Commenter: Melanie Laronda, RDH, BS

12/11/19 3:26 pm

Certification for Dental Assistants

As a former clinical dental hygiene instructor, I agree that the importance of both radiation safety and infection control protocol needs to be part of the entire dental team's education.

CommentID: 78203

Commenter: Kimberly A Arny

12/11/19 9:52 pm

AGREE

If Virginia required credentialled assistants, this would not be necessary,as they would be tested in radiology, infection control, emergency procedures, and other areas. Be proactive!!

CommentID: 78380

Commenter: Kristin Page, RDH

12/12/19 1:21 pm

DAs should be certified in infection control

Many DAs don't understand the weight of good infection control. This helps protect the public from there dangers that exist withboor infection control. The patient is our number one priority and this is a major component to his/her safety.

CommentiD: 78470

Commenter: Patricia A. MacDougall

12/12/19 1:56 pm

DA Infection Control and Radiation Safety

I agree with the petitioner's amendment.

CommentiD: 78472

Commenter: Sheila B. Sheats, RDH, NVDHC Chair

12/12/19 2:48 pm

DA Certification

A agree, however, instituting this for all the many assistants that have OJT would have to be advised to this. How would this be implemented? The schools (DA assisting, proprietary, and community college) would need to offer these certifications. The DDS would need to ensure that their staff was properly certified. I feel that hygienists have had many, many courses and yearly OSHA (BBP) updates yearly. Thank you

CommentID: 78473

Commenter: Tammy Swecker

12/12/19 2:57 pm

Dental Assistant Certificate

Dental assistants need formal education to protect themselves and patients. Dental assistants need more than just on the job training. Infection control and Radiation Safety are just some of the courses all dental assistants should be required to take. They should also have to take a test on the laws that govern the practice of dentistry so they know what is a delegable and nondelegable duty.

CommentID: 78474

Commenter: Joan Pellegrini, RDH, BSDH, MSDH, PhD

12/12/19 3:13 pm

Certification for dental assistants

As a long-time care provider and educator, I support regulation for dental assistants being certified in OSHA, infection control and radiation health/safety. Additionally, the dental assistants should be current in their certification in Basic Life Support (BLS/CPR). These areas of certification are a protection for the patient, as well as other members of the dental team.

CommentID: 78475

Commenter: Angela Smith, BS, CDA

12/12/19 3:38 pm

DA Certification

At a minimum, dental assistants need formal education on Radiation Safety and Infection Control as well as CPR certification. Breaches of infection control are happening all over the country in all sorts of healthcare situations, and we need to gain control of this problem by making sure those people who perform these procedures most often in dental offices, the dental assistants, have the proper training. As for radiation health and safety, this training needs to be more than a few hours on radiation. Most often, it's the dental assistant in a practice taking the radiographs. Knowing proper sensor placement and tube head placement is as important as knowing how X-rays are generated to keeping the patient exposure level at the absolute minimum. The proper technique not only means reduced exposure but also proper diagnosis and treatment for the patient. This law should pass without hesitation.

CommentID: 78476

Commenter: Cynthia Saxton Flowers RDH, CDA

12/12/19 6:24 pm

I agree with Petition

As a former Dental Assistant, I am in favor to have all Dental Assistants be certified in Infection Control and Radiation Safety. The CDC has recognized that one of the main duties as a DA is infection control. It is the utmost importance to protect our public and staff from the spread of disease.

CommentID: 78478

Commenter: Gloria Langmeyer CDA CDPMA PAST PRESIDENT VDAA

12/12/19 7:28 pm

Certification for DA I totally agree

CommentiD: 78479

Commenter: Jeannie Lipscomb, CDA

12/12/19 7:31 pm

Certification for Dental Assistants

Agreed that knowledge in both areas is important. The Dental Assisting National Board (DANB) has offered certification for both Radiation Health and Safety and Infection Control for many years. Additionally, both of these exams are part of the CDA examination.

CommentID: 78480

Commenter: Virginia T Dugge CDA Retired

12/13/19 10:11 am

Certification for Dental Assistants

All Dental Assistants need to be certified for the protection of their patients as well as for their own protection and knowledge.

As a former president of the VDAA back in the 80's I had been fighting for this for over 25 years before retiring.

I highly recommend that the BOD finally makes this happens!

Thank you.

Virginia T Dugge

CommentID: 78488

Commenter: Deborah Vernon, CDA

12/13/19 11:04 pm

Support of formal testing and credentialing of Dental Assistants

As a Certified Dental Assistant with 30+ years in dentistry, it is my sincere belief that having dental assistants properly trained and tested in radiation and infection control is vital to the health and safety of not only the patients and staff, but the community in general. *This is a public health issue*. Even a cursory search would reveal dozens of infection control breaches, affecting thousands, including deaths. These are not isolated "once in a blue moon" incidents. They can happen, and have happened, anywhere - dental schools, public health clinics, corporate and private practices, and more. Dental staff who know the how, what and why of pathogens and how to stop them are an absolute necessity in ALL dental practices. Please pass this regulation. Thank you!

CommentID: 78504

Commenter: Shannon Pace Brinker, CDA

12/15/19 12:16 am

I agree with this Certification

Appropriate infection control procedures must be performed to ensure patient and staff safety. Following the CDC and OSHA guidelines for infection control can prevent or reduce the risk of disease transmission to patients and DHCP. With only 35k dental assistants who are certified in the US, this is a must to required dental assistants be certified in Infection Control in order to work in a dental practice. I have taught over 60k dental assistants in the US and this is the widest area of concern and clinical misunderstanding. We must protect our patients. Requirements for education should be the standard for every dental professional. I support this change

CommentID: 78510

Commenter: Julie Martin BSDH, RDH

12/15/19 7:25 am

DA infection control certification and radiation safety

As a former DA and current RDH in VA, I strongly feel that DA's in VA should be certified in infection control with no grandfathering. I continuously witness many incidents of cross-contamination in the dental offices by DA's, due to a lack of knowledge and training.

I feel that not only should DA's be certified in radiation health and safety, but the certification should include proper placement of film to prevent repeated exposure.

I recommend that the VA BOD votes in favor of this petition to keep the public safe.

Julie A. Martin, BSDH, RDH

CommentID: 78511

Commenter: Heidi Hessler-Allen, CDA

12/16/19 6:23 am

Support certification requirements for all dental assistants

CommentID: 78517

Commenter: Summer Barnett, CDA

12/16/19 10:20 am

Absolutely!

CommentID: 78519

Commenter: Rebecca Coelho CDA, RDH

12/16/19 11:17 am

RHS and ICE are important!

I teach radiology and infection control classes to dental assisting students. Students have NO concept of infection control at the start of class, they touch their face and other surfaces with gloves on and then try to perform procedures on patients! This poses a huge concern for cross contamination. Radiology is also very important. Radiation causes permanent damage to tissues. If a student doesn't understand how radiation works they will not take seriously why it is so important to take images correctly the first time to minimize exposure to the patient. Dental assistants also need to have an understanding of radiology to help educate patients about why xrays are necessary and important...... patients try to refuse xrays all the time!

CommentID: 78520

Commenter: RHONDA LUCAS RDH, BSDH, CDA

12/18/19 2:46 pm

I AGREE

Infection Control is the main duty of ALL dental professionals. First and upmost, we must protect ourselves and our patients form contamination and diseases.

CommentID: 78539

Commenter: Smithfield Dental

12/19/19 6:57 pm

l agree

CommentID: 78542

Commenter: Heather Fonda, CDA

12/22/19 10:25 pm

I Agree! DA's need ICE & RHS Certifications!

I am writing in support of the proposed regulation change (petition 313) requiring dental assistants to be infection control and radiology certified through DANB or NELDA before they are allowed to practice in the Commonwealth of Virginia. Having graduated from an accredited dental assisting program as a CDA in December of 2018, I am well aware that dentistry, like other medical fields, has its potential for health altering hazards. My education and subsequent DANB certifications have provided me with the knowledge I need to protect my patients, myself, my team, and my community from injury and communicable disease. An on-the-job trained dental assistant without certifications, however, will likely have no idea what airborne or bloodborne pathogens are, what standard precautions are, or even that there is a difference between disinfection and sterilization. All of which are paramount knowledge in the avoidance of maleficence. Patients and people, in general, have immense societal trust in their healthcare providers; dentists and their team members included. Let's not ever let anyone down! Allowing substandard practice is unacceptable. I

ask you to please see the validity and criticality of this proposed change. The patients and dentists in the Commonwealth of Virginia deserve competent certified dental assistants.

CommentID: 78563

Commenter: Vicki Brett, CDA, RDH, BSDH

12/24/19 3:47 pm

Safety for All

I am writing in support of the rulemaking petition proposing to require dental assistants in Virginia to pass the Infection Control (ICE) and Radiation Health and Safety (RHS) exams administered by the Dental Assisting National Board, Inc. (DANB) or to earn DANB's NELDA certification.

