E X H I B I T S

(COMMENCED AT 10:04 A.M.)

HEARING OFFICER ROBERTS: Welcome. We are here today regarding a public hearing concerning the Rules and Regulations for Dentists, Dental Hygienists and Dental Assistants. This hearing is being conducted under the provisions of Rhode Island General Laws 23-17 and 42-35. Today is Tuesday, September 11, 2018. My name is Sullivan Roberts, Rules Coordinator for the Rhode Island Department of Health, also known as RIDOH, and I will be the Hearing Officer for today's proceeding.

Before we start, and to prevent any interruption of the proceedings, at this time, I would like to ask those of you with cell phones, pagers and watch alarms to turn them off or set them to vibrate.

(PAUSE)

HEARING OFFICER ROBERTS: The purpose of the hearing today is to afford interested parties an opportunity to comment on the proposed Regulations, allow as many people as possible to be heard and to ensure that an

accurate record of all comments is obtained.

This hearing is intended for your participation only and is not intended to provide a forum or discuss being, debating, arguing or otherwise having any dialogue on the Regulations before us with RIDOH personnel as part of this public hearing. If you would like to speak, the procedure we will use is as follows: Please register to speak at the rear of the room. Speakers will be taken in order of registration. Up to five minutes will be allowed for your presentation, unless the lack of speakers allows for additional time. Any interruptions due to the Stenographer's need to clarify your testimony will not count against your allotted time. If you are reading off of a prepared document such as a paper copy or electronic version of your testimony, we politely request that you speak clearly and at a unhurried pace so the Stenographer can appropriately capture your testimony in its entirety.

I will indicate when you have one minute of time remaining. If you are

unable to complete your testimony in the time allotted, you may have an opportunity to speak if any time is remaining after the other speakers who have signed up complete their testimony. When you are called, come to the podium, identify yourself by name and affiliation, if any. Please spell your name and give the full name of your organization, if you used an acronym, such as NASA. Make your presentation and make sure you conclude in the allotted time of five minutes. If you have a written copy of your statement, we would appreciate if you could provide it for the record. If you read from an electronic version of your testimony, we would appreciate if you could provide a hard copy or e-mail us your testimony.

In accordance with the requirements of the Administrative Procedures Act, additional written comments on these proposed amendments will be accepted by Monday, September 17, 2018. After the conclusion of the public comment period, RIDOH has four options under State law.

The first option is to file the Regulations as posted with the Secretary of State.

The second option is to file with minor technical changes such as correcting spelling, punctuation, et cetera.

The third option is to make non-technical changes in what you see before you today, which would be addressed in RIDOH's concise explanatory statement filed with the final Regulations and could also necessitate a new public hearing and associated public notice posting.

And the fourth option is not file the proposed Regulations, in which case the current Regulations would remain in effect. Unless specified by law or regulation or at the discretion of RIDOH, once filed, the Regulations become effective 20 days after filing and have the force of law upon that date.

Are there any questions on how the public hearing will be conducted today?

(PAUSE)

HEARING OFFICER ROBERTS: At this time, for the record, we will have a presentation of exhibits. The first exhibit is the Notice of Proposed Rule Making posted on the Rhode Island Secretary of State's web site on August 15, 2018.

(EXHIBIT 1, NOTICE OF PUBLIC HEARING, MARKED)

HEARING OFFICER ROBERTS: The second exhibit is a copy of the proposed Regulations with provisions indicated also posted to the Rhode Island Secretary of State's web site on August 15, 2018.

(EXHIBIT 2, PROPOSED REGULATIONS, MARKED)

HEARING OFFICER ROBERTS: The third exhibit is a copy of the existing Rules and Regulations Pertaining to Dentists, Dental Hygienists and Dental Assistants, last filed with the Rhode Island Secretary of State in June of 2017.

(EXHIBIT 3, EXISTING REGULATIONS, MARKED)

HEARING OFFICER ROBERTS: The fourth exhibit is a copy of Rhode Island General Laws 5-31.1-4 and 5-31.1-5, the enabling statutes for these Regulations.

(EXHIBIT 4, RIGL 5-31.1-4 AND 5-31.1-5, MARKED)

HEARING OFFICER ROBERTS: The fifth and final exhibit is a copy of the e-mail dated August 10, 2018 from the Office of Regulatory Reform to Sullivan Roberts confirming that RIDOH was authorized to move forward with promulgation of these Regulations.

(EXHIBIT 5, OFFICE OF REGULATORY REFORM LETTER, MARKED)

HEARING OFFICER ROBERTS: At this time, I would like to call the first speaker. Charles J. Cote.

DR. COTE: So, my name is Charles J. Cote, I'm a Board certified pediatrician and pediatrician anesthesiologist. I have been the primary author of the American Academy of Pediatrics Association Guidelines since the first publication in 1985 and every

iteration since then, so I feel very qualified to be able to address issues in this proposed legislation that attempt to quote from our AAP Guideline.

During the intervening years, I became aware of the adverse drug reports from the Food and Drug Administration, and through the Freedom of Information Act, I requested those reports. Obtained about 700. We also got reports from the United States Pharmacopeia and a survey that we sent to members of the Academy of Pediatrics. Two anesthesiologists, one ER physician and one ICU physician debated the causes of the adverse health problems and we ended up with 95 cases where we felt we could agree on what happened. And of those 95 cases, 60 had death or neurologic injury as the end point and 29 of these were related to dental care. 80 percent of these children seem to present with a desaturation, meaning that they turn blue and should have been able to be rescued, but the practitioners involved did not have the necessary skills to rescue the child.

Interestingly, there was a

three-fold greater instance of cardiac arrest associated with these non-hospital events compared with hospital events with a 93 percent mortality. So, when something went wrong in the dental office setting, the outcomes were dismal. Parenthetically, eleven of these dentists were described as oral surgeons, although we really couldn't tell what their true education or training was. I can say had I known that this dentistry was going to be so highly represented, I would have invited an oral surgeon or pediatric dentist or both to help us analyze the data.

I have grave concerns about the current bill, because at the beginning it states that this bill is consistent with the guidelines of the American Academy of Pediatrics, and I take, I have a lot of concerns about that, because it clearly does not have anything at all related to the Academy of Pediatrics. And I have detailed a whole bunch of different areas where this is a problem, but we don't have time to talk about that.

What I'm concerned about, though, is this independent practice of an oral surgeons who can direct sedation with a dental assistant, who's, the dental anesthesia assistant certification exam DANCE, D-A-N-C-E, which is fulfilled by taking 36 hours of an Internet course and taking an examination. In these 36 hours, they are supposed to learn basic science, how to evaluate and prepare patients, understand anesthetic drugs and anesthetic techniques, anesthesia, anesthesia equipment and monitoring and office anesthesia emergencies. It took me three years to learn that, and yet, these people are expected to learn this in 36 hours of Internet time.

The other thing that's of interest, there doesn't seem to be any educational requirements for these DANCE-trained individuals. It doesn't even say they have to have a high school certificate. It appears that they have on-the-job training with an oral maxillofacial surgeon, and then they take this test, and then they are DANCE certified. So, it says that, in their

guideline, that there has to be either basic life support or CPR certified, and it doesn't mention PAL certified; and if they are going to be taking care of children, obviously I think they need to be PAL certified.

I think you know all know that when something hatches, push comes to shove, you want to have medically trained people there to assist with the emergency; and these individuals have no real life experience that could provide them with the medical knowledge to assist an oral surgeon with any life-threatening emergency, such as a child who stopped breathing due to the effects of the medication. The child developed spasms of the muscle of the voice box. Seizure from a local anesthetic. Drug overdose or allergic reaction or other medical emergencies that can arise. These can happen in anybody's hands. Certainly I have had these happen to myself over the years. Is there a timer?

HEARING OFFICER ROBERTS: Yes.

DR. COTE: How much time do I have left?

HEARING OFFICER ROBERTS: That was your five minutes.

DR. COTE: You didn't give me a warner.

HEARING OFFICER ROBERTS: If you're unable to complete your testimony in the time allotted, you may have an opportunity to speak after the other speakers who are signed up complete their testimony. Thank you. The next speaker is Cynthia Johnson.

MS. JOHNSON: Good morning. Good morning, I'm Cynthia Johnson. I am a professor at the Community College of Rhode Island, and I am speaking to the 2.9 Public Health Dental Hygiene Practice Act. The reason why I'm speaking on this is because in the new guidelines it has spoken about not having the courses come from an accredited institution. CCRI and myself and a few of the faculty were contacted by the Department of Health once this Practice Act was put into place last, excuse me, summer of 2017. So, when we were contacted, we were asked to create some courses based upon the Practice Act. One was medical

emergencies. Another was infection control. Another was being investigated for risk management. With the -- we met several times with Dr. Zwetchkenbaum, and we had come up with two courses that we were going to run, which was the medical emergencies for the public health dental hygienist and also the infection control for the public health dental hygienist. These classes are web-based courses. They run for five weeks; and from the feedback we have gotten from the people that took the course, and it was very positive; and I do have their evaluations with me here today.

The reason why I'm speaking upon this is because now they are trying to make these courses come from a non-accredited site. We were told back in April that the risk management course could be taken or another course in the Rhode Island Dental Association. So, myself and several of the dental hygienists took that course. I, myself, am a public dental hygienist. I also met with Dr. Zwetchkenbaum and made another course, the risk management course. The risk management course

that I have created, again, is on line. It's web-based. It run for five weeks, and it goes over the all the collaborative agreement and all of the tool kit they will need to become dental public health hygienists. One of the web sites that I could go to become a public health hygienist and take the risk management course I went to and I noted that there was some information that was lacking in those particular web sites as well as the course that I took with the Rhode Island Dental Association in May. I have many people, health hygienists, that have come to me that took that course and wanting more guidance. I was happy to give them that guidance within that; but within the risk management course that we offer at CCRI, we incorporated all of those questions and answers.

Also, within the risk management course at CCRI, we incorporated a business management plan as well and we also reviewed the rules and regulations of the public health dental hygienists, which were very confusing for some of the people in this program in the

courses that we teach. From our courses and from our evaluations, it has been noted that every dental hygienist that took the course felt that they had gained something. They had felt that they had changed their practices within our course work and had gained better knowledge within our courses that we taught.

So, I am here today seeking support from the Department of Health, from Dr. Zwetchkenbaum, from the Board to keep these courses to be an accredited course, knowing all the work and the consciousness that our college puts forth in teaching our courses in general and also with these public health hygiene courses, we offer a lot of support to our the students, and we offer a lot of guidance to our students within these courses. Even once they go out and they receive these credentialing, they still come back and I'm still answering their questions, which if they take some other courses, they might not receive that support. I am asking for the continued support of the Board and the Department of Health considering that you had come to us first within these

courses. Thank you so much.