The risk of transmission of infection in a dental office is a serious concern, and these concerns have been heightened by a series of high-profile breaches of infection control protocols reported in the media, including the following:

- In 2014, New Jersey public health officials discovered 15 cases of endocarditis linked to improper
 infection prevention procedures at one oral surgery office; of the 15 confirmed endocarditis patients, 12
 underwent cardiac surgery and one died from complications of endocarditis and subsequent cardiac
 surgery. [i]
- In a highly publicized incident in Oklahoma in 2013, more than 4,200 dental patients required testing for infectious diseases after receiving treatment in the office of an oral surgeon whose staff was found to be using improper sterilization practices. Of those tested, 89 were positive for hepatitis C, with at least one of these cases confirmed through genetic testing as a patient-to-patient transmission of the disease. [iii] Though it is unclear whether this oral surgeon's assistants had any formal training or education, it is known that they did not hold DANB's Certified Dental Assistant certification and had not taken DANB's Infection Control exam, which is a component of the CDA certification.

At the time of the incident, Oklahoma did not have any laws or regulations requiring dental assistants to receive any specific education or training in infection control or to hold independent professional certification in dental assisting from DANB or any other entity. The supervising dentist, in a statement to investigators, indicated that he delegated all sterilization responsibilities to his dental assisting staff, yet the errors made by these assistants demonstrated that they lacked even a basic knowledge of infection control principles, including those on which they would have been comprehensively tested had they taken DANB's Infection Control exam and/or been holders of DANB's CDA certification.

 The Oklahoma incident described above followed a series of significant but less well publicized infection control breaches, including one in which more than 500 veterans were notified that they might have been exposed to hepatitis B, hepatitis C, and HIV after having procedures performed in a VA dental clinic where proper infection control protocols were not followed.

In Virginia, there have been at least two allegations of breaches in the past two years, including one incident in which a dentist in a Richmond pediatric dental office informed patients that the practice's one high-speed handpiece was not being heat sterilized between patients, but only wiped with an intermediate disinfectant. The practice is also accused of improperly maintaining water lines. [iv] In another case, a lawsuit filed in May 2019 alleges that employees/agents of a dental clinic owned by a company based in Roanoke used improperly sterilized instruments on at least 50 patients. [v]

The DALE Foundation, the official affiliate of the Dental Assisting National Board, Inc. (DANB), conducted a research study in 2016 focused on the value of dental assistants to dental practices. The cornerstone of the study was a survey that researchers circulated to dentists, dental assistants and dental hygienists in general dental practices; the survey included questions about delegation of duties to dental assistants.

The survey responses revealed the following related to delegation of infection control-related tasks to dental assistants:

 69% of responding dentist and dental assistants indicated that "perform sterilization and infection control procedures" is one of the top five functions most frequently delegated to dental assistants 99% of responding dentists and dental assistants indicated that "perform sterilization and infection control procedures" is a function delegated to dental assistants; 28% indicated that this function was performed by qualified dental assistants, and 71% indicated that this function is performed by all dental assistants, including those who have not met any specific requirements [Vi]

The consequences to the public of improper performance of infection prevention and control procedures can be very serious. Survey data indicate that dental assistants are performing sterilization and infection control procedures in 99% of general dental practices. However, because Virginia does not regulate first-level dental assistants (Dental Assistants I), we don't know how many dental assistants in Virginia do not have adequate training in infection control.

According to occupational employment statistics available from the U.S. Bureau of Labor Statistics, there were approximately 8,520 dental assistants employed in Virginia in May 2018. In January of that year, there were 2,400 dental assistants with Virginia addresses who had passed DANB's Infection Control (ICE) exam since 1997, which is less than one third of all employed dental assistants. While it is possible that the approximately two thirds of dental assistants in Virginia who have not passed DANB's ICE exam have received some type of formal education or training in infection prevention and control, there is simply no way to know. The good news is that, if Virginia adopts a requirement that all dental assistants must pass the ICE exam, approximately one third of assistants will have already met this requirement.

I am in full agreement with dental assistants being required to take DANB's Infection Control Exam. I have worked in dentistry in Virginia for 37 years as a clinician, a dental sales consultant, and an educator and administrator. From my own experiences, I can say that the need for all dental assistants to be educated in infection control is crucial for the safety of dental professionals and our patients.

I worked for 27 years in the same dental office. In my first few years as a dental assistant, I also thought infection control was not an issue, because the dental office where I worked employed highly educated dental assistants (including me) that believed in continuing education and maintaining current knowledge of the latest technology. When I started temping as a dental hygienist on my days off, I realized that not every office maintained the same standards. On several occasions, a dental assistant in the office where I was temping would give me an orientation to the office's sterilization process and procedures, and I was frequently shocked at the deviations in best practices that I saw.

As a dental sales representative, I visited hundreds of dental offices in Virginia and had the opportunity to learn quite a bit about the way different offices operate. I wish I had kept a record of how many offices didn't know the OSHA guidelines and the mandated rule to have office training in the bloodborne pathogens standard each year. I am not aware of anyone checking to see if dental offices comply with this mandate.

Ten years ago, I became an educator and director of a dental assisting program that has four campuses located throughout Virginia. This role has ignited a passion in me for the profession of dental assisting and reinforced my belief that there is a critical need for dental assistants who are properly trained and educated and who are certified.

My students all take and pass DANB's Infection Control Exam before going on externship/internship and have demonstrated mastery of proper infection control concepts and procedures. They regularly bring stories back to class of appalling deviations from the best practices they have learned. While I recognize these are second-hand anecdotal accounts, they cause me to be deeply concerned about the health and safety of dental patients in Virginia.

In 2015, I served on the Regulatory Advisory Committee on the Education and Practice of Dental Assistants I and II. The committee recommended that the Virginia Board of Dentistry adopt infection control requirements for dental assistants. In the Board's discussion, it was stated that there are no issues with infection control in Virginia. I am certain that the Board members expressing this view were indeed following best practices in their own offices. But I am not aware of anyone checking or inspecting offices for proper infection control, and so I am not sure where the belief that there is "no issue" comes from.

To fully protect the public, I ask the Board to address the incorrect infection control protocols or disinfecting and sterilization issues that are happening all over Virginia by adopting a requirement that all dental assistants be required to pass DANB's Infection Control exam.

Regarding radiography requirements:

As of March 2019, 3,698 individuals had passed DANB's Radiation Health and Safety (RHS) exam since 1997, representing less than half of all dental assistants in Virginia. This means that more than half of Virginia dental assistants have qualified to perform radiography procedures by passing the ARRT certification exam, which is not specific to dentistry and contains very little, if any, content on dental radiography, or by taking a course from a CODA-accredited program. Because many of the radiography courses offered in Virginia are themselves not accredited (though they may be offered by an accredited program), they do not follow a standard curriculum and there is significant variability in content, duration of hands-on instruction and assessment in these courses.

DANB's RHS exam is a standardized exam, the content of which is based on a formal study to determine the tasks that are actually performed by dental assistants on the job and the knowledge that is needed to perform those tasks safely and competently. Dental assistants who pass DANB's RHS exam demonstrate mastery of a standardized body of knowledge. Requiring DANB's RHS exam for all dental assistants who perform radiography procedures will provide the Virginia Board of Dentistry with the means of verifying that dental assistants who perform radiography have the required knowledge to do their jobs safely.

I agree with the petition.

[[]i] Ross, KM, Mehr, JS, et al. "Outbreak of bacterial endocarditis associated with an oral surgery practice: New Jersey public health surveillance, 2013 to 2014." J Am Dent Assoc. 2018 Mar;149(3):191-201. https://www.ncbi.nlm.nih.gov/pubmed/29397871.

[[]iii] CNN Staff. "Hepatitis C case linked to Oklahoma dentist's office." CNN.com. Cable News Network, 18 Sep. 2013. Web. 11 April 2017. http://www.cnn.com/2013/09/18/health/oklahoma-dentist-investigation-results/>.

[[]iii] Sutherly, Ben. "At least 9 Dayton VA dental patients test positive for hepatitis." DaytonDailyNews.com. Dayton Daily News, 3 Mar. 2011. Web. Accessed 26 May 2016. http://www.daytondailynews.com/news/news/local/at-least-9-dayton-va-dental-patients-test-positive/nMpfc/.

[[]iv] Hipolit, Melissa. "Whistleblower claims local pediatric dental office did not properly sanitize equipment, water lines." WTVR.com. 17 Jan 2018. https://wtvr.com/2018/01/16/dentist-blows-whistle-on-local-pediatric-dental-office/

[[]v] Garrity, Mackenzie." Virginia dental practice used unsterile equipment, class-action suit alleges." BeckersDental.com. Becker's Dental + DSO Review. 10 May 2019. https://www.beckersdental.com/dentists/34693-6-dentists-making-headlines-3.html

[[]vi] Correspondence with DALE Foundation staff. 19 Dec 2019. Comment D: 78681

Code of Virginia

Article 4. Practice of Dental Assistants.

§ 54.1-2729.01. Practice of dental assistants.

A. A person who is employed to assist a licensed dentist or dental hygienist by performing duties not otherwise restricted to the practice of a dentist, dental hygienist, or dental assistant II, as prescribed in regulations promulgated by the Board may practice as a dental assistant I.