HEARING OFFICER ROBERTS: Thank you. The next speaker is Julie Galleshaw.

MS. GALLESHAW: Hi, can you hear me?

AUDIENCE: Yes.

MS. GALLESHAW: All right. I, first, would like to introduce myself. I'm Julie Galleshaw, J-U-L-I-E, G-A-L-L-E-S-H-A-W, professor of dental health at the Community College of Rhode Island. I am also a newly licensed public health dental hygienist. I would like to specifically speak to Section 2.9.1, qualifications within the draft pertaining to 2.9, the Public Health Dental Hygiene Practice. I was at the original meeting of the draft as a public member. I took part in several meetings in which lengthy discussion took place on the specifics of this particular section of the Regulations. The final version that was submitted has been changed by this Department in format, punctuation and intent.

I am here because I feel these

changes have taken away the intent of producing safe and competent public health dental hygienists for the community. The Department and Board are here to ensure that all dental professionals practicing in the State of Rhode Island meet the requirements for licensure to protect the public. With that said, the new version in front of us today has been changed from its original draft; and in my opinion, not upholding the standard of creating a competent public health dental hygienist. The first error and change made by the Department of Health was the change in placement of the colon. The colon was to be after the words public health fundamentals, colon. In order to start the enumeration of the courses to be taken to meet the educational requirements and not placed after the word insurance. I am submitting with this statement the original documents draft and the corrected version as evidence of what needs to be corrected to regain the original documents intent of what qualifications need to be met in order to obtain a public health dental hygiene license.

The second change made by the Department of Health is in Section 2.9.1B1-B after the word accreditation, the words, comma, or by the program appointed by the Board or the Department were added. I feel the Department of Health has overstepped its authority by placing these words and superceding the Board. The Board in all areas of the Rules and Regulations is the determining entity for course approval for the Department and not the Department itself. Nor is the word Department defined in these Rules and Regulations to mean the Department of Health, specifically to dentistry. Nor is it stated anywhere else in these Rules and Regulations the Department is to be able to approve any course for licensure or license renewal. If the intent of whomever added these words was to reflect that the Board, as defined in these Rules and Regulations, has the ability to approve a course, then I recommend that the words or an and accredited course approved by the Board be the only submission in words not, comma, or by a program or approved by the Department. That

those words be removed and replaced by this statement or and an accredited course approved by the Board.

I submit the following sections within these Rules and Regulations that specifically state that it is by approval of the Board and not the Department. Examples throughout these Rules and Regulations is evident in the following sections: Section 2.4.6 A-3. Section 2.4.6, B, F and G. Sections 2.7.5 C and Section 2.8.4 D.

It is with great hope that this committee will do its diligence and correct these errors. Respectfully submitted. Thank you.

HEARING OFFICER ROBERTS: Thank you. The next speaker is Russell Chin.

DR. CHIN: My name is Russell Chin, C-H-I-N. I'm a general dentist in Rhode Island, and I'm here as a private dentist. I would like to make some recommendations to the Rules that we are talking about.

First one is 2.10.3, Number 4. I want to strike, "plus medication." Number 5,

insert the word, "sedative." Number 13, I want to strike "activation" and insert "detailing." Number 14, I want to strike "entirely." Continuing on to 2.11.1C, the word "when" should be inserted, and "where" removed. On Section 2.11.3 B1, the word "dentist" should be inserted and "dental" strike. On B-3, I want to include or insert "CERP or PACE," P-A-C-E, approval. On C2, the word "moderate" needs to be stricken and "minimal" inserted on the first line and on the second line of C2 again the word "minimal" inserted and "moderate" stricken. On C3, insert "CERP or PACE approve". And on C5 remove "entirely" Continuing to D2, insert "or equivalent". And D3, I'm adding a whole line, "a current certification of advanced cardiac life support." Going down to E1C, insert "or equivalent." On G3, insert "and PALS," P-A-L-S. On 2.11.4A, 1C, strike "minimal sedation"? On B1, insert the word "and" and strike "or." Continuing on to C3, insert "and" and strike "or." On C3B, insert "calibrated." On D3, insert "and" and strike "or." On E2,

insert "successful completion of a on-site office evaluation performed by a Board member and a Board memoranda appointed by an advisory consultant." On 2.11.7A, first line, insert the word "calibrated." On 2.11.9, C1, B, insert "ACLS and PALS, if needed," and strike, "BLS." Going out to D2B, insert "and." On C, insert "DANCE," D-A-N-C-E. Going on to 5C, insert with "BLS" and on Number 7, insert "and PALS." Number 8, insert "PALS if treating children." Section 2.13.2, A1, remove "the American Dental Association."

(INTERRUPTED BY TIMER)

HEARING OFFICER ROBERTS: Thank you. Your allotted time is up. If you are unable to complete your testimony in the time allotted, you may have an opportunity if any time is available. The next speaker is Steve Brown.

DR. BROWN: Good morning. I'm Dr. Steve Brown. I'm an oral surgeon in the State of Rhode Island, and I am -- today I'm representing the Rhode Island Society of Oral and Maxillofacial Surgery. Generally, we are

thankful for the Board for putting such an effort into these new Regulations. I think they are long overdue. It's been a process that I know has taken a few years for this to happen. These new and Rules and Regulations are consistent with the new ADA policy as well as the American Association of Pediatric Dentists and most recent AMS Guidelines for Sedation and Anesthesia by Dentists. The new Regulations significantly increase the educational requirement for the administration of minimal and moderate sedation for the adult patients by dentists. Deep sedation and general anesthesia administration are reserved for oral and maxillofacial surgeons, dental anesthesiologists, medical anesthesiologists or licensed practitioners with equivalent training approved by the Board. These new Regulations significantly encompass anesthesia services provided by dental anesthesiologists and acknowledges the vital service they for identification to the public.

The administration of sedation and anesthesia to pediatric patients has been

separated and the requirements to administer these services to pediatric patients has been strengthened. This is because the physiological and anatomical make-up of pediatric patients is much different than the adult, and additional training and simulation is required. Office inspections have been streamlined. Office inspections for moderate deep and general anesthesia are being conducted by a team. Post permits and portable dental facility permits will address the need for dental anesthesiologists.

Having said that there are a number of typographical errors, omissions, problems with the Regulations as they are now written, and I would recommend, and I, we agree with most of what Dr. Chin had stated. These need to be corrected, and I think another meeting of the -- such as this needs to be done so that we can all look at these Regulations and agree. I think the most glaring example of a problem is Section 2-11.3, Section E, Number 1. Applicants for individual anesthesia permits and general anesthesia and deep

sedation must meet the following criteria: The word one must be removed. It says have fulfilled one of the following educational training requirements. The first two, A and B, are correct; but the third, C, having completed a Board approved simulation course that uses high fidelity simulation is not appropriate. That section needs to be removed. There are other examples, and I think Dr. Chin made a good statement as to those problems.

I think another thing that the Board should look at are the definitions exactly of what a qualified dentist is and what a qualified provider. Maybe we ought to put examples of each. I think in the Regulation it's not clear as to what practitioner can do and what his responsibilities are. There are other problems with these that we will submit in writing, but generally, we concur with these new Regulations. Thank you.

HEARING OFFICER ROBERTS: Thank you.

HEARING OFFICER ROBERTS: The next speaker is William A. McDonald.

DR. McDONALD: Good morning. My name is William McDonald. I am a dentist anesthesiologist. I'm a Providence College graduate. And I practice dental anesthesia, mobile anesthesia in Connecticut. I have been on the facility at the University of Connecticut Medical School and Dental School for many years. I teach sedation, general anesthesia and medical emergencies to medical and dental students; and over the years, I have provided anesthesia for more than 200 dentists in Connecticut, Massachusetts and Rhode Island -- I'm sorry, Connecticut, Massachusetts and New York. Last year I provided anesthesia for dental patients in more than 60 offices.

I came this morning because I'm very concerned about the safety that is being jeopardized in these proposed Regulations. Also, it appears that there's a limit of access to care for patients in Rhode Island because of these Regulations. Also, the dentist anesthesiologists are having great difficulty in being inspected. And also, general practitioners and non-oral surgeons would have

difficulty in getting permits so that they could have anesthesia provided for their patients.

Most importantly, the thing that should be addressed is that, for children, there should be a separate, trained anesthesia provider, whether it is a physician anesthesiologist or an oral surgeon, nurse anesthetist or dental anesthesiologist. The Academy of Pediatric Dentistry and the American Academy of Pediatric Dentistry both make that recommendation. CODA states that for oral surgery training, children are considered 18 and under; so, everyplace that children are mentioned in this document it should be 18. There should be a separate person trained to do the anesthesia. Oral surgeons have five months of anesthesia training during their programs. They are supposed to do 50 cases of deep sedation with general anesthesia during their training for eight children 18 and under. Dentist anesthesiologists have 36 months of training and they have to treat 125 children ages seven and under. Dentist

anesthesiologists practice like physician anesthesiologists where one person provides the surgery and one person provides the dentistry. The oral surgeons in general practice doing two things at once. Is there a hospital in Rhode Island that would let a physician or surgeon do surgery and anesthesia at the same time? I doubt that. Dr. Cote mentioned the issue of the DANCE where somebody has 36 hours of training administering anesthesia. Michael Jackson, as we all know, died as the result of the administration of Propofol. That was administered by a Board certified cardiologist.

In Rhode Island, the DANCE assistant appears to be able to administer opioids such as Fentanyl. In New Haven last month -- there were a hundred overdoses in New Haven Green as a result of Fentanyl. Is there any hospital in Rhode Island that would allow somebody with 36 hours of training to administer Propofol or an anesthetic agent? For the record, no dentist assistants in Connecticut are allowed to administer any anesthetic or medications. Is there really a

need for a host permit? If the anesthesia provider has an anesthesia permit, the facility is permitted, why would you have to have an anesthesia host permit? Why would there have to be an agreement between that dental office and the hospital? Would Rhode Island Hospital or any other hospital in the state turn down a patient in medical emergency? Why should a dentist have to have a hospital appointment? In one point, nitrous oxide is considered an inhalant, therefore, dental assistants may not be able to do that. I think that has to be readdressed. In the wording for inspections, it states surgery. If a general dentist office to be inspected, fillings, root canals, cleanings are not considered as being surgery.