B. A person who (i) has met the educational and training requirements prescribed by the Board; (ii) holds a certification from a credentialing organization recognized by the American Dental Association; and (iii) has met any other qualifications for registration as prescribed in regulations promulgated by the Board may practice as a dental assistant II. A dental assistant II may perform duties not otherwise restricted to the practice of a dentist or dental hygienist under the direction of a licensed dentist that are reversible, intraoral procedures specified in regulations promulgated by the Board.

Regulations of the Board

18VAC60-30-10. Definitions.

Part I

General Provisions

A. The following words and terms when used in this chapter shall have the meanings ascribed to them in § 54.1-2700 of the Code of Virginia:

"Board"

"Dental hygiene"

"Dental hygienist"

"Dentist"

"Dentistry"

"License"

B. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"CODA" means the Commission on Dental Accreditation of the American Dental Association.

"Code" means the Code of Virginia.

"Dental assistant I" means any unlicensed person under the direction of a dentist or a dental hygienist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely an administrative, secretarial, or clerical capacity.

"Dental assistant II" means a person under the direction and direct supervision of a dentist who is registered by the board to perform reversible, intraoral procedures as specified in <u>18VAC60-30-60</u> and <u>18VAC60-30-70</u>.

"Direct supervision" means that the dentist examines the patient and records diagnostic findings prior to delegating restorative or prosthetic treatment and related services to a dental assistant II for completion the same day or at a later date. The dentist prepares the tooth or teeth to be restored and remains immediately available in the office to the dental assistant II for guidance or assistance during the delivery of treatment and related services. The dentist examines the patient to evaluate the treatment and services before the patient is dismissed.

"Direction" means the level of supervision (i.e., immediate, direct, indirect or general) that a dentist is required to exercise with a dental hygienist, a dental assistant I, or a dental assistant II or that a dental hygienist is required to exercise with a dental assistant to direct and oversee the delivery of treatment and related services.

"General supervision" means that a dentist completes a periodic comprehensive examination of the patient and issues a written order for hygiene treatment that states the specific services to be provided by a dental hygienist during one or more subsequent appointments when the dentist may or may not be present. Issuance of the order authorizes the dental hygienist to supervise a dental assistant performing duties delegable to dental assistants I.

"Immediate supervision" means the dentist is in the operatory to supervise the administration of sedation or provision of treatment.

"Local anesthesia" means the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

"Monitoring" means to observe, interpret, assess, and record appropriate physiologic functions of the body during sedative procedures and general anesthesia appropriate to the level of sedation as provided in Part VI (18VAC60-21-260 et seq.) of Regulations Governing the Practice of Dentistry.

"Radiographs" means intraoral and extraoral radiographic images of hard and soft tissues used for purposes of diagnosis.

18VAC60-30-80. Radiation Certification.

A dental assistant I or II shall not place or expose dental x-ray film unless he has one of the following: (i) satisfactory completion of a radiation safety course and examination given by an institution that maintains a program in dental assisting, dental hygiene, or dentistry accredited by CODA; (ii) certification by the American Registry of Radiologic Technologists; or (iii) satisfactory completion of the Radiation Health and Safety Review Course provided by the Dental Assisting National Board or its affiliate and passage of the Radiation Health and Safety Exam given by the Dental Assisting National Board. Any certificate issued pursuant to satisfying the requirements of this section shall be posted in plain view of the patient.

DENTAL ASSISTANT REQUIREMENTS BY STATE

Ctata	Desnivements for Infection Cont.	Infection Control Notes	Dogwinsmanta for De disconsider	Dodioanaka Nata
<u>State</u> Alabama	Requirements for Infection Control Follow CDC Requirements	<u>Infection Control Notes</u>	Requirements for Radiography No Requirements	<u>Radiography Notes</u>
Alaska	Pollow CDC Requirements		No Requirements	All Dental assistants may legally operate dental x-ray equipment and perform dental radiographic procedures delegated by and under the indirect supervision of an Alaska state-licensed dentist.
Arizona			Required to pass the national DANB Radiation Health and Safety exam and receive Arizona Radiologic Proficiency Certificate (issued by DANB)*	
Arkansas	Follow OSHA and CDC Requirements	Have extensive infection control regulations	Required hold DANB CDA Certification <u>OR</u> graduate from CODA-Accredited school, <u>OR</u> Successfully complete and submit a Certificate of completion of a radiography course approved by the Board*	
California	Required for renewal to take two units of CE in Infection Control specific to California regulations.	Have extensive infection control regulations	Must be state certified in radiography. Must successfully complete a California Board-approved radiation safety course <u>OR</u> have passed a radiation exam conducted by the California Board prior to 1/1/85 *	
Colorado	Follow OSHA and CDC Requirements		Complete minimum safety education and training (there are specifications within the regulations) OR Education and training provided by on-the-job approved by Board OR Successful completion of DANB RHS OR CDA exam	
Connecticut			Required to pass the DANB Radiation Health and Safety Exam*	
Delaware			Required to Pass DANB RHS OR CDA	
DC			Required to pass DAND's RHS/CDA <u>OR</u> successfully complete a dental radiography training program approved by the Board <u>OR</u> complete in-office training and demonstrate competency	
Florida	Follow EPA, OSHA, and CDC requirements		Graduate from a Board approved program OR be state certified as a dental radiographer OR complete 3 months of on-the-job training, successfully complete board approved course, then apply for certification	
Georgia			Complete 6 hours of minimum instruction in areas defined by Georgia DHS	
Hawaii	Follow OSHA and CDC Requirements		No Requirements	
Idaho	Follow CDC and ADA requirements		No Requirements	
Illinois			No Requirements	
Indiana			Must obtain a limited dental radiographic license which require passing the DANB CDA OR RHS OR exam approved by Indiana State Department of Health	
Iowa	Shall complete continuing education in the area of infection control. Shall be standards required by CDC.		Must hold a current registration certificate and active radiography qualification issued by the Board and a dentist must provide general supervision	
Kansas		Have extensive infection control regulations	No Requirements	
Kentucky			Pass DANB RHS exam <u>OR</u> complete CODA approved course in radiation safety <u>OR</u> complete a 6 hour course approved by Board	
Louisiana			complete course approved by the Board and be under direct supervision of a licensed dentist	
Maine			Successfully complete DANB RHS <u>OR</u> CDA <u>OR</u> CODA-accredited program with a radiography exam	
Maryland			Successfully complete a Board approved course and pass the DANB RHS <u>OR</u> CDA exam*	
Massachusetts	Must complete a course on CDC guidelines and received certification from supervising dentist. Must follow CDC and OSHA.		Must be on the job trained and complete a course and pass the DANB RHS <u>OR</u> other exam approved by the Board <u>OR</u> be a Massachusetts EFCA, CA or FTDA and complete a CODA program in radiological techniques	_
Michigan			Must complete a course that is CODA equivalent	
Minnesota	Infection control course is mandatory to maintain licensure. Must also follow CDC standards.		Must be a LDA <u>OR</u> receive a limited-license permit successfully complete Board approved and CODA accredited program and pass DANB RHS exam*	

DENTAL ASSISTANT REQUIREMENTS BY STATE

State	Requirements for Infection Control	Infection Control Notes	Requirements for Radiography	Radiography Notes
			t hold a DANB CDA <u>OR</u> complete board approved seminar <u>OR</u> graduate from	
Mississippi			CODA school	
Missouri			No Requirements	
Montana		Succ	ressfully complete DANB RHS exam and certificate OR graduate from CODA	
		SHCC	school <u>OR</u> hold certification in dental radiography from US military* essfully complete a 2 day course approved by the Board OR pass DANB DCA	
Nebraska		succ	OR complete CODA school*	
Nevada	A minimum of 4 hours of CE in Infection Control every two years while employed.	I	icensed Dentist must attest that the DA is qualified to operate radiographic equipment	
New Hampshire	Must complete a Board approved course and exam in infection control. Must follow CDC standards.	pass	t hold a DANB CDA certification <u>OR</u> complete 200 experience clinical hours, dental assisting course, qualify in infection control, AND successfully complete nd duty course in dental radiology by the Board, AND pass DANB RHS exam*	
New Jersey			ust be a Dental Radiologic Technologist by completing a NJ Board approved course, Pass the DANB RHS exam OR hold a DANB CDA certification*	
New Mexico		Have extensive infection control regulations	Pass DANB RHS exam and Pass State radiography clinical exam*	
New York			No Requirements	
North Carolina		Pass	DANB CDA exam <u>OR</u> an exam approved by the Board <u>OR</u> complete CODA school <u>OR</u> be a DAII*	
North Dakota	Must complete a infection control course within 2 years prior to application. Must do two hours of infection control training to continue to be licensed.		Must be a Registered Dental Assistant <u>OR</u> Qualified Dental Assistant	
Ohio			ust be certified as a Dental X-ray Machine Operator. Must complete a Board roved course OR hold a license in another state OR be a Certified Assistant.*	
Oklahoma	Must Follow CDC standards		Complete a course of study approved by the Board*	
Oregon	Supervising dentist are responsible for assuring that	AĮ	oply to DANB for state certificate of radiologic proficiency, complete course	
Pennsylvania	DAs are trained in infection control.		approved by the Board, pass DANB RHS <u>OR</u> CDA exam* Must pass the DANB RHS exam	
Rhode Island	1 hour per year of CDC training on infection control.		Complete a course in dental radiography that is CODA accredited	
South Carolina	Must comply with CDC standards	Dip	oloma from CODA-Accredited school <u>OR</u> DANB CDA <u>OR</u> DAND RHS <u>OR</u> certificate in radiation safety from South Carolina Dental Association *	
South Dakota		Beı	registered as a Dental Radiographer, complete a 16 hour program approved by the Board OR hold DANB CDA*	
Tennessee	Must Follow CDC standards	Be	a registered DA, Successfully complete Board approved radiology course <u>OR</u> Hold current DANB CDA <u>OR</u> Pass DANB RHS exam *	
Texas	Must Follow CDC and OSHA standards	Have extensive infection control regulations	Must be a Registered Dental Assistant	
Utah		Com	plete a CODA accredited program <u>OR</u> pass DANB RHS or complete a course approved by the Board	
Vermont		N	Must be a Expanded Function Dental Assistant OR DANB Certified Dental Assistant. Successfully completed CODA-accredited course*	
Virginia	Follow CDC and OSHA standards per guidance document 60-15.	progr	satisfactorily complete radiation safety course and exam by CODA-accredited am <u>OR</u> earn certification from American Registry of Radiologic Technologists <u>OR</u> satisfactorily complete and pass DANB RHS.	
Washington	Required training in current practices in infection control.	All de	ental assistants operating x-ray equipment shall be adequately instructed in safe operating procedures and shall be able to demonstrate competency. *	
West Virginia			No Requirements	
Wisconsin			No Requirements	
Wyoming	Education program to become a dental assistant must include Infection Control.		Must complete course in dental radiography approved by the Board.*	
			* Means there are additional requirements not listed within the chart	



VIRGINIA BOARD OF DENTISTRY

Overview of Regulatory Advisory Panel regarding Sedation Regulations

• Sedation Inspections and Locations

Recommendations

- The Committee recommended that each location for sedation should be registered with the Board.
- The Committee recommended that dentist holding a permit should notify the BOD within 30 days of a change of address.
- The Committee recommended that the change in location be reflected in the MLO database.
- The Committee recommended that the each location and each dentist should have a permit for sedation.
- The Committee recommended that dentists will receive a copy of their inspection report with listed deficiencies at the time of inspection. It is recommended that dentist will be asked to correct those deficiencies within a period (15 to 30 days) and provide proof of correction.
- The Committee recommended that inspections be announced, when possible, but that there is an option of inspections being unannounced due to inspectors' schedules. The Committee recommended that if an inspection could be announced, that it is within a short period of time (1 week prior to inspection).

Not Recommended

The Committee did not recommend that a re-inspection be required prior to renewal. The Committee stated this was unnecessary, because actions would be taken if there were violations of the regulations during the last inspection, limited workforce in how the current inspection process operates, and if a facility had significant violations there would be more frequent visits to ensure compliance.

Other Discussion

 The Committee considered that the permit could be a longer length of time depending on compliance at inspection; however, the committee took into consideration that this could cause confusion, since currently sedation permits are renewed at the same time as licenses.



More Information Needed

 Having a rating score or a pass/fail score was discussed but the Committee would need more information to consider. BOD would need to define "pass" and "fail".

Inspection prior to permit being issued

Recommendations

 The Committee recommended that there should be announced initial pre-permit inspections.

Other Discussion

- The Committee proposed a possible "conditional" permit to be issued at the prepermit inspection that stated compliance with equipment, appropriate training of staff, physical plant requirements, and drug control act requirements. Then a permanent permit be issued when the dentist has performed sedation in relation to the permit issued and after the dentist is in compliance per record review from a follow up inspection. However, it was also discussed that during the pre-permit inspection the inspector will ensure that the dentist has all the necessary equipment and training required and therefore, a "conditional permit" would not be necessary.
- It was discussed that on the pre-inspection application that the dentists have been attesting that they have all the required equipment but during subsequent inspections they do not have all the necessary equipment.

• Types of Permits

Recommendations

 The Committee did recommend additional regulations for pediatric sedation and possibly a pediatric sedation permit. The Committee recommended the BOD review the National Pediatric Guidelines.

Not Recommended

o The Committee did not recommend an oral sedation permit.



• Recordkeeping

Recommendations

 The Committee recommended that regulations should address that the patient record should reflect the intended level of sedation for each patient and procedure.

• OMS Requirements for Inspections

Recommendations

- The Committee recommended that an OMS be required to submit AAMOS office examination reports when they occur. The Committee also recommended scanning this report into MLO.
- The Committee recommended that if an OMS is waiting to be certified by AAMOS and in the meantime, obtained a sedation permit, that the OMS be required to notify the BOD when they become AAMOS certified. This will require the OMS to have their sedation permit removed, to prevent further inspection and require the OMS to send the AAMOS office examination report.

• Guidance Document 60-3

Recommendations

- The Committee recommended that the term "announced" and "unannounced" be defined or more specific within the guidance document.
- The Committee recommended that the guidance document be updated to state that the dentist is required to notify the BOD when there are facility changes.
- The Committee recommended that the guidance document be updated to require, in the patient record, that the intended level of sedation be documented.

Other Concerns from the Committee

Recommendations

- The Committee recommended adding regulations regarding when dentist cancels an announced inspection.
- The Committee stated concerns about dentists utilizing a laryngoscope stating that, as a dentist, they have limited training and practice and there was a concern that if utilized the dentist would cause more damage. They stated it was more reasonable for a dentist to utilize CPR and call 911 and let an EMT who has



more experience and practice to utilize a laryngoscope. Therefore, it was recommended to review this requirement within the regulations.

- The Committee recommended that within regulations, there be the same emergency procedures for minimal sedation as there is in moderate sedation.
- The Committee recommended a requirement in regulations for emergency lighting.
- The Committee recommended addressing, in a future newsletter, from the BOD to licensee on what is involved in a sedation inspection.

Sedation Inspections by State

<u>State</u>	Each Location Must be Registered	Dentist and Location Must be Registered	Must receive on- site inspection prior to permit being issued	Minimal Sedation Permit	Oral Sedation Permit	Moderate Sedation Permit	Deep/ General Permit	Pediatric Sedation Regulations/ Permit	Re-inspection required prior to renewal	Length of time permit is good for	Location cannot be registered without equipment	Record Keeping must indicate intended level of sedation	Onsite inspection s have a pass/fail or rating score	<u>Discharge</u> <u>Regulations;</u> <u>Sedation</u> <u>related</u>
Arizona	X	X	X		X	X	X		X	1 year	X		X	
Arkansas	X	X	X			X	X	X	X	5 years	X		X	
California	X	X	X			X	X		X	2 years	X		X	
Colorado			X	X		X	X	X	X	5 years				
Connecticut	X	X	X			X	X			3 years	X		X	
Delaware	X	X	X	X		X	X			2 years	X		X	
Florida	X	X	X			X	X	X		2 years	X		X	
Georgia	X	X	X			X	X		Depending	2 years	X			
Idaho	X	X				X				5 years	X			
Kansas						X	X	X		2 years				X
Maine	X					X	X	X		?	X			X
Maryland	X	X	X			X	X		X	5 years	X		X	
Massachusetts	X	X	X	X		X	X	X		2 year	X			
Mississippi	X	X	X			X	X	X	X	5 years	X			
Missouri	X	X	X			X	X		X*see notes	5 years	X			
Montana	X	X	X			X	X		X	5 years	X			
Nebraska	X	X	X	X		X	X		Discretion	?	X			
Nevada	X	X	X			X	X		X	2 Years	X			
New Hampshire		X	X			X	X		X	5 years	X	X	X	
New Jersey	X	X	X	X		X	X		X	2 years	X			
New Mexico	X	X	X	X		X	X	X		6 years	X			
North Carolina	X	X	X	X		X	X	X	Depending	?	X		X	
North Dakota	X	X	X			X	X		X	5 years	X			
Ohio	X	X	X			X	X		X*see notes	2 Years	X		X	
Oklahoma	X	X	X			X	X	X	X*see notes	1 year	X		X	
Pennsylvania	X	X	X	X		X	X	X	X	6 years	X			
West Virginia	X	X	X			X	X				X			

EXAMINTION COMMITTEE RECOMMENDATIONS FOR CLINCAL COMPENTENCY EXAMINATIONS

At its January 31st meeting the Committee decided to recommend that the Board:

- Require a minimum passing score of 75% for acceptance.
- Not accept examination results where the passing grade received was based on compensatory scoring for parts of the examination. This action would affect acceptance of the CRDTS and WREB examinations. Compensatory scoring, as used by these testing agencies, means the grade for parts of the exam are determined by reviewing the scores given by each examiner then manipulating the examiner scores to compensate for a low score to arrive at the final score for that part of the exam.
- Adopting the following definitions:
 - > "Clinical" means having to do with the direct observation and treatment of patients.
 - > "Clinical competency examination" means evaluation, diagnosis, and prevention through live patient or manikin based methods relating to the care and treatment of patients.