I worked, as I said, in 60 different offices last year. Would I have to be inspected 60 different times? We have had difficulty in Connecticut where those people that control the inspections have made it very difficult for non-oral surgeons to be inspected. A dentist anesthesiologist was told there was no one who could do inspections for

him. A periodontist's office was cancelled at the last minute. Reschedule has taken more than eight months to get inspected.

And then the question of the evaluators. Oral surgeons have five months of training. Dental anesthesiologists have six months of training. Those trained in moderate station have to do 20 cases. Also, in this comment it talks about nitrous oxide analgesia. That term hasn't been used in 40 years. There are no CODA approved nitrous oxide analgesic courses, so the terminology has to be corrected.

HEARING OFFICER ROBERTS: Your allotted time is up. If you are unable to complete your testimony in the time allotted, you may have an opportunity to speak if any time is remaining after the other speakers who have signed up complete their testimony. The next speaker is Sam Zwetchkenbaum.

DR. ZWETCHKENBAUM: Good morning. I'm Sam Zwetchkenbaum, Z-W-E-T-C-H-K-E-N-B-A-U-M, dental director in the oral health program. The following changes

are recommended to the Regulations. Number one, public health dental hygiene education provider, Section 2.9.1B, B, changed to successful completion of the following courses within 24 months prior to license issuance. Public health fundamentals, colon, CBC guidelines, inspection control, comma, risk management for practice in a public health setting and management of medical emergencies, comma, which are offered by an educational institution with a program accredited by the Commission on Dental Accreditation, comma, or a program approved by the Board or the Department. Rationale, the current course available is excellent, however, similar to most continuing education is not subject to CODA approval or evaluation. Fully closing the door to any other opportunities such as can be provided through other Rhode Island resources inhibits the ability of other able organizations to enter this area. For example, for courses in medical emergencies or infection control, Brown School of Medicine, RIC College of Nursing or Salve Regina may wish to be a

provider. For a course in risk management, organizations with significant experience such as Rhode Island Dental Association, Eastern Dentists Insurance Company and other malpractice carriers offer comprehensive training in areas truly in their wheelhouse. Allowing these additional opportunities to be reviewed as alternatives makes sense.

Number two, dental radiology education provider. Section 2.10.3A, 11, lists as non-delegable procedures exposures of radiographs without successful completion of a course in dental radiography which is offered by an education institution with a program accredited by the Commission on Dental Accreditation and which fulfills institutional requirements as set forth in RIGL 40-20-1. Recommended changes to the dental Regulations. Exposures of radiographs without successful completion of a course in dental radiography, which complies with Commission on Dental Accreditation Standards for radiological techniques and safeguards in dentistry and approved by the Board or the Department and

which fulfills institutional requirements as set forth in the Rules and Regulations for Diagnostic X-rays and an Associated Imaging Systems in the Healing Arts. Rationale, the current available course similar to most continuing education is not subject to CODA evaluation or approval. Opening the door to opportunities that can be provided through additional resources would increase opportunities for future dental assistants. Assuring the course meets CODA standards would allow conformance with necessary training components. Other states provide a mechanism of board approval of radiology programs based on guidelines established by the board. North Carolina, almost ten times larger in population than Rhode Island, has over 50 sites approved by their board to provide radiology training. In Massachusetts, their board assures that programs based in their career and tech centers comply with CODA standards and thereby approves them.

Number three, inclusion of WREB, W-R-E-B, as one of the acceptable Dental Board

exams. Recommend change 2.5.A.1C from having, successfully passed the ADEX exam, including the periodontal examination portion, within five years from the date of application for licensure in Rhode Island. 2, have successfully passed the ADEX or Western Regional Examination Board, WREB exam, including the periodontal examination portion within five years from the date of application for licensure in Rhode Island. Rationale, WREB is accepted at multiple Northeast states and offered at several of the largest regional dental schools, including Tufts Dental. Faculty from Tufts find the examination to be of high quality and regularly subject to evaluation. Unique to WREB is the CTP or Comprehensive Treatment Planning exam which tests fundamental and vital skills. Including WREB as an acceptable examination increases likelihood for recent graduates to apply for positions in Rhode Island.

HEARING OFFICER ROBERTS: Are there any other persons present who would like to continue their testimony or make a statement

concerning their proposed Regulations?
Mr. Cote?

DR. COTE: I promise to take less than five minutes. Dr. Charles Cote, C-O-T-E. So, it's astonishing to me that these DANCE certified individuals are allowed to fulfill the position of an independent observer to assist the oral surgeon with general anesthesia and deep sedation. And it's astonishing to me that dental hygienists require three years of training and over 4,000 hours of training to become a dental hygienist but you can become DANCE certified and assist with medical emergencies with 36 hours of Internet training and no practical hands-on experience. So, I'm going to finish, on Page -- to summarize, the AAP and CAPD, American Academy of Pediatric Dentistry Guidelines, is very specific. If the intended level of sedation is minimal sedation, you must have the skills to rescue a patient from moderate sedation. If your intended level of sedation is moderate, you must have the skills to rescue from deep sedation; and if your

intended level of sedation is deep, you must have the skills to rescue from a state of general anesthesia, because we all know that a patient may easily progress from one to the other. The independent observer wording in the Academy of Pediatrics document is that the independent observer whose only responsibility is to continuously monitor the patient is required. That's for deep sedation. This individual must, at a minimum, be trained in PALS and capable of assisting with any medical emergencies. And that's the key phrase, and capable of assisting with an emergency.

The single provider model where the oral surgeon is performing the procedure and directing the anesthetic sedation at the same time is fraught with danger because when something goes wrong with this practice model, there's no other skilled medical or dental professional present to assist with managing the patient and rescuing the patient.

Caleb's Law in California was proposed because of the death of a five-year-old in an oral surgeon's office. His

aunt, Annie, sent me the office records. It was clear that this particular individual was not skilled in rescuing the patient and did not have anybody in the office who could assist him with the rescue of this five-year-old child. When Caleb's oxygen levels dropped and he stopped breathing, he apparently panicked. No reversal agents were given. No oral devices were placed to clear the obstructed airway. He could not perform basic bag-mask ventilation. He attempted intubation and knocked out a number of teeth, and he even attempted a surgical airway from the side of the neck, but he didn't understand the anatomy of the airway. By the time 911 arrived, Caleb was pulseless.

So, if there had been an extra skilled anesthesia trained person there, this would have been something that we see every day and would have been very easily taken care of. But in this situation, obviously, they failed to rescue Caleb; and had they had that person there, I wouldn't be talking to you about Caleb's Law. This is an extreme example of why skilled anesthesia providers must be present,

but it's particular important in a non-hospital environment; because when something happens to me in the hospital setting, we press that code button and help is coming out of the woodwork in seconds. When something happens in an office setting, the only backup is 911 and that may I take five to 20 minutes for them to arrive; and that's why one practitioner cannot and should not perform two services at the same time.

I guess I would ask each of you if you would ever get on a commercial airline flight where there was a polite and no copilot. Well, instead of the copilot, we are going to substitute with the flight attendant, and she or he is going to fulfill the role of the copilot. Obviously, that's very wrong. If something happened, they certainly wouldn't be able to assist the pilot with an emergency. It's kind of like that GEICO ad, oh, yes, that's a giant cavity. We can't do anything about it. We are just here to tell you that there's something wrong.

I think what this legislation is

doing is it's asking you to cardify into law and support this very dangerous, solo practice where they are providing both anesthesia and doing the procedure at the same time. There's nowhere in medicine where this kind of practice is allowed except perhaps in the emergency room where there's an urgent procedure that's going to take a few minutes. And in that situation, they have skilled nurses who are trained to deal with medical emergencies on a daily basis, and they fulfill that role as the independent observer.

A DANCE certified person is, does not have those kind of skills. They could even be a high school dropout. There's no requirement for education, as far as I could tell, when I looked at that document. So, think about if you would ever allow yourself, your child or your grandchild to be put at that kind of a risk. Think about that. Thank you very much.

HEARING OFFICER ROBERTS: Thank you. Mr. Chin?

DR. CHIN: Continuing on, on

Section 2.13.2, 1A strike the American Dental Association. 1B, strike American Dental Association. 2.13.2C, 1A, strike American Dental Association. B, strike American Dental Association. In Section 2.15.1, strike three entirely and strike 4 entirely. And going back to 2.2 H, strike American Dental Association. In Section 2.3A, 30C, strike C entirely. Number 31, insert "director" after mobile dental facility. And 32 insert "permit holder." 37, strike "non" on the first line for nonfacility. On 2.4.3 on the second line, insert CDA and DA. And 2.4.5A, 1A, insert "dental". And 2.46, Number 3, insert "or Canadian dental school" and strike "or its designated agency approved by the Board." In 2.4.7A.2, insert "U.S. CODA or Canadian dental school." On 4, insert "equivalent" on Line 2 and strike "organizations." On 5, insert "for immediate past five years." On 2.5A1, C1, insert "equivalent" on the first line as well as "equivalent" on the second line and on the third line strike "similar." And going down to 3, strike "a clinical exam," insert "an

equivalent clinical exam." On 2.6B, that should be stricken or modified to July 1. On 2.7.2A, 3, insert the word "equivalent." On 2.7.3A, 2, insert CODA. Section 4, insert the word "equivalent" and strike out the word "organizations", and on 5, insert "in the past five years." Section 2.7.4B, 4, insert "equivalent" on the first line and on the second line insert "equivalent" and strike "similar." On 2.8.4D, insert "ACLS" and strike "basic life support, BLS." On 2.9.1B, 1B, strike "or program approved by the Dental Board or the Department." 2.92C, 1, insert "CODA." On 3, insert "equivalent." Strike out "organizations." On 2.9.3A, 6F, insert "contact the MBO director or PDO director." On B, "can provide emergency dental referral or propofol referral." Thank you.

HEARING OFFICER ROBERTS: Mr. McDonald?