The Committee also discussed membership in examinations and asked Mr. Rutkowski to research the implications of not being a member of any testing agency and being a member of more than one testing agency for discussion during the March 13 Board meeting.

Pending receipt of Mr. Rutkowski's findings, the Committee adopted a motion to recommend that the Board become a member of CITA and end its membership in SRTA.

AMENDING THE DEFINITION OF DENTISTRY IN THE CODE OF VIRGINIA

ADDING A1C TESTING IN THE DEFINITION OF DENTISTRY

At it's December 2018 meeting the Board charged the Regulatory-Legislative Committee with proposing an amendment to the definition of "Dentistry" in response to public comment asking that HbA1c testing be included in the scope of the practice of dentistry. The Committee completed its work on the assignment during its February 28, 2020 meeting.

CURRENT DEFINITION OF "DENTISTRY" IN THE CODE OF VIRGINIA:

"Dentistry" means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent and associated structures and their impact on the human body.

ADDITION TO THE DEFINITION OF "DENTISTRY" PROPOSED BY THE COMMITTEE:

"Dentistry" includes the monitoring of patient blood glucose levels through HbA1c screening, prior to comprehensive, complex, or long term treatment. HbA1c screening is discretionary.

ADDITION TO THE DEFINITION OF "DENTISTRY" PROPOSED BY STAFF AFTER THE COMMITTEE MEETING:

"Dentistry" includes blood glucose or HbA1C screening which may be done prior to comprehensive, complex, or long term treatment.

A1C TESTING INFORMATION

TAKEN FROM THE REGULATORY-LEGISLATIVE COMMITTEE 11/15/19 AGENDA PACKAGE

A1c Testing

The A1C test is a common blood test used to diagnose type 1 and type 2 diabetes and to monitor how well you're managing your diabetes. The A1C test goes by many other names, including glycated hemoglobin, glycosylated hemoglobin, hemoglobin A1C and HbA1c.

The A1C test result reflects your average blood sugar level for the past two to three months. Specifically, the A1C test measures what percentage of your hemoglobin — a protein in red blood cells that carries oxygen — is coated with sugar (glycated). The higher your A1C level, the poorer your blood sugar control and the higher your risk of diabetes complications. (Mayo Clinic, 2018)

Current CDT Codes

Code D0411 was added to the CDT Code effective January 1, 2018 and the full published entry is:

D0411 HbA1c in-office point of service testing Code (American Dental Association, 2019)

D0412 was added to the CDT Code effective January 1, 2019 and the full published entry is:

D0412 blood glucose level test – in-office using a glucose meter This procedure provides an immediate finding of a patient's blood glucose level at the time of sample collection for the point of service analysis. (American Dental Association, 2019)

Why would dentist administer the A1c?

Dentists are not expected to diagnose diabetes but in-office monitoring of patient blood glucose levels on an ongoing basis or immediately prior to treatment are appropriate activities. Findings from monitoring the patient's glycemic control may prompt a dentist to amend the patient's oral care treatment planning. (American Dental Association, 2019)

There are several factors associated with increased risk of diabetes, some of which may already be in their dental records, such as:

- Obesity or being overweight
- Ethnic background (diabetes happens more often in Hispanic/Latino Americans, African Americans, Native Americans, Asian-Americans, Pacific Islanders, and Alaska natives)
- Sedentary lifestyle (exercise less than three times a week)
- Family history (parent or sibling who has diabetes) (American Dental Association, 2019)

If a person with diabetes or at risk for the condition is about to undergo a long complex dental procedure, it is important to know their current blood glucose level – and the D0412 procedure determines the patient's blood glucose level at the time of sample collection. HbA1c measures the proportion of hemoglobin that is glycosylated (to which glucose is bound) and provides a summary measure of a patient's average circulating blood glucose level over the previous 2 to 3-month period. (American Dental Association, 2019)

Even though the patient's HbA1c percentage may indicate good glycemic control, glucose levels vary during the course of a day. Therefore, the patient's actual blood glucose level at the time of procedure delivery could be very low, or very high. (American Dental Association, 2019)

A dentist can determine, using the D0412 procedure, how the patient's blood glucose level, may affect treatment scheduled for the day's appointment.

- A glucose level below 70mg/dl is the clinical definition of hypoglycemia alert level, which means the patient is at risk of a hypoglycemic event during the procedure. Therefore, the procedure ought not be initiated until the patient's blood sugar level is in the acceptable range.
- A glucose level over 300 mg/dl could lead to delayed healing of the surgical site and severe infection. This suggests that elective surgical procedures be rescheduled and delivered when the patient's circulating glucose level is in the acceptable range. (American Dental Association, 2019)

Dentistry by State regarding A1c testing

<u>New Jersey</u>: In 2018, New Jersey Dentist were able to get paid for performing chairside diabetes screenings for at-risk patients (Stainton, 2017). In 2014, the New Jersey State Board of Dentistry ruled that dentists in New Jersey could screen at-risk patients for diabetes, and although such in-office screening is within the scope of licensure in the state, this testing is not to be presumed to be the standard of care (Richard H. Nagelberg, 2017). The New Jersey State Board of Dentistry has explicitly state that HbA1c screening is not presumed to be a standard of care (American Dental Association, 2019).

Definition of Dentistry: 45:6-19. "Practicing dentistry" defined Any person shall be regarded as practicing dentistry within the meaning of this chapter who (1) Uses a dental degree, or the terms "mechanical dentist" or the use of the word "dentist" in English or any foreign language, or designation, or card, device, directory, poster, sign, or other media whereby he represents himself as being able to diagnose, treat, prescribe or operate for any disease, pain, deformity, deficiency, injury, or physical condition of the human tooth, teeth, alveolar process, gums, cheek, or jaws, or oral cavity and associated tissues; or (2) Is a manager, proprietor, operator, or conductor of a place where dental operations are performed; or (3) Performs dental operations of any kind gratuitously, or for a fee, gift, compensation or reward, paid or to be paid, either to himself or to another person or agency; or (4) Uses himself or by any employee, uses a Roentgen or X-ray machine for dental treatment, dental radiograms, or for dental diagnostic purposes; or (5) Extracts a human tooth or teeth, or corrects or attempts to correct malpositions of the human teeth or jaws; or (6) Offers and undertakes, by any means or method, to diagnose, treat or remove stains or concretions from human teeth or jaws; or (7) Uses or administers local or general anesthetics in the treatment of dental or oral diseases or in any preparation incident to a dental operation of any kind or character; or (8) Takes impressions of the human tooth, teeth, jaws, or performs any phase of any operation incident to the replacement of a part of a tooth, teeth, or associated tissues; or (9) Performs any clinical operation included in the curricula of recognized dental schools or colleges.

<u>New York</u>: As part of their scope of professional practice, dentists licensed in New York State can perform "physical examinations" necessary to provide dental treatment safely and effectively. It is permissible for dentists to do blood glucose testing on their own patients as part of a complete physical examination when necessary. Dentists <u>cannot</u> diagnose diabetes and need to refer any patient with questionable test results to their physician. (New York State Dental Association, 2019)

<u>Definition of Dentistry:</u> § 6601. Definition of practice of dentistry.

The practice of the profession of dentistry is defined as diagnosing, treating, operating, or prescribing for any disease, pain, injury, deformity, or physical condition of the oral and maxillofacial area related to restoring and maintaining dental health. The practice of dentistry includes the prescribing and fabrication of dental prostheses and appliances. The practice of dentistry may include performing physical evaluations in conjunction with the provision of dental treatment.

<u>Oregon:</u> At its Board Meeting on December 14, 2018, the Board of Dentistry recognized that it is within the scope of practice for a licensee to perform in-office A1C diabetes screening test for at-risk patients. The Board noted that: a) such testing is not presumed to be the standard of care; and b) for A1C screenings beyond the normal range, licensees should refer patients to a physician for a formal evaluation, diagnosis, and treatment (Oregon Dental Association, 2018).

Definition of Dentistry: (7)(a) "Dentistry" means the healing art concerned with:

- (A) The examination, diagnosis, treatment planning, treatment, care and prevention of conditions within the human oral cavity and maxillofacial region, and of conditions of adjacent or related tissues and structures; and
- (B) The prescribing, dispensing and administering of prescription drugs for purposes related to the activities described in subparagraph (A) of this paragraph.
- (b) "Dentistry" includes, but is not limited to, the cutting, altering, repairing, removing, replacing or repositioning of hard or soft tissues and other acts or procedures as determined by the Oregon Board of Dentistry and included in the curricula of:
- (A) Dental schools accredited by the Commission on Dental Accreditation of the American Dental Association;
 - (B) Post-graduate training programs; or
 - (C) Continuing education courses.

North Carolina: The new American Dental Association CDT Code D0411 became effective on January 1, 2018. The code concerns a finger stick capillary HbA1c glucose test procedure. The test is a measure of the amount of glucose attached to red blood cells and directly relates to the average blood glucose levels over a certain time frame. The test can be utilized by physicians as part of a potential diagnosis of diabetes. Because only a physician can diagnose diabetes, dentists should not administer an HbA1c test to diagnose or pre-screen for diabetes. Consequently, ADA CDT Code D0411 cannot be billed in North Carolina for an HbA1c test administered to pre-screen or diagnose diabetes.

It is within the proper scope of the practice of dentistry, however, for a dentist with appropriate training, knowledge, and experience to administer the HbA1c test and use the test results to make decisions about potential dental treatment. As noted in the ADA guide on CDT Code D0411, a dentist also would need to comply with all applicable federal and state regulatory requirements to offer such tests, including the federal regulation

-- Clinical Laboratory Improvement Amendments of 1988 (CLIA). ADA CDT Code D0411 may be billed if a dentist properly administers the HbA1c test to determine appropriate dental treatment. If a dentist receives the results of an HbA1c test properly administered to determine dental treatment, which results along with other known risk factors also raise concerns about potential diabetes or pre-diabetes, it is appropriate for the dentist to make a referral to a physician for a potential diagnosis and treatment (North Carolina State Board of Dental Examiners, 2018).

<u>Definition of Dentistry</u>: b) A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:

- (1) Diagnoses, treats, operates, or prescribes for any disease, disorder, pain, deformity, injury, deficiency, defect, or other physical condition of the human teeth, gums, alveolar process, jaws, maxilla, mandible, or adjacent tissues or structures of the oral cavity;
- (2) Removes stains, accretions or deposits from the human teeth;
- (3) Extracts a human tooth or teeth;
- (4) Performs any phase of any operation relative or incident to the replacement or restoration of all or a part of a human tooth or teeth with any artificial substance, material or device;
- (5) Corrects the malposition or malformation of the human teeth;
- (6) Administers an anesthetic of any kind in the treatment of dental or oral diseases or physical conditions, or in preparation for or incident to any operation within the oral cavity; provided, however, that this subsection shall not apply to a lawfully qualified nurse anesthetist who administers such anesthetic under the supervision and direction of a licensed dentist or physician;
- (6a) Expired pursuant to Session Laws 1991, c. 678, s. 2.
- (7) Takes or makes an impression of the human teeth, gums or jaws;
- (8) Makes, builds, constructs, furnishes, processes, reproduces, repairs, adjusts, supplies or professionally places in the human mouth any prosthetic denture, bridge, appliance, corrective device, or other structure designed or constructed as a substitute for a natural human tooth or teeth or as an aid in the treatment of the malposition or malformation of a tooth or teeth, except to the extent the same may lawfully be performed in accordance with the provisions of G.S. 90-29.1 and 90-29.2;
- (9) Uses a Roentgen or X-ray machine or device for dental treatment or diagnostic purposes, or gives interpretations or readings of dental Roentgenograms or X rays;
- (10) Performs or engages in any of the clinical practices included in the curricula of recognized dental schools or colleges;
- (11) Owns, manages, supervises, controls or conducts, either himself or by and through another person or other persons, any enterprise wherein any one or more of the acts or practices set forth in subdivisions (1) through (10) above are done, attempted to be done, or represented to be done;
- (12) Uses, in connection with his name, any title or designation, such as "dentist," "dental surgeon," "doctor of dental surgery," "D.D.S.," "D.M.D.," or any other letters, words or descriptive matter which, in any manner,

represents him as being a dentist able or qualified to do or perform any one or more of the acts or practices set forth in subdivisions (1) through (10) above;

(13) Represents to the public, by any advertisement or announcement, by or through any media, the ability or qualification to do or perform any of the acts or practices set forth in subdivisions (1) through (10) above.

Factors to consider

- Scope of Practice/knowledge
- Referral considerations: closing the referral loop, what to do with the results if pt. doesn't have a PCP.
- Equipment needed
- Ethical obligations
- Documentation

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Clinical Laboratory Improvement Amendments (CLIA)

How to obtain a CLIA Certificate of Waiver

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. While every effort has been made to ensure the accuracy of this restatement, this brochure is not a legal document. The official CLIA program requirements are contained in the relevant law, regulations and rulings. Please note that state, local, and accreditation requirements may be more stringent.

What is a laboratory?

Under CLIA, a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.



I am a physician performing urine dip sticks and finger sticks for blood glucose in my office as part of the patient's visit. Am I considered to have a laboratory and do I need a CLIA certificate?

Generally yes, as those tests likely qualify as waived laboratory testing, you need a CLIA Certificate of Waiver and you must follow the manufacturer's instructions. This kind of testing requires a CLIA certificate regardless of how many tests you perform, even if you do not charge the patient or bill Medicare or other insurances. However, you may not need a CLIA certificate if your laboratory is located in the states of New York or Washington, as those States operate their own laboratory regulatory programs. Contact the appropriate State Agency to determine if you need a CLIA certificate.

What is a waived test?

As defined by CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews manufacturer's applications for test system waiver.

Where can I find a list of waived tests?

For a list of waived tests sorted by analyte name, visit the FDA website at: <u>CLIA – Currently Waived Analytes</u>

Can I perform tests other than waived tests if I have a Certificate of Waiver?

No, only those tests that are CLIA-waived can be performed by a laboratory with a Certificate of Waiver.

How do I enroll in or apply to the CLIA program?

You can enroll your laboratory in the CLIA program by completing an application (Form CMS-116) available on the CMS CLIA website or from your local State Agency. Send your completed application to the address of the local State Agency for the State in which your laboratory is located. Additionally, check with your State Agency for any other state-specific requirements. If you do not have online access and do not have information about your State Agency, you may contact the CLIA program at 410-786-3531 for the address and phone number of your State Agency.

If I have more than one office and perform waived testing at more than one site, do I need additional certificates

You will need a CLIA certificate for *each* site where you perform testing, *unless* you qualify for one of the exceptions listed below:

- If your testing location changes, such as with mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, the testing may be covered under the certificate of the designated primary site or home base, using its address.
- If you are performing limited public health testing, you may file a single application to cover multiple locations. Limited public health testing is defined as not-for-profit or Federal, State or local government laboratories that engage in limited testing (not more than a combination of 15 moderately complex* or waived tests per certificate). So you may be able to cover the waived testing you perform at more than one office if you meet this exception.
- If your testing locations are within a hospital and are located at contiguous buildings on the same campus and under common direction, you may file a single application for the laboratory sites within the same physical location or street address.

Contact your <u>State Agency</u> if you have questions or you are filing a single application for more than one testing site.

*Laboratory tests regulated under CLIA are categorized by the FDA as either waived, moderate complexity or high complexity based on set criteria.

Will I receive an identifying CLIA number?

You will receive a ten-character alpha-numeric code on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

When can I start performing the waived testing?

After you apply for your certificate, you will receive a fee coupon assessing a fee. Follow the instructions on the fee coupon for payment. After your payment is received, your certificate will be mailed to you. You generally may begin testing once you have received your CLIA certificate, but you also need to check with your <u>State Agency</u>, since some states have additional state-law requirements.

If I only perform waived tests, what does CLIA require that I do?

For waived testing, CLIA requires that you:

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturer's instructions for the waived tests you are performing; and
- Notify your <u>State Agency</u> of any changes in ownership, name, address or Laboratory Director within 30 days, or if you wish to add tests that are more complex.

How and when will I be inspected?

Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program, but may be surveyed in response to a complaint or if they are performing testing that is not waived.

What does it mean to follow the manufacturer's instructions for performing the test?

To follow the manufacturer's instructions for performing the test means to follow *all of the instructions in the package insert from "intended use" to "limitations of the procedure."* The manufacturer's instructions can be found in the package insert for each test. It is good laboratory practice and important to read the entire package insert before you begin testing. Be sure the package insert is current for the test system in use, the correct specimen type is used, the proper reagents (testing solutions) are added in the correct order, and the test is performed according to the step by step procedure outlined in the package insert.

Some waived tests also have quick reference instructions included, which are cards or small signs containing diagrams or flow charts with essential steps for conducting the test. Be sure that quick reference instructions are current for the test system in use and are available to the individuals performing the test.

How do I know if I have current manufacturer's instructions?

Always use the package insert or quick reference instructions that come with the test system you just opened. If you are unsure whether you have current instructions, contact the manufacturer at the telephone number listed in the package insert.

Why is it important to follow the current manufacturer's instructions?

It is important to always follow the current test system's instructions precisely to be sure your results are accurate. This includes performing any quality control procedures that the manufacturer recommends or requires. Over time, a manufacturer may make

modifications to a test system that result in changes to the instructions. Failure to use the current instructions could cause inaccurate results that may result in a misdiagnosis or delay in proper treatment of a patient.

Do I need to follow all the manufacturer's instructions on how to perform the test?

Yes, *all* the information in the test package insert instructions is considered part of the manufacturer's instructions and must be followed. Some examples of this information are:

- Observing storage and handling requirements for the test system components;
- Adhering to the expiration date of the test system and reagents, as applicable;
- Performing quality control, as required by the manufacturer;
- Performing function checks and maintenance of equipment;
- Training testing personnel in the performance of the test, if required by the manufacturer:
- Reporting patients' test results in the units described in the package insert;
- Sending specimens for confirmatory tests, when required by the manufacturer; and
- Ensuring that any test system limitations are observed.