DR. McDONALD: William McDonald again. Just to continue, the question of the inspections talks about surgery and the issue is if the inspection were done in a non-oral

SURGEON'S office, a general practitioner that's not considered surgery, so this terminology has to be readdressed. The next question is does each office have to be inspected, and the other issue is does a patient have to be put to sleep in each office. In my case, I would have to be inspected 60 times to put 60 patients asleep. How many people do you have to put to sleep that demonstrate that you're safe at doing that? The other question is, is the host permit. The question is why would there have to be an agreement between any office, physician office, dental office that Rhode Island Hospital would accept their patients? I don't understand that or the fact that there is a need to have the dentists be on the hospital staff. How many, how many Rhode Island dentists are on hospital staff? The other issue is with the dentists anesthesiologists, it appears they have to have a portable individual anesthesia permit. There has to be a facility permit, and do they have to have an individual anesthesia permit also? The question is that being redundant? The facility

host permit, what's the advantage to that other than limiting access to care and restraint of trade. It really makes it very difficult for the host. I see no reason to have that. The other thing I did mention before is there are no CODA approved nitrous oxide analgesia courses. The term nitrous oxide analgesia hasn't been used in more than 40 years in dental education. On Page 38, Number 2, it should read "be a candidate or hold a diplomatic status of the American Board of Anesthesiology. The oral surgeons also refer to candidates in the line before that. And under 2.13 A1, 3, Page 53, why should any nitrous oxide anesthesia machine in a dental office be able to administer a hypoxic mixture -- in other words, give a hundred percent nitrous oxide. There's no reason to have that. It mentions the fact that if a machine can deliver less than 25 percent oxygen, you have to have an in-line oxygen analyzer. That would mean the machine could give a 100 percent nitrous oxide, which is obviously a hypoxic mixture.

I also notice in the Regulations there's no mention for nitrous oxide systems to have either the appropriate pin index safety system or diameter index safety system. Thank you.

HEARING OFFICER ROBERTS: Are there any other persons presented who would like to make a statement concerning the proposed Regulations? Please just state and spell your name for the record.

DR. BROWN: Steve Brown, S-T-E-V-E-N, Brown, B-R-O-W-N. I just wanted to add in the very last section where we talk about continuing education, what's considered continuing education. The very last section, Section 7 says cardiopulmonary information resuscitation afford the person three hours of continuing education. I would hope that the Board would add in there as well ACLS training and PALS training to apply toward to an individual's annual or bi-annual continuing education requirements. Thank you.

HEARING OFFICER ROBERTS: Thank you. Are there any other persons present?

THE WITNESS: Hello, my name is Ray English, the third. I'm a new oral surgeon in Rhode Island. I recently completed my training and have come back to Rhode Island because I'm a native of this state. The crisis in Rhode Island is not dental anesthesia but access to care. And one of the reasons for this is that Rhode Island has made it difficult for dentist specialists to practice here due to reimbursement issues; and my fear is that if we continue to restrict our ability to practice, that's only going to exacerbate the problem. So, I'm thankful to the Board for putting together new Regulations that increase training because that's important, but I would keep access to care in mind when we finalize these Regulations because that's what matters. When a patient comes to our office with an acute dental abscess, it is important to treat them in a timely manner. The hospital system cannot accommodate all of our dental needs. Thank you and that's it.

HEARING OFFICER ROBERTS: Thank you. Are there any other persons...

DR. Hello. My name is doctor McCardi, and I'm a Board certified dental anesthesiologist who's been practicing in Rhode Island since 2007. Graduate of Boston University, University of Southern California and Mt. Sinai Hospital where I did my anesthesiology residence. Since 2008, I have been staff anesthesia at Franciscan Children's Hospital in Brighton, Massachusetts. I have held clinical appointments at the dental schools, Boston University, Tufts University and Harvard University providing didactic and clinical instruction. All right. Where was I? So, I have provided didactic and clinical instruction regarding sedation and general anesthesia for pediatric residents, dental residents, periodontal residents and continue education courses for private practice dentists since 2007. I have maintained a mobile office-based anesthesia practice originating in Massachusetts and Rhode Island. And the practice has grown to cover four states, including New Hampshire and Maine and encompassing four anesthesiologists, all dental

anesthesiologist providers.

In 2018, to give you an idea of our patient volume, we have conducted over 2400 general anesthetics. Over the last eleven years, we have zero instances of morbidity and mortality. And while an inherent risks exist for any provider at any level of sedation or general anesthesia, adherence to known standards of care often mitigate risks to an appropriate level.

For any football fans out there, we all know Coach Parcells. And his saying of you're only as good as your last game. One thing that Parcells did was surrounded himself with a talent that was experienced and qualified in an expense of our new friend, Bill Belichick.

I followed the Rhode Island dental anesthesia regulation process since late 2015. What I cannot follow is the logic of ignoring aspects of the American Society of Anesthesiology, the American Academy of Pediatrics or the American Academy of Pediatric Dentistry and the parameters of care regarding

the qualifications of collaborative professionals, ignoring standards of care regarding utilization of the separate licensed anesthesia professional or filing to surround oneself with staff that are truly qualified and experienced and not just certified by a private organization. Any panel of advisory consultants should include a diverse group of providers with various degrees of sedation and anesthesia training.

We had an anesthesia committee set up for these Regulations and I'm not going to make any contention comments, but I believe there are people in this room that will state that was an infective committee, and I'm sure they will by right. Aside from that, you know, the panel itself should be led by professionals who have completed formal anesthesia training, whether it be an MD or a DO, a DDS or a DMD like some of the members here in this room, or CRNs, who are also dedicated towards putting the public well-being of the profession ahead of their own agenda along with primarily the welfare and the public safety of our patients.

And I don't think that's happened with this document. I really don't.

Aside from that, you know, there's no question we have concerned professionals willing and able to provide their time and efforts to improve safety, access to care with the benefit of the patients and the profession in mind. Charles Cote is end-all authority on any of these national regulations, and he came down today to speak, and I think, honestly, we have a meeting. I understand there's time constraints, but to tap out on five minutes, which I understand is part of the process, I'm sure, if asked, he would donate his time. Bill McDonald came from Connecticut. We know Mark Rosenberg has done so. There's others that would gladly do it. I think when we make regulations that, while I agree with Dr. English, access to care is an issue and so is safety. I think it's hard to put one above the other, much like the practice of anesthesia itself. It's most in hindsight, and we have to remember that with some foresight.

Following today's testimony, I hope

the Department of Health urges the Dental Board to revise numerous aspects of this proposed Regulations. Although I'm sure everyone is eager to complete what's been a long process with a great deal of effort on all parts, it's far more important to make sure those Regulations are capable of their intention. I hope it's clear that the currently proposed draft needs a great deal of revision, and I think there's people in this room and people involved in the process up to this point that are capable of that, and I hope that it's done. Thank you for your time.

HEARING OFFICER ROBERTS: Thank you. Are there any other persons present who would like to make a statement concerning the proposed Regulations?

(PAUSE)

HEARING OFFICER ROBERTS: Thank you all for your attendance and for the information you have observed, and this hearing is now closed. Thank you.

(HEARING CLOSED AT 11:10 A.M.)

C E R T I F I C A T E

I, Mary Ellen Hall, hereby certify that the foregoing is a true, accurate and complete transcript's of my notes taken at the above-entitled public hearing.

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of September, 2018.

_____
MARY ELLEN HALL, NOTARY PUBLIC/
CERTIFIED COURT REPORTER

JOB DATE: SEPTEMBDER 11, 2018

# Concerns Regarding the Single Operator Model of Sedation in Young Children

Rita Agarwal, MD,[a] Anna Kaplan, MD,[b] Raeford Brown, MD,[c] Charles J. Coté, MD[d]

In July 2016, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) released their joint updated "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures."[1] The purpose of this update, as stated by the authors and supported by the AAP and AAPD, was to "unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities…; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes." They described the substantial differences between sedation for children and adults, and emphasized the subtlety and rapidity with which young children can pass from 1 level of sedation to another unintended level. The need to have practitioners that can quickly recognize the signs of deeper levels of sedation and have the skills, equipment, and support personnel to rescue the child from potential adverse responses to these unintended levels of sedation is critical.

## CALEB'S STORY BY ANNA KAPLAN, MD, CALEB'S AUNT

My nephew Caleb was a strong, healthy, 6-and-a-half year old when he died. Caleb was scheduled to have a mesiodens tooth extracted, a supernumerary tooth between the 2 central incisors. His oral surgeon had recommended general anesthesia. Caleb's parents did not consent lightly to this method of anesthesia. They talked through the options with their doctors, family, and friends. They knew of the minimal but serious risks of anesthesia. However, our family had no idea or reason to know that dentists and oral surgeons provide anesthesia significantly differently than the medical model.

Caleb's surgery occurred in a private office with an oral surgeon and 2 dental assistants. There was no dedicated separate anesthesia provider, not even a nurse present. The oral surgeon administered fentanyl, midazolam, propofol, and ketamine intravenously, then went to work on Caleb's teeth. No one noticed that Caleb had stopped breathing until the pulse oximeter read 69%.

Rescue efforts appeared to be woefully inadequate. According to the available records, no one attempted bag and/or mask ventilation. The oral surgeon attempted intubation (knocking out a number of teeth) and was unsuccessful; he attempted cricothyroidotomy and was also unsuccessful. There was no attempt to insert a nasal trumpet, oral airway, or laryngeal mask airway. More importantly, despite having an IV in place, there was no attempt to reverse the fentanyl or midazolam. When the paramedics arrived, no one was doing cardiopulmonary resuscitation. Caleb's electrocardiogram showed pulseless electrical activity. He had been without oxygen for at least 20 minutes. In

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All authors contributed to the conceptualization of the manuscript after the adoption of the American Academy of Pediatrics Annual Leadership Forum: Resolution 42, "Not One More Child Shall Die in a Dental Chair: Remembering Caleb"; Dr Kaplan is the author of California's Caleb's Law and AB 224; Drs Agarwal, Coté, and Kaplan did considerable research on sedation safety and complications; Dr Brown reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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the emergency department, he was immediately and successfully intubated, but it was too late. For the next 48 hours, our family stood by Caleb in the PICU as his medical condition deteriorated, until finally, a neurologist told us he had passed. Caleb's parents held him as he was removed from the ventilator.

Over the next months, our family provided support as best we could for Caleb's devastated parents. This profound personal loss spurred our family to educate ourselves further regarding dental practice models and procedures. Looking beyond Caleb's case, it was surprising to learn that this was a common model in dental practice. Our family discovered that Caleb's death was not an isolated incident, but no one was doing anything to change it. We set out to shine a light on this issue and hopefully prevent other families from suffering similar unimaginable losses. Caleb's Law began when our family (Caleb's mother and father, my husband, and myself) met with our California State Assembly member Tony Thurmond. We described what had happened to Caleb and proposed a bill to make dental anesthesia safer. I worked closely with Mr Thurmond to both draft a bill and present it to the State Assembly.

The first version of the bill proposal drafted by our family required that there be a dedicated qualified anesthesia provider to monitor pediatric patients undergoing deep sedation or general anesthesia. This version of the bill hit major opposition from the California Dental Association and the California Association of Oral and Maxillofacial Surgeons. The American Academy of Pediatrics, California (AAP-CA), a 501(c)4 separately incorporated from the national AAP, stepped in as the sponsor of the legislation. The AAP-CA provided clout and credibility. They helped us muster lobbying resources, physicians eager to testify for children's safety, and had deep experience with child health advocacy. Two authors (C.J.C., R.A.) provided background and testimony as witnesses for hearings and meetings with legislators and broadened the coalition of academics that were now advocating for change. The California Society of Anesthesiologists and the California Society of Dentist Anesthesiologists also joined us with support of the bill. Together this coalition, which included our family, worked to shepherd the bill through the legislature and to the governor for signature. This became known as Caleb's Law Part 1.

Caleb's Law Part 1 (www.calebslaw.org) passed in 2016 and accomplished 3 important changes: (1) it mandated improved data collection by the Dental Board of California by requiring them to collect specified epidemiologic information for each adverse event and encouraged the dental board to contract with a nonprofit anesthesia registry to begin real-time data collection for sedation encounters in the dental office; (2) mandated that the dental board perform a study of sedation safety; and (3) specified the contents of a disclosure form for parents concerning anesthesia-related risks in a dental setting.

The California Dental Board completed their study in December 2016. Our family and Assemblyman Thurmond, together with the AAP-CA, have now sponsored a new 2-year bill to codify these recommendations, which include among several others that there should be a separate anesthesia provider for young children undergoing deep sedation and general anesthesia. This bill, AB 224,[2] is known as Caleb's Law Part 2. However, the dental lobby continues to challenge the recommended changes, arguing that there are insufficient data to justify change and that a separate anesthesia provider would increase costs to patients and decrease access to care. This point is especially suspect, given that dentists and oral surgeons usually bill their patients separately for surgery and anesthesia. Caleb's oral surgeon, for example, billed $670 for the procedure and $755 for the general anesthesia.

Caleb was a completely healthy child. He did not have an allergic reaction or a latent heart defect. His death was completely preventable. Had a medically skilled independent clinician as recommended by the AAP/AAPD guidelines been used, Caleb would likely not have died. Instead, 2 medically unskilled and inadequately trained dental assistants were unable to assist, chaos ruled, and a tragedy occurred.

## DISCUSSION

Younger children are recognized to be at increased risk for side effects and complications with sedation and/or anesthesia. The medical community routinely follows the AAP/AAPD and the American Society of Anesthesiologists (ASA) guidelines regarding procedural sedation. The AAP/AAPD guidelines state:

"During deep sedation, there must be 1 person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS [Pediatric Advanced Life Support] and capable of assisting with any emergency event. At least 1 individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction."[1]

In hospitals, clinics, offices, and most places where moderate or deep sedation is practiced in young children, the person monitoring the patients and administering the medications is at least a qualified nurse, and most often a physician. Most institutions require significant additional training or education for all clinicians involved in sedation

**TABLE 1** Level of Education Required in Dental Paraprofessional Positions

| Level of Education | Basic | Advanced |
|---|---|---|
| Dental assistant | High school | On-the-job, certificate course |
| Dental anesthesia assistant | High school, 12 mo practice | Online education (36 h), national examination |
| Dental sedation assistant (CA) | High school, 12 mo practice | On-site, hands on, and online education (110 h); state examination |
| Dental hygienist | 2–4 y dental hygienist | Associate or (less commonly) bachelor's degree, national certifying examination |

Adapted from Boynes SG. Dental Anesthesiology: A Guide to the Rules and Regulations of the United States of America. 5th ed. Chicago, IL: No-No Orchard Publishing; 2011; Dental Anesthesia Assistant National Certification Examination. Available at: www.aaoms.org/continuing-education/certification-program-daance. Accessed June 2017; and Dental Board of California. How to become a dental sedation assistant permit holder. Available at: www.dbc.ca.gov/verification/index.shtml. Accessed May 15, 2017. CA, California.

services. Sedation modules, courses, and hands-on workshops are taught locally and nationally and include airway management workshops. Both the Food and Drug Administration and the ASA specifically state "propofol used for sedation or anesthesia should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure."[3]

In contrast to physicians' offices and clinics, the dentists and oral surgeons often use the single operator model. The single operator model allows for 1 anesthesia permit holder (as defined by the state in which the dentist or oral surgeon is practicing) to administer both the sedatives and/or anesthetics and perform the dental work. Each individual state determines the requirements for licensing and scope of practice. Many of these practitioners will have a dental assistant help monitor the patient. The American Association of Oral and Maxillofacial Surgeons had published guidelines approving oral surgeons to administer anesthesia with only 2 dental assistants for support. They justify this practice by claiming that 1 dental assistant's only job is to monitor the patient while the other assists the dentist. The oral surgeon in this model is the only one trained in anesthesia, sedation, resuscitation, and medical care. State dental boards do little to track adverse outcomes in dental offices despite the authors of several medical articles reporting disproportionate rates of injury and death from anesthesia in dental offices as compared with medical settings.[4,5] The requirements for the education and training of dental assistants vary considerably from state to state.[6] They often have no more than a high school education, with many having only on-the-job training (Table 1). A dental assistant in most states is not licensed to draw up or administer medications, cannot perform airway rescue maneuvers, and in all likelihood does not have the education or training to recognize changing levels of sedation. There is a Dental Assistant Anesthesia National Certification Examination that requires 36 hours of online education and the successful passage of an online examination.[7] This certification is required in a few states (WA, OR) for a dental assistant (or in some cases dental hygienists) to be allowed to monitor and assist with sedation of children. The Dental Assistant Anesthesia National Certification Examination still does not qualify participants to draw up or independently administer medications. California has a Dental Sedation Assistant Certification that requires 110 hours of in-office education and training.[8] Advanced cardiac life support and PALS training are not required, although Caleb's Law Part 2 (AB 224), which is currently being reviewed in the California State Assembly, would require PALS training. The only person capable of administering medications and assisting with airway emergencies is the dentist or oral surgeon performing the procedure. Thus, the only backup for rapidly summoning additional skilled help is by calling 911, which may take many minutes and may have emergency medical technicians who lack skills to manage a child's airway. The dental office is in fact a high-risk venue, which makes adequate skilled staffing even more important. With the single operator model, the dentist or oral surgeon would have to simultaneously manage the airway, draw up and/or administer rescue medications, recognize and run the code, and manage cardiopulmonary resuscitation. This is an impossible task for even the most skilled clinician.

In medicine, adverse events are routinely reported to the institution's quality improvement or risk management offices. Additionally, multiple national agencies (Joint Commission, Food and Drug Administration, Centers for Disease Control and Prevention, etc) and societies have developed databases to collect as much information on these events as possible, with the intent to understand faulty processes and improve outcomes. The same data collection does not occur in dentistry. The state dental boards are the sole recipient of these data. Before the passage of Caleb's Law in California and the simultaneous review of dental sedation practices in Texas, not 1 dental board in all 50 states was systematically tracking these data. This year, Texas and California will be the first 2 states to start tracking data on adverse events.

When Caleb's family evaluated their anesthesia options, they calculated the risks on the basis of the dominant medical model. They had no reason

to consider that their oral surgeon would administer anesthesia and conduct the procedure simultaneously. Dentists and oral surgeons have been able to provide anesthesia services on the basis of the reputation of safety created by the medical community, without disclosing to the patients that they fail to follow the same standards. Those who argue for the continuation of the single operator model cite a lack of data to prove that this practice is any less safe than having a separate qualified anesthesia provider. This argument is disingenuous. Over 15 years ago, Coté et al[4,5] reported 29 deaths or permanent neurologic injury in dental offices, with failure to rescue a nonbreathing child contributing to 80% of adverse outcomes. The Anesthesia Patient Safety Foundation, the Anesthesia Incident Reporting System, and other databases that collect information on anesthesia or sedation complications have had minimal submissions for dental sedation and/or anesthesia, so the true incidence is unknown.

The authors of a 2015 article in the *Journal of the American Dental Association* examined the incidence of death or brain injury in patients undergoing deep sedation or general anesthesia by an oral surgeon who is also doing the procedure (single operator model).[9] They used the Oral and Maxillofacial Surgery National Insurance Company anesthesia closed-claims database from 2000 to 2013; this company insures ~80% of practicing oral and maxillofacial surgeons. They determined that ~39 million anesthetics were performed in adults and children, and 113 deaths or brain injuries occurred. They estimated that 1 case of death or brain injury occurs for every 348 602 anesthetics, and at least 1 instance or more occurred nationally every month. These complications are occurring in presumably healthy patients of all ages, undergoing minor noninvasive procedures. These findings can be compared with the Wake Up Safe initiative (sponsored by the Society for Pediatric Anesthesia), which gathers data on the risk and incidence of complications in pediatric anesthesia.[10,11] Wake Up Safe is an organization of 32 pediatric anesthesia departments designed to reduce the risk and incidence of complications in pediatric anesthesia by gathering, interpreting, and taking action on data collected from these departments. Hospitals and institutions voluntarily share their deidentified morbidity and/or mortality information as well as their total numbers of cases and demographics. There have been no anesthesia-related deaths or neurologic injuries in almost 2 million healthy children (D. Tyler, MD, personal communication, http://wakeupsafe.org, 2017). Another database, the Pediatric Sedation Research Consortium,[11] is a collaborative, multi-institutional, multidisciplinary group dedicated to making pediatric sedation safer and more effective.[12–14] All sedations performed in participating institutions, offices, and clinics regardless of specialty are reported, including data from a few dental providers. There are currently 48 participating institutions. There have been no deaths or significant complications in over 500 000 reported cases to date (J. Cravero, MD, personal communication, Past President and Co-Founder of the Pediatric Sedation Research Consortium, 2017). Although there have been adverse events, each was managed successfully.[15,] Thus, the morbidity and mortality of healthy children ranking as a I or II on the ASA scale who are undergoing either general anesthesia or procedural sedation reported by these initiatives (0 of 500 000 to 0 of 2 000 000) appear to be well below that reported from the dental community in healthy children and adults (1 of 348 602), likely because of the ready availability of skilled personnel to successfully rescue the child.

## CONCLUSIONS

The AAP has made a commitment to improving care for children undergoing dental sedation, encouraging all practitioners to follow the AAP/AAPD guidelines. The Annual Leadership Forum included a resolution on preventing deaths in dentists' and oral surgeons' offices as 1 of their Top 10 Resolutions.[16] Some states make the single operator model of sedation and/or anesthesia more difficult to practice, and the Alberta and British Columbia Dental Association have permanently suspended the single operator model.[17] As advocates for the safety of all children, we must persevere until the same rules and guidelines apply to all children undergoing deep sedation or general anesthesia in all locations, in all states, and in all types of practices. Physicians can advocate for these changes by contacting their local AAP chapters and districts or state senators and/or assembly members and offer to help craft legislation similar to what is being done in California. It is unacceptable that healthy children continue to die or sustain permanent neurologic injury because a single provider was unable to rescue the child from an evolving adverse event. Pediatricians can educate parents about the risks of sedation, and encourage them to ask questions (HealthyChildren.org).