Can I follow the quick reference guide instead of following the package insert?

No, the quick reference guide is only a synopsis of the entire package insert.

When performing waived testing, am I required to do everything in the instructions, even if some of the items are manufacturer's recommendations or suggestions?

Yes, you must follow all instructions when such terms as "always," "require," "shall," and/or "must" are used by the manufacturer.

You have the option to follow the recommendations or suggestions of the manufacturer. However, adhering to the manufacturer's recommendations and suggestions will help ensure the accuracy and reliability of the test, and is considered good laboratory practice.

As a laboratory director, what kinds of things can I do to help ensure the accuracy and reliability of the waived testing in my laboratory?

In order to ensure the accuracy and reliability of waived testing in your laboratory, you should develop and maintain good laboratory practices. Some examples are listed below:

- Provide specific training to the testing personnel so that you are certain they:
 - Collect specimens appropriately;
 - Label and store specimens appropriately;
 - Understand and then follow the manufacturer's instructions for each test performed;
 - Know how to perform the testing;
 - Know how to document and communicate the test results; and
 - Are able to identify inaccurate results or test system failures.
- Observe and evaluate your testing personnel to make certain the testing is accurate.
 - Do they positively identify the patient and specimen?
 - Do they collect a proper specimen?
 - Do they know how the specimen should be preserved, if applicable?
 - If the specimen needs to be transported, do your testing personnel understand and adhere to the transport requirements?
- Check for extreme changes in such things as humidity, temperature, or lighting; as these may affect test results.
- Make sure that the patient specimen is handled properly from collection to test completion.

Where can I find more information about good laboratory practices?

The Centers for Disease Control and Prevention has published recommendations for "Good Laboratory Practices for Waived Testing Sites" in *Morbidity and Mortality Weekly Reports (MMWR); Recommendations and Reports.* The MMWR publication provides comprehensive recommendations for facilities that are considering introducing waived testing or offering a new waived test, and good laboratory practices to be followed before, during, and after testing. You can find this article on the CDC CLIA Waived Testing website.

Additionally, there are free educational materials on waived testing on the <u>CDC Division</u> of <u>Laboratory Systems website</u>.

Can I make any changes to the test system instructions?

No, it is not acceptable for you to make changes to the current instructions provided with the test system. This could change the "intended use" of the test system as approved by FDA and result in a test that is *no longer waived*. For example, if a test specifies urine as the waived specimen type and you test a different body fluid, then you are no longer performing a waived test and your laboratory is subject to an inspection and additional CLIA requirements. You must be sure that testing personnel follow the directions exactly, and add the proper reagents in the correct order and amount given by the manufacturer to ensure correct test results.

Where can I get additional information?

For additional information, you can email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov.

CLIA Law & Regulations

CDC CLIA website

FDA CLIA website

Hyperlink Table

Embedded Hyperlink	Complete URL			
CLIA – Currently Waived Analytes	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm			
Form CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/ Downloads/CMS116.pdf			
CMS CLIA website	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/ index.html?redirect = /CLIA/			
State Agency	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/ <u>Downloads/CLIASA.pdf</u>			
"Good Laboratory Practices for Waived Testing Sites"	https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf			
CDC CLIA Waived Testing website	https://wwwn.cdc.gov/clia/Resources/WaivedTests/default.aspx			
CDC Division of Laboratory Systems website	https://www.cdc.gov/csels/dls/educational-materials.html			
CLIA Law and Regulations	https://wwwn.cdc.gov/clia/Regulatory/default.aspx			
CDC CLIA website	https://wwwn.cdc.gov/clia/default.aspx			
FDA CLIA website	https://www.fda.gov/MedicalDevices/DeviceRegulationand Guidance/IVDRegulatoryAssistance/ucm124105.htm			



Disciplinary Report

Today's report reviews the 2019 Calendar year case activity and 2020 Calendar quarter 1 case activity.

Calendar Year 2019

The table below includes all cases that have received Board action since January 1, 2019 through December 31, 2019

Year 2019	Cases Received	Cases Closed No/Violation	Cases Closed W/Violation	Total Cases Closed
Jan	33	20	1	21
Feb	36	33	1	34
Mar	34	39	4	43
Apr	48	30	3	33
May	46	71	2	73
Jun	33	46	4	50
Jul	37	19	3	22
Aug	30	37	2	39
Sept	43	31	6	37
Oct	46	25	2	27
Nov	40	49	1	50
Dec	34	24	4	28
TOTALS	460	424	33	457

Closed Case with Violations consisted of the following:

Patient Care Related:

- <u>11 Standard of Care: Diagnosis/Treatment:</u> Instances in which the diagnosis/treatment was improper, delayed, or unsatisfactory. Also, include failure to diagnose/treat& other diagnosis/treatment issues.
- <u>4 Cases of Unlicensed Activity</u>: Practicing a profession or occupation without holding a valid license as required by statute or regulation to include: practicing on a revoked, suspended, lapsed, expired license, as well as aiding and abetting the practice of unlicensed activity.
- <u>4 Standard of Care-Malpractice Reports:</u> a judgement or settlement as well as other malpractice related issues.
- <u>2 Cases of Drug Related-Patient Care</u>: Dispensing in violation of DCA (to include dispensing for non-medicinal purposes, excessive prescribing, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use.
- <u>2 Inability to Safely Practice</u>: Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions.



Disciplinary Report

- **2** Abuse/Abandonment/Neglect: Any sexual assault, mistreatment of a patient, inappropriate termination of provider/patient relationship, leaving a patient unattended in a health-care environment, failure to do what a reasonable person would do in a similar situation.
- <u>1 Fraud-Patient Care:</u> Performing unwarranted/unjust services or the falsification/alteration of patient records.
- <u>1 Standard of Care- Surgery</u>: Improper/unnecessary performance of surgery, improper patient management, and other surgery-related issues.

Non-Patient Care Related:

- <u>3 Business Practice Issues</u>: Advertising, default on guaranteed student loan, solicitation, records, inspections, audits, self-referral of patients, required report not filed, prescription blanks, or disclosure.
- **1 HPMP**: Dismissal, vacated stay and non-compliance.
- 1 Compliance: Violation of a board order term or probation violation.
- <u>1 Record Release:</u> Failure or delay in the release of patient records. Charging excessive fees for records requests.

CCA's

There were <u>7</u> CCA's issued in 2019. The CCA's issued consisted of the following violations (some CCA's had several violations and some just had one violation):

- All 7 had Business Practice Issues
- 2 had Standard of Care: Diagnosis/Treatment
- 1 had Unlicensed Activity:
- 1 had Fraud-Non-Patient Care: Improper patient billing

Suspensions/Revocations

There were 4 Suspensions or Revocations issued in 2019. They were:

- 1 Mandatory Suspension for Criminal Activity: 4 Felonies
- 1 Stayed Suspension for Inability to Safely Practice and Drug Related- Patient Care
- 1 Revocation for Drug Related-Patient Care
- <u>1 Indefinite Suspension for Inability to Safely Practice</u>



Disciplinary Report

Calendar Year 2020

The table below includes all cases that have received Board action since January 1, 2020 through February 29, 2020.

Year 2020	Cases Received	Cases Closed No/Violation	Cases Closed W/Violation	Total Cases Closed
Jan	44	26	4	30
Feb	45	35	6	41
TOTALS	89	61	10	71

Closed Case with Violations consisted of the following:

Patient Care Related:

- <u>6 Standard of Care: Diagnosis/Treatment:</u> Instances in which the diagnosis/treatment was improper, delayed, or unsatisfactory. Also, include failure to diagnose/treat& other diagnosis/treatment issues.
- <u>1 Cases of Drug Related-Patient Care</u>: Dispensing in violation of DCA (to include dispensing for non-medicinal purposes, excessive prescribing, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use.
- <u>1 Inability to Safely Practice</u>: Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions.
- <u>1 Abuse/Abandonment/Neglect:</u> Any sexual assault, mistreatment of a patient, inappropriate termination of provider/patient relationship, leaving a patient unattended in a health-care environment, failure to do what a reasonable person would do in a similar situation.

Application Related:

• 1 Reinstatement: An application or request for re-issuance of a previously held license.

CCA's

There has been **1** CCA issued in 2020. The CCA issued consisted of the following violation:

1 Standard of Care: Diagnosis/Treatment

Suspensions/Revocations

There has been **1** Suspension issued in 2020.

• 1 Mandatory Suspension for Criminal Activity: 1 Felony

Ethics and Boundaries Assessment Services LLC



Ethics and Boundaries Assessment Services LLC (EBAS) offers an essay exam that assesses an individual's understanding of ethics and boundaries in a professional setting.

- Boundaries
- Unprofessional Conduct
- Professional Standards
- Fraud
- Substance Abuse



EBAS Essay Exam

Examinees are presented with realistic, hypothetical scenarios and asked to submit an appropriate response.

From the scenarios presented, the examinee is required to

- Identify ethical issues
- Discuss consequences
- Discuss solutions
- Explain how the unethical actions compromise the community's safety and welfare

Test Administration

The EBAS exam is an online essay exam administered at Prometric Testing Centers. Prometric offers easy appointment scheduling and predictable exam delivery.