## ABBREVIATIONS

AAP: American Academy of Pediatrics
AAPD: American Academy of Pediatric Dentistry
AAP-CA: American Academy of Pediatrics, California
ASA: American Society of Anesthesiologists
PALS: pediatric advanced life support

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# Concerns Regarding the Single Operator Model of Sedation in Young Children

Rita Agarwal, Anna Kaplan, Raeford Brown and Charles J. Coté

*Pediatrics* originally published online March 2, 2018;

# Concerns Regarding the Single Operator Model of Sedation in Young Children

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# Policy for Selecting Anesthesia Providers for the Delivery of Office-Based Deep Sedation/General Anesthesia

Originating Council
Council on Clinical Affairs
Adopted
2018

## Purpose

The American Academy of Pediatric Dentistry (AAPD) recognizes that it is the exclusive responsibility of dental practitioners, when employing anesthesia providers to administer office-based deep sedation/general anesthesia, to verify and carefully review the credentials and experience of those providers.[1] An understanding of the educational and training requirements of the various anesthesia professions and candid discussions with potential anesthesia providers can assist in the vetting and selection of highly skilled licensed providers in order to help minimize risk to patients.

## Methods

This policy is based on a review of current dental and medical literature pertaining to the education and training accreditation requirements of potential anesthesia providers.

## Background

Historically, care necessitating deep sedation/general anesthesia was provided in a surgical center or hospital-based setting by an anesthesiologist selected and vetted by the facility or institution. The dental surgeon had little, if any, choice as to who would provide these services. Current trends find an increasing number of dental providers electing to complete such care in the confines of their office using the services of an anesthesia provider.[2] Over the last decade, office-based deep sedation/general anesthesia in the dental office has proven to be safe and effective when delivered by a highly competent and attentive individual.[3] Substantial societal cost savings associated with the delivery of cases outside of a surgical center or hospital setting have also been well documented.[4]

With the use of office-based deep sedation/general anesthesia, the primary dental provider takes on the significant responsibility of creating a team of highly qualified professionals to deliver care in an optimal and safe fashion. Deep sedation/general anesthesia techniques in the dental office require at least three individuals:

- Independently practicing and currently licensed anesthesia provider.
- Operating dentist.
- Support personnel.[1]

No other responsibility is more important than identifying an anesthesia provider who is highly competent. Significant pediatric training, including anesthesia care of the very young, and experience in a dental setting are important considerations, especially when caring for young pediatric and special needs populations. Advanced training in recognition and management of pediatric emergencies is critical in providing safe sedation and anesthetic care.[1] Close collaboration between the dentist and the anesthesia providers can provide access to care, establish an enhanced level of patient cooperation, improve surgical quality, and offer an elevated level of patient safety during the delivery of dental care.

Federal, state, and local credentialing and licensure laws, regulations, and codes dictate who legally can provide office-based anesthesia services. Practitioners choosing to use these modalities must be familiar with the regulatory and professional requirements needed to provide this level of pharmacologic behavior management.[1] The

operating dentist must confirm any potential anesthesia provider's compliance with all licensure and regulation requirements. Additional considerations in anesthesia provider selection may include proof of liability insurance and recommendations from professional colleagues. Lastly, dentists must recognize potential liability issues associated with the delivery of deep sedation/general anesthesia within their office.

It is important to acknowledge that not all anesthesia providers have equal training and experience delivering care during procedures performed within and around the oral cavity, especially in the pediatric or special healthcare needs patient populations or on a mobile basis. The following table summarizes the educational requirements of various anesthesia professions.

**Table. Anesthesia Education and Training Comparison**

| Anesthesia Provider | Permitted to Function Independent of Supervision by Anesthesiologist | Minimum Duration of Program Required for Certification | Minimum Number of DS/GA Cases | Minimum Number of Pediatric Cases | Definition of Pediatric Patient | Minimum Number of Special Needs DS/GA Cases | National Examination/ Certification Organization |
|---|---|---|---|---|---|---|---|
| **Certified Anesthesiologist Assistant[5]** | No | 24 mon | 400 GA cases | | 0-18 | N/A | National Commission for Certification of Anesthesiologist Assistants |
| **Certified Registered Nurse Anesthetist[6]** | In some states | 24 mon | 25/400[B] | < 2 yrs: 10<br>2-12 yrs: 30 | ≤12 yrs | N/A | National Board of Certification and Recertification for Nurse Anesthetists |
| **Dentist Anesthesiologist[7]** | N/A | 36 mon | 800 | 125 | ≤7 yrs | 75 | American Dental Board Anesthesiology and/or National Dental Board of Anesthesiology |
| **Medical Anesthesiologist[8]** | N/A | 48 mon | N/A | 100 | ≤12 yrs | N/A | American Board of Anesthesiology |
| **Pediatric Medical Anesthesiologist[9]** | N/A | 12 month fellowship following medical anesthesiology residency | N/A | N/A | | N/A | American Board of Anesthesiology (Pediatric anesthesiology examination)[10] |
| **Oral and Maxillofacial Surgeon[11]** | Yes | 5 months anesthesia service supplemented by OMFS service [γ];<br><br>48 months | 300 | 50 | ≤18 yrs | N/A | National Dental Board of Anesthesiology for anesthesia training;<br><br>American Board of Oral and Maxillofacial Surgery for surgery training |

*Legend: DS/GA – Deep Sedation/General Anesthesia OMFS – Oral and Maxillofacial Surgery*

*γ - During the oral and maxillofacial surgery training program, a resident's assignment to the department of anesthesiology "must be for a minimum of 5 months, should be consecutive and one of these months should be dedicated to pediatric anesthesia".[11] This anesthesia experience is supplemented throughout the training program to ensure competence in deep sedation/general anesthesia on adult and pediatric patients.*

Because of the diversity in anesthesia education among potential providers, operating dentists should further investigate an individual's training and experience. A candid discussion with a potential anesthesia provider to establish the individual's comfort and experience with unique patient populations (e.g., patients with development disabilities or medical comorbidities, infants and toddlers) is extremely important, especially if it is anticipated that this will represent a large portion of a dental practice's deep sedation/general anesthesia focus. Selection of a skilled and knowledgeable anesthesia provider is paramount in providing patients with the safest and most effective care possible.

## Policy Statement

The AAPD encourages dental practitioners, when employing anesthesia providers to administer office-based deep sedation/general anesthesia, to verify and carefully review the credentials and experience of those providers. In addition to the credentialing process, the AAPD encourages dentists to engage a potential anesthesia provider in a candid discussion to determine expectations, practices, and protocols to minimize risk for patients. Sample questions to assist in this conversation appear below.

### SAMPLE QUESTIONS TO ASK A POTENTIAL OFFICE-BASED ANESTHESIA PROVIDER

These sample questions, developed by the AAPD, are provided as a practice tool for pediatric dentists and other dentists treating children. They were developed by experts in pediatric dentistry and offered to facilitate excellence in practice. However, this list does not establish or evidence a standard of care. In supplying this list of sample questions, the AAPD is not engaged in rendering legal or other professional advice. If such services are required, competent legal or other professional counsel should be sought.

1. What is your experience with pediatric patient populations? …special healthcare needs populations?
2. What is your background/experience in providing office-based deep sedation/general anesthesia care? …and specifically for pediatric dental patients?
3. How do you evaluate a dental facility and staff prior to initiating anesthesia services? What expectations and requirements do you have for the dentist, auxiliary staff and facility?
4. What equipment do you use to administer and monitor deep sedation/general anesthesia in the office, and what is your maintenance protocol for this equipment?
5. What equipment and/or medications should be maintained by the dental facility?
6. What are some potential emergencies associated with the delivery of deep sedation/general anesthesia in the pediatric dental office, noting any that may be unique to these clinical circumstances?
7. What is your training/experience in recognition and management of pediatric anesthetic emergencies?
8. In the event of a medical emergency, what is your plan of action? What are the roles of the dentist and auxiliary staff during a medical emergency?
9. Do you have an affiliation with any area hospitals in case a patient requires transfer?
10. What patient selection criteria (e.g. age, weight, comorbidities) do you use to identify potential candidates for office-based deep sedation/general anesthesia?
11. When a decision has been made that a patient is a candidate for office-based sedation/general anesthesia, what is the office's role in preparing a patient for office-based deep sedation/general anesthesia? How/when do you prepare the patient for the procedure?
12. What is your protocol for monitoring a patient post-operatively?
13. What are your discharge criteria and follow-up protocols for patients who receive office-based deep sedation/general anesthesia?
14. Would you describe a typical general anesthesia case from start to finish?
15. What is your protocol for ordering, storing and recording controlled substances for deep sedation/general anesthesia cases?
16. What are the patient fees associated with office-based deep sedation/general anesthesia services?
17. How/where are patients records related to the office-based administration of/recovery from deep sedation/general anesthesia stored?

## References


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Tufts UNIVERSITY | School of Dental Medicine

September 4, 2018

Ellen R. Balasco, Esq.
Chief of Center for Professional Boards and Licensing
Rhode Island Department of Health
3 Capitol Hill, Ste.104
Providence, RI 02908



Dear Attorney Balasco:

I am national recognized (CV attached) expert on sedation and anesthesia in dentistry. I participated as a volunteer consultant to the Rhode Island Working Group on drafting updated Sedation/Anesthesia Rules and Regulations for Rhode Island and was present for every meeting of this group, but never was presented the final draft of this group. Therefore, I would like to comment on the proposed changes to the Chapter 40-Professional Licensing and Facility Regulation, Sub Chapter 05-Professional Licensing.

**2.2**
**Incorporated Materials**

These must include the latest Practice Guidelines for Moderate Sedation that have been approved by medicine and dentistry.

D4

**Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018: A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology**

http://anesthesiology.pubs.asahq.org/article.aspx?articleid=2670190&_ga=2.128993356.1947217376.1535839869-1295743337.1535839869

**2.3 Definitions**

**D.** The National Dental Board of Anesthesiology (NDBA) has been changed to infer Fellow status in ADSA. Thus, NDBA examinees are able to become ADSA Fellows with a single set of exams.

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The American Dental Board of Anesthesiology (ADBA) recognizes graduates of CODA approved candidates of Dental Anesthesiology residencies.