Experienced Graders

EBAS graders come from diverse backgrounds and have one thing in common, they all have regulatory experience.

Essays are scored by seven graders, none of which are from the examinees state.

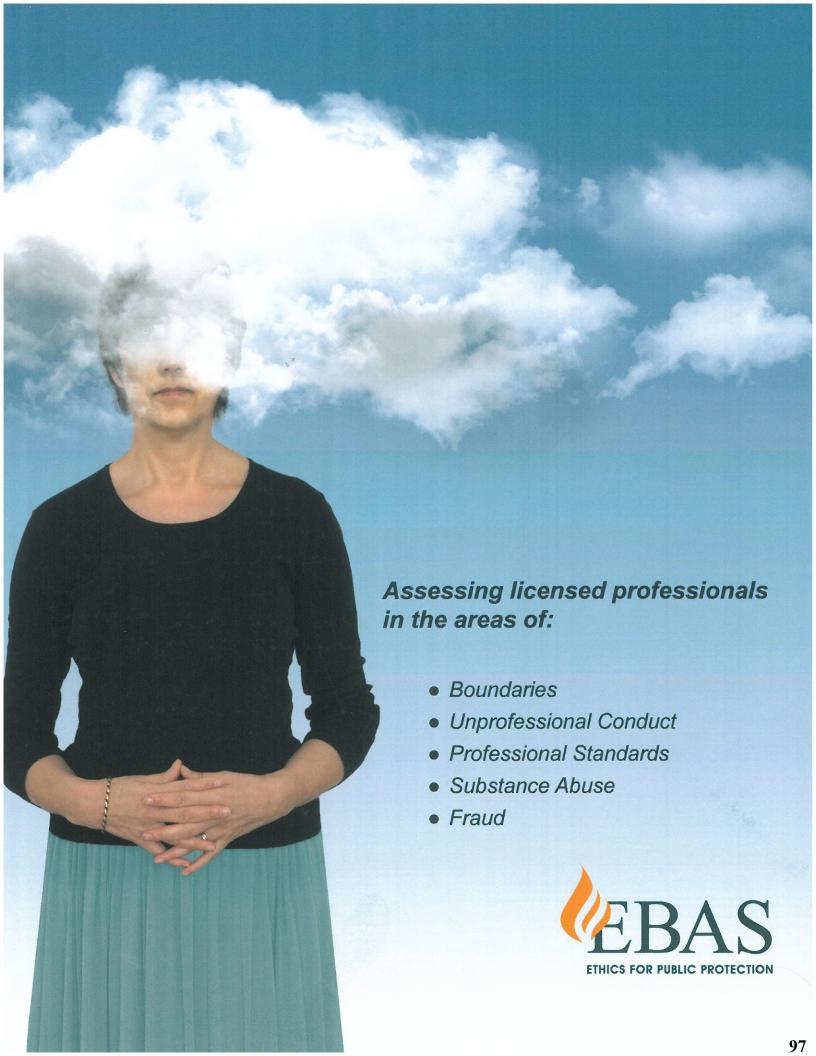
Score Report

Each essay has a maximum score of 16 points and 12 points is a passing score.

A Score Report is sent to the examinee and regulatory board designated on the application, approximately three weeks after the exam is taken.



901 54th Avenue Greeley, CO 80634



THEY DID WHAT FFF

Engaging in a financial arrangement

with a patient

Sexual relationship with patient

Photography without patient consent

Making financial decisions on behalf of the

patient.

Verbal or sexual harassment

Criminal conviction

Unprofessional Conduct Domestic violence

HIPAA violation and use of social media

Escalated personality conflict with colleagues

Refusal to treat a patient **Professional Standards**

Patient abuse or abandonment

OSHA violation

Failure to make appropriate referrals

Impairment due to the use of alcohol or other

substances/drugs (legal or illegal)

Drug diversion

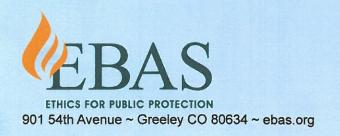
Falsifying records and signatures

Misrepresentation of credentials

Practicing on an expired license

Falsification of credentials

WE COVER THAT !!!



Substance Abuse

Fraud

ETHICS AND BOUNDARIES ASSESSMENT SERVICES LLC



Assessing Licensed Professionals in the Areas of

- Boundaries
- Unprofessional Conduct
- Fraud
- Professional Standards
- Substance Abuse



Ethics and Boundaries Assessment Services LLC



Ethics and Boundaries Assessment Services LLC

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WWW.EBAS.ORG

888.676.3227



Application

Apply for the exam at www.EBAS.org.

Electronically submit your application and funds or print a blank application, enter the information manually, and mail the application and guaranteed funds to EBAS.

EBAS-Application 901 54th Avenue Greeley CO 80634

Fee: \$300 per section \$1500 for complete exam

EBAS does not accept business or personal checks.

Retaking the exam, follow the same process.

Scheduling Your Exam

You will be notified by email when you can schedule your exam. The email will contain your EBAS ID number, which is necessary to schedule the exam.

To make an appointment:

Online: Visit Prometric at www.Prometric.com

Telephone: Call Prometric at 888-287-8238.

There is a \$50 reschedule/cancellation fee if done within 29-5 days of the appointment date.

Score Report

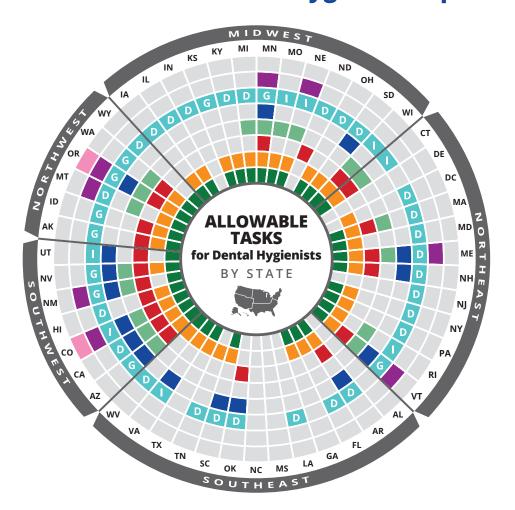
Essays are scored by seven graders all with regulatory experience, none of which are from your state.

Each essay has a maximum score of 16 points and 12 points is a passing score.

If you score below 12 points, only the failed essay topics from the original exam need to be retaken.

A Score Report will be sent to you and the regulatory board designated on your application approximately three weeks after the exam is taken.

Variation in Dental Hygiene Scope of Practice by State



The purpose of this graphic is to help planners, policymakers, and others understand differences in legal scope of practice across states, particularly in public health settings.

Research has shown that a broader scope of practice for dental hygienists is positively and significantly associated with improved oral health outcomes in a state's population.^{1,2}

Dental Hygiene Diagnosis

Prescriptive Authority

Local Anesthesia

D Direct I Indirect G General

Supervision of Dental Assistants

Direct Medicaid Reimbursement

Dental Hygiene Treatment Planning

Provision of Sealants

Direct Access to Prophylaxis

Not Allowed / No Law

Dental Hygiene Diagnosis

The identification of oral conditions for which treatment falls within the dental hygiene scope of practice, as part of a dental hygiene treatment plan.

Prescriptive Authority

The ability to prescribe, administer, and dispense fluoride, topical medications, and chlorhexidine.

Local Anesthesia

The administration of local anesthesia.

LEVEL OF SUPERVISION

- **Direct:** The dentist is required to be physically present during the administration of local anesthesia by the dental hygienist.
- Indirect: The dentist is required to be on the premises during the administration of local anesthesia by the dental hygienist.
- **General:** The dentist is required to authorize the administration of local anesthesia by the dental hygienist but is not required to be on the premises during the procedure.

Supervision of Dental Assistants

The ability to supervise dental assistants when performing tasks within the dental hygiene scope of practice.

Direct Medicaid Reimbursement

The direct Medicaid reimbursement of dental hygiene services to the dental hygienist.

Dental Hygiene Treatment Planning

The ability of a dental hygienist to assess oral conditions and formulate treatment plans for services within the dental hygiene scope of practice.

Provision of Sealants Without Prior Examination

The ability of a dental hygienist working in a public health setting to provide sealants without prior examination by a dentist.

Direct Access to Prophylaxis from a Dental Hygienist

The ability of a dental hygienist working in a public health setting to provide prophylaxis without prior examination by a dentist.

Not Allowed / No Law

Sources: 1. Langelier M, Baker B, Continelli T. Development of a New Dental Hygiene Professional Practice Index by State, 2016. Rensselaer, NY: Oral Health Workforce Research Center, Center for Health Workforce Studies, School of Public Health, SUNY Albany; November 2016. 2. Langelier M, Continelli T, Moore J, Baker B, Surdu S. Expanded Scopes of Practice for Dental Hygienists Associated With Improved Oral Health Outcomes for Adults. Health Affairs. 2016;35(12):2207-2215.

 $http://www.oralhealthworkforce.org/wp-content/uploads/2017/03/OHWRC_Dental_Hygiene_Scope_of_Practice_2016.pdf$

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