**2.8.2**

The wording of this section is concerning as the acts described for a DAANCE assistant are roles that would normally be fulfilled by educated, licensed professionals (Physician Anesthesiologist, Dentist Anesthesiologist, Certified Registered Nurse Anesthetist, or advanced trained RN or EMT-P (paramedic). To make a blanket statement saying "no person shall perform any act ..." with the exception of a DAANCE assistant is very confusing to other recognized caregivers.

**2.11.2 Professional Licensing Requirements**

**A.2** Should read, "Authorizes a dentist who has successfully completed CODA approved Dental Anesthesia Residency..."

**2.11.3**
**F. Applicants for a Pediatric Individual Anesthesia Permit**
**2 and 3**
There is double standard here one of the qualifiers here is that an OMFS has to "be a candidate for board certification" while the Dental Anesthesiologist "must be a diplomate of the ADBA.

With definition of a pediatric patients being 13 or younger, I feel it is very important to understand the actual pediatric training required by CODA. For OMFS, the requirements are 50 pediatric patients under the age of 13 versus for Dental Anesthesiology; it is 125 cases under the age of 7. There are great physiological, anatomical and pharmacological differences between younger pediatric patients than older ones and I am very concerned about the younger spectrum as to true competency and safety.

**2.11.4 Qualifications for a Facility Permit**
**C. Qualifications for a Moderate Sedation Facility Permit**
**E. Qualifications for a Facility Host Permit**

**"An applicant for a moderate sedation or host facility permit for moderate, deep sedation or general anesthesia shall obtain written agreement from a hospital to accept emergency patients or show evidence of membership on a hospital staff.**

This facility qualifier does absolutely nothing in promoting a culture of safety and all hospitals accept emergency patients no matter whether the patient has been administered any form of sedation/anesthesia or not. Whether an emergency in a dental office is a result of sedation/anesthesia, local anesthesia, a medical emergency due to a pre-existing condition, acute emergency (e.g. allergy, MI, stroke, etc.) or just happenchance and needs emergency care, the emergency response system (911) is activated and the EMT/EMS

provider decides the most appropriate hospital for transport. A written agreement to accept medical emergency patients is a moot point and the membership of on a hospital staff does not mean anything in terms of competency in sedation/anesthesia. When a dental emergency patient is transferred to a hospital, their care is immediately transferred initially to the first responder and then to an emergency room physician.

I have been a consultant to many state boards of dental registration for their sedation/anesthesia rules and regulations and have never encountered this provision. It will totally decrease access to care for patients who need moderate sedation due to their anxiety or their special needs. If in fact this provision is important to the practice of dentistry, them it should be extend to all dentists requiring membership on a hospital staff.

**2.11.9 Personnel Requirements**
7,8,9
References are not updated and should read 2017
**10**
According to Rhode Island Dental Practice Act, all licensed dentists must be current in Basic Life Support.
**Section F 1. b**

For moderate/deep sedation and general anesthesia ventilation must be monitored by end-tidal CO2.

**2.13 Physical Facility, Equipment and Safety**
**D Moderate Sedation**
**1 c.**
Change to capnograph

**2.13.2 Clinical Guidelines**
**A. General Anesthesia/Deep Sedation**
**2. C**
Body Mass Index (BMI) should be mandated as it is in ADA Guidelines for Sedation.
5 c 1
Maintenance of a time oriented anesthetic record of oxygenation, ventilation; cardiac monitoring (e.g. ECG, Blood Pressure, Heart Rate) must be recorded at 5-minute intervals.
**B. Moderate Sedation**
**CC**
The national standard of care for moderate sedation on all patients is the monitoring of end-tidal CO2. It is not an either/or or when needed.
**b. Documentation**
**(2)**
End tidal CO2 should be added.
**Recovery and Discharge**
**F. Use of reversal agents**

If this is included here, it should also be included in the deep sedation/general anesthesia section.

**E. Dental Pediatric Anesthesia**

**1. D**

Just because one is board eligible or diplomats of ABPD, does not confer competency for moderate sedation on pediatric patients. This is very program specific and the program director must declare competency to get a permit.

**Conclusions**

1. There are many inconsistencies in the document and they mainly deal with referring to Guidelines and then not adhering to them (e.g. AAPD/AAP, ADA, ASA, etc.
2. There is reduncy throughout the document and many sections do not dovetail well with other statements covering the same areas.
3. Why one needs an AED to administer nitrous oxide-oxygen sedation and does not it for the practice of dentistry with local anesthesia is still beyond me? Requiring all dentists to have BLS and not including a mandate to have an AED does not make sense to me. All of the states surrounding Rhode Island (Massachusetts, Connecticut, New York, etc). have this as a requirement for licensure.

4. I still feel that the pediatric section is weak and does not reflect the clinical and educational qualifiers to protect our youngest patients.

Sincerely,

Morton Rosenberg, DMD
Interim Compliance Officer
Tufts University School of Dental Medicine
Professor (Emeritus) of Oral and Maxillofacial Surgery
Tufts University School of Dental Medicine
Professor of Anesthesiology and Perioperative Medicine
Tufts University School of Medicine

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Dr. Robert Bartro
Administrator
RI Board of Dental Registration

RE; Proposed Regulation changes

Dr. Bartro,

I am asking the members of the RI Board of Dental Registration to consider the following suggested changes to the proposed regulations that were presented on September 11th 2018. Thank you in advance for your consideration.

Title 216-Department of Health
Chapter 40-professional Licensing and facility Regulation
Subchapter 05-Professional Licensing
Part 2 Dentists, Dental Hygienists and Dental Assistants

2.10.3 Non-Delegable (Exclusionary) Procedures/Duties

A # 11: This reads: Exposure of radiographs without successful completion of a course in dental radiography which is offered by an educational institution with a program accredited by the Commission on Dental Accreditation and which fulfills institutional requirements as set forth in R.I. Gen. laws 40-20-1;

Proposed: Exposure of radiographs without successful completion of a course in dental radiology offered by either a CODA approved educational institution or a clinical educational program approved by the Department of Health and the Board of Dentistry and successfully passing the DANB Radiation Health and Safety (RHS) examination or any other exam approved by the Dental Board of Registration.

Rational:

Rules and regulations as currently written, is restrictive in allowing dental assistants from other States who's regulations do not match RI's, but have met the requirement of DANB, which is a recognized examination board in dental assisting. Since there is only one CODA approved program in RI-the ability to employ assistants in a timely manner is restricted. Previously the RI Dental Board has approved weekend radiology courses offered by Tufts and BU as meeting basic requirements.

Thank you for taking the time and consideration of this concern.

Respectfully submitted,
Marie Jones-Bridges, CDA,CDHC, RDH-PHDH, BS
September 17. 2018

Dr. Robert Bartro
Administrator
RI Board of Dental Registration

RE; Proposed Regulation changes

Dr. Bartro,

I am asking the members of the RI Board of Dental Registration to consider the following suggested changes to the proposed regulations that were presented on September 11th 2018. Thank you in advance for your consideration.

Title 216-Department of Health
Chapter 40-professional Licensing and facility Regulation
Subchapter 05-Professional Licensing
Part 2 Dentists, Dental Hygienists and Dental Assistants

2.9 Public Health Dental Hygiene Practice:

2.9.1- Qualifications

B-b: which currently reads " Successful completion of the following courses within twenty-four (24) months prior to license issuance: Pubic Health Fundamentals, CDC Guideline (infection Control)Risk management for practice in a public health setting and Management of medical emergencies, which ae offered by an educational institution with a program accredited by the Commission on Dental Accreditation.

**Recommended change:** Successful completion of the following courses within twenty-four (24) months prior to license issuance**: (remove semi colon replace with comma as was in the original submission)**Pubic Health Fundamentals, CDC Guideline (infection Control)Risk management for practice in a public health setting and Management of medical emergencies, which ae offered by an educational institution with a program accredited by the Commission on Dental Accreditation or by a program approved by the Board or the Department.

Reason: Removal of the colon, this change was made within the Department of Health, and changes the original meaning and intent of this statement. The courses identified as a requirement for licensure were only three: CDC Guidelines, Risk Management and Medical Emergencies. As the current document reads, an additional course in Public Health Fundamentals would be required. PH fundamentals are a required course in all dental hygiene curriculums. The intent of the other three courses was to ensure that these courses in particular were current by the PHDH candidates before issuance of the PHDH license.

Secondly, the addition of the last statement allows for courses outside of CODA programs which are appropriate and meets the requirements of the Continuing Education Criteria to be accepted. As the proposed regulations reads: potential PHDH candidates are limited to accessing courses offered by additional subject experts and would be the discretion and schedule of the CODA institution timeframe in offering the courses.

As one of the original members of the subcommittee of the PHDH regulations, the original intent was not to make obtaining PHDH licensure a cumbersome task, but to increase access to care by hygienists who wanted to expand the environments in which they could provide preventive care under current scope of practice. The current courses presented do not offer a credential, only meeting the regulation requirement.

Respectfully submitted,
Marie Jones-Bridges, CDA,CDHC, RDH-PHDH, BS
September 17. 2018

# RIOMS

September 17, 2018

Paula Pullano
Department of Health
Rhode Island Department of Health, Division of Policy,
Information and Communications
3 Capitol Hill
Providence, RI 02908-5097

**In re: Rules and Regulations for Dentists, Dental Hygienists and Dental Assistants (216-RICR-40-05-2)**

Dear Ms. Pullano:

Please accept the below written comments regarding the proposed revisions to the Rules and Regulations for Dentists, Dental Hygienists and Dental Assistants. These comments are submitted on behalf of the Rhode Island Association of Oral and Maxillofacial Surgeons (RIOMS).

- Section 2.1 (8th line down) should say "continuing education for dentists, dental hygienists **and DAANCE-certified maxillofacial surgery assistants**"
- Section 2.3(A)(30)(d) definition of minimal sedation is repetitive and needs clarification as to whether there should be a distinction between the two sentences
- Section 2.3(A)(41) Qualified Dentist- should provide clarification and give examples (OMS or Dental Anesthesiologist)
- Section 2.3(A)(42) Qualified Provider – should provide clarification and give examples (M.D. or CRNA)
- Section 2.8.4(D) should say ACLS not BLS
- Section 2.10.1(D) DAANCE is misspelled
- Section 2.11.1 General Requirements for Administration of Anesthesia in Dental Office

- (C) Says as a condition for approval for an Individual Anesthesia Permit or a Facility Permit the Board shall conduct an onsite inspection of all equipment, medications, staff, etc. for the purpose of administering Deep Sedation/General Anesthesia and Moderate Sedation. It does NOT include an inspection for Minimal

- However, Section 2.11.4(B)(1) Says that approval for a Minimal Sedation Facility Permit SHALL REQUIRE completion of an on-site office evaluation

- Need to delete office inspection requirement in 2.11.4(B)(1) if not required

- Section 2.11.2 Professional Licensing Requirements (Should read "Permitting Requirements")

  - An anesthesia permit is not a license

- Section 2.11.2(A) qualified dentist should be capital "Q"

- Section 2.11.2(A)(5) Needs further description. A Facility Host Permit applies to those office bringing in an outside dentist or provider to provide anesthesia service. There is a separate Pediatric Facility Permit if providing anesthesia to patients under the age of 13yrs old. Need to clarify that those Host facilities that plan to have a Qualified Dentist or Provider treat patients under 13yrs old will also need Pediatric Facility Permits. For future renewals this will also apply to OMFS offices. Host permit holders who utilize Qualified Dentists or Providers will need to list in their application all such providers on the form for each host facility. The permits will be site and provider specific.

- Section 2.11.2(A)(5) the word Permit is typo and needs to be consolidated

- Section 2.11.3(B) Applicants for a Nitrous Oxide Individual Anesthesia Permit must meet the following qualifications:

  - What is the difference between #1 and #3 as far as qualifications other than that #1 specifies a certain number of hours

  - Omit #3 repetitive

- Section 2.11.3(C)(1) insert 2016 at the end of sentence

- Section 2.11.3(C)(2) says comprehensive training in moderate sedation. Should say minimum instead

- Section 2.11.3(D)(1) (Requirements for Moderate Sedation). Says 60 hours of Moderate Enteral or Parenteral Sedation. Should it say "and"? Don't we want all providing moderate sedation to be trained in parenteral sedation for rescue purposes?

- Section 2.11.3(E)(1) (Individual Anesthesia Permit for General Anesthesia/Deep Sedation) Should be "AND" instead of "OR" between (b) and (c). This is a significant error. The way it is written it says the applicant must have fulfilled only ONE of the following. That means someone can complete only a Board approved simulation course that uses high fidelity human simulation without any educational training.

    - Also under the same section the words "advanced training program in anesthesia" under (a) should be omitted
    - We cannot write regulations for programs that *may* be developed in the future. The Regulations need to close any loopholes and avoid ambiguities when it comes to required training for administering anesthesia, partiulalry if there is no definition as to what is "advanced training." Regulation revisions can be made in the future of different programs are developed.

    - The section should include ACLS

    - The same qualifications should be listed as they are in Section 2.11.3(F)(1),(2),(3) and (4). These should NOT be applicable ONLY to a pediatric permit

- Section 2.11.3(G)(3) (Portable Individual Anesthesia Permit) should include PALS along with ACLS

    - Permit requirements should also include an attestation as to the safety of all equipment, medications and staff. This attestation should not only be from the Host Facility Permit applicant but for the Portable Permit holder who is often bringing in equipment, medications and staff

    - As of now we have no oversite on the Portable Providers equipment or medications that they are bringing into our state.

    - There is also no simulation or emergency scenario evaluation required for Portable Individual Anesthesia Permit applicants however there is for all others applying for moderate or deep sedation/general anesthesia permits. This should be required

- Section 2.11.4(A)(1) should say "that confirm applicant" instead of "that said applicant"

- Section 2.11.4(C)(3) (Moderate Sedation Facility Permit) Should say "on-site office evaluation performed by a Board appointed office evaluation team" Not just one member or one advisory consultant

- Should add in "an office evaluation team shall consist of two or more persons chosen and approved by the Board and the Director" for consistency with immunity provision

- Section 2.11.4(C)(4) (Moderate Sedation Facility Permit) should say "shall obtain a written agreement from a hospital..."

- Section 2.11.4(D)(3) (Deep Sedation/General Anesthesia) should say "on-site office evaluation performed by a Board appointed office evaluation team" instead of "Board member or a Board appointed advisory consultant" so that it is consistent with section above that more than one person is involved in the inspection

- Section 2.11.4(D)(4) should say "shall obtain a written agreement from a hospital..."

- Section 2.11.4(E)(2) should say "shall obtain a written agreement from a hospital..."

- Section 2.11.9(D)(2)(b) advanced cardiac life support should be capitalized

- Section 2.11.9(D)(4) (General Anesthesia/Deep Sedation) Should specify DAANCE-certified maxillofacial surgery assistant. The way it is written makes it seem as though whichever member of the anesthetic team designated as the patient monitor may assist in the delivery of anesthesia. This is not accurate

- Section 2.11.9(D)(7), (8), (9) should say Guidelines for the Use of Sedation and General Anesthesia by Dentists (2016) instead of October 2007

- Section 2.13.2(A)(3) Monitoring and Documentation for General Anesthesia/Deep Sedation says "Monitoring. A Qualified Dentist administering deep sedation/general anesthesia must remain in the operatory room until the patient meets the criteria for recovery ...The licensed dentist must not leave the facility until he or she has personally observed that the patient meets the criteria or discharge...."

    - This should not be limited to Qualified Dentist. Should say both Qualified Dentist or Qualified Provider. Should not say licensed dentist at all.

        - Part (5) says the dentist must continually evaluate blood pressure. This should say Qualified Dentist or Qualified Provider

- Section 2.13.2(A)(4) Recovery and Discharge – (c) and (e) should say "Qualified Dentist or Qualified Provider" NOT Licensed Dentist. A regular Licensed Dentist should not be monitoring oxygenation or handling discharge instructions. It should be a Qualified Dentist or Provider with the appropriate Permit.

- Section 2.13.2(A)(5)(a) (Emergency Management) should say "Qualified Dentist or Qualified Provider"

- Section 2.13.2(B)(3)(a)(1) and 2.13.2(B)(3)(a)(1)(EE) Monitoring and Documentation (same issue as above in Section 2.13.2(A)(3)) should say Qualified Dentist or Qualified Provider

- Section 2.13.2(B)(4)(b) and (c) should say "Qualified Dentist or Qualified Provider"

- Section 2.13.2(B)(5)(b) (Emergency Management) should say "Qualified Dentist or Qualified Provider" the Qualified Provider should be held to the same emergency standards

- Section 2.13.2(C)(4)(b) and (c) should be "Qualified Dentist or Qualified Provider"

- Section 2.13.2(E)(4)(d) and Section 2.13.2(E)(5)(a) should be "Qualified Dentist or Qualified Provider"

- Section 2.13.2(E)(5)(b) qualified dentist should be capitalized

- Section 2.15.1(D) why are they removing that any hearings or reviews shall be held in accordance with the Administrative Procedure Act? This is the standard used for conducting all administrative hearings.

In the event there are any further questions about the above recommended comments please contact me.

Sincerely,

*//s// Frank Paletta*

Frank Paletta, MD, DMD, FACS
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To: Paula Pullano

Department of Health
Rhode Island Department of Health, Division of Policy, Information, and Communi cations 3 Capitol Hill Providence, RI 029085097

My name is Kathleen Stack and I am a licensed RDH in Rhode Island, Massachusetts and Connecticut. This is my response to the call for open public comments for **Rule 216-RICR-40-05-2**. My comments are directed towards section 2.9 Public Health Dental Hygiene Practice, 2.9.1 Qualifications for licensing.

In 2015, I sent a letter supporting the passage of Public Health Dental Hygienists in Rhode Island to the State legislators. In this letter I described my prior experiences as a Public Health Dental Hygienists in two States, Michigan and Connecticut. Presently, PHDH are practicing in many other States, others have licensing for Collaborative Agreement Practice, Remote Supervision or in the case of Oregon, Limited Access Permit (LAP).

State requirements to practice in these settings are listed on the American Dental Hygienists' Association's website. http://www.adha.org/resources-docs/7513_Direct_Access_to_Care_from_DH.pdf

The requirement of three separate CODA courses to be taken to apply for licensure as a PHDH in Rhode Island is well beyond the additional educational requirements for any State issuing a similar license for this scope of practice. Although I believe the Rhode Island CODA courses are of value especially for someone new to public health and/or going into certain settings, I do not feel they are necessary for all settings or for dental hygienists with this type of experience. Therefore, I think it necessary to modify 2.9.1 as written and to include*" or **by a program approved by the Board or the Department".***

My initial experience as a PHDH was in Michigan while I was completing my MPH in Dental Public Health. At that time, I had 12 years of full-time experience as a clinician. This experience was considered adequate for my taking on a position in a public health setting that was funded by a grant to provide dental

hygiene services to children that did not have dental insurance. No additional training or courses were required. My ability to provide care to these children under Michigan's law was an example of increased access to care due to the removal of the barriers to care.

While living in Connecticut, I was hired to set-up and manage a mobile preventative dental program for the community of Windham, Ct. Funding for this program was from a Rural Oral Health Grant received from Health Resources and Services Administration (HRSA).

Connecticut's requirement for a PHDH is as follows:

Connecticut 1999 Sec. 20-126l Public Health Dental Hygienist: Dental hygienist with 2 years' experience may practice without supervision in institutions, public health facilities, group homes and schools.

In the two years setting up, supervising and managing this program, I also provided dental hygiene services in the Windham schools and community sites. These community sites included a soup kitchen, homeless shelter, senior center, half-way house etc.

In the process of setting up this program we researched and purchased what portable equipment we needed. This included research on infection control and the use of a Statim sterilizer for instruments.

My experiences as a PHDH should be adequate for licensing. In addition to the clinical experience, I have a Master's in Public Health from the University of Michigan's School of Public Health. I also taught Community Dental Health at CCRI from 2012-2017. As mentioned above it is not that the CODA classes are not valuable. I believe they are not necessary for an experienced PHDH.

In addition to the amount of time required for the completion of the three CODA courses, there is the cost. Based on the poor job market for dental hygienists in the past 10 years or so, I believe there are many struggling financially. The ability to become a PHDH is a wonderful opportunity to increase access to care for those whom historically have not received care due to various barriers.

It is regrettable that a RDH desiring an opportunity to provide care to the underserved might be prohibited/delayed by his/her own lack of financial resources. Are scholarship funds, loans etc. being made available to those in need? If not, we are not allowing this legislative change to have as full an impact as possible. The primary goal is to provide care to the traditionally underserved.

My request is that the Rule 216-RICR-40-05-2 be amended to include*: or by a program approved by the Board or the Department.* This should allow for taking the prior experiences of PHDH licensed in other States into consideration.

Sincerely, Kathleen M. Stack, RDH, BS, MPH

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