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(COMMENCED AT 10:04 A.M.) 1 HEARING OFFICER ROBERTS: 2 Welcome. We are here today regarding a public 3 hearing concerning the Rules and Regulations 4 for Dentists, Dental Hygienists and Dental 5 Assistants. This hearing is being conducted 6 under the provisions of Rhode Island General 7 8 Laws 23-17 and 42-35. Today is Tuesday, September 11, 2018. My name is Sullivan 9 10 Roberts, Rules Coordinator for the Rhode Island Department of Health, also known as RIDOH, and 11 I will be the Hearing Officer for today's 12 13 proceeding. Before we start, and to prevent 14 any interruption of the proceedings, at this 15 time, I would like to ask those of you with 16 cell phones, pagers and watch alarms to turn 17 them off or set them to vibrate. 18 19 (PAUSE) HEARING OFFICER ROBERTS: 20 The 21 purpose of the hearing today is to afford 22 interested parties an opportunity to comment on the proposed Regulations, allow as many people 23 as possible to be heard and to ensure that an 24

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1	accurate record of all comments is obtained.
2	This hearing is intended for
3	your participation only and is not intended to
4	provide a forum or discuss being, debating,
5	arguing or otherwise having any dialogue on the
6	Regulations before us with RIDOH personnel as
7	part of this public hearing. If you would like
8	to speak, the procedure we will use is as
9	follows: Please register to speak at the rear
10	of the room. Speakers will be taken in order
11	of registration. Up to five minutes will be
12	allowed for your presentation, unless the lack
13	of speakers allows for additional time. Any
14	interruptions due to the Stenographer's need to
15	clarify your testimony will not count against
16	your allotted time. If you are reading off of
17	a prepared document such as a paper copy or
18	electronic version of your testimony, we
19	politely request that you speak clearly and at
20	a unhurried pace so the Stenographer can
21	appropriately capture your testimony in its
22	entirety.
23	I will indicate when you have
24	one minute of time remaining. If you are

unable to complete your testimony in the time 1 allotted, you may have an opportunity to speak 2 if any time is remaining after the other 3 speakers who have signed up complete their 4 testimony. When you are called, come to the 5 podium, identify yourself by name and 6 affiliation, if any. Please spell your name 7 and give the full name of your organization, if 8 you used an acronym, such as NASA. Make your 9 presentation and make sure you conclude in the 10 allotted time of five minutes. If you have a 11 written copy of your statement, we would 12 appreciate if you could provide it for the 13 record. If you read from an electronic version 14 of your testimony, we would appreciate if you 15 could provide a hard copy or e-mail us your 16 testimony. 17 In accordance with the 18 requirements of the Administrative Procedures 19 Act, additional written comments on these 20 21 proposed amendments will be accepted by Monday, September 17, 2018. After the conclusion of 22 the public comment period, RIDOH has four 23 options under State law. 24

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6 The first option is to file the 1 Regulations as posted with the Secretary of 2 State. 3 The second option is to file 4 with minor technical changes such as correcting 5 spelling, punctuation, et cetera. 6 The third option is to make 7 8 non-technical changes in what you see before you today, which would be addressed in RIDOH's 9 10 concise explanatory statement filed with the final Regulations and could also necessitate a 11 new public hearing and associated public notice 12 posting. 13 And the fourth option is not 14 file the proposed Regulations, in which case 15 the current Regulations would remain in effect. 16 Unless specified by law or regulation or at the 17 discretion of RIDOH, once filed, the 18 Regulations become effective 20 days after 19 filing and have the force of law upon that 20 21 date. 22 Are there any questions on how 23 the public hearing will be conducted today? (PAUSE) 24

7 HEARING OFFICER ROBERTS: 1 At this time, for the record, we will have a 2 presentation of exhibits. The first exhibit is 3 the Notice of Proposed Rule Making posted on 4 the Rhode Island Secretary of State's web site 5 on August 15, 2018. 6 (EXHIBIT 1, NOTICE OF PUBLIC 7 HEARING, MARKED) 8 9 10 HEARING OFFICER ROBERTS: The second exhibit is a copy of the proposed 11 Regulations with provisions indicated also 12 posted to the Rhode Island Secretary of State's 13 web site on August 15, 2018. 14 (EXHIBIT 2, PROPOSED 15 REGULATIONS, MARKED) 16 HEARING OFFICER ROBERTS: 17 The 18 third exhibit is a copy of the existing Rules and Regulations Pertaining to Dentists, Dental 19 Hygienists and Dental Assistants, last filed 20 21 with the Rhode Island Secretary of State in June of 2017. 22 (EXHIBIT 3, EXISTING 23 REGULATIONS, MARKED) 2.4

8 HEARING OFFICER ROBERTS: The 1 fourth exhibit is a copy of Rhode Island 2 General Laws 5-31.1-4 and 5-31.1-5, the 3 enabling statutes for these Regulations. 4 (EXHIBIT 4, RIGL 5-31.1-4 AND 5 5-31.1-5, MARKED) 6 HEARING OFFICER ROBERTS: 7 The 8 fifth and final exhibit is a copy of the e-mail dated August 10, 2018 from the Office of 9 10 Regulatory Reform to Sullivan Roberts confirming that RIDOH was authorized to move 11 forward with promulgation of these 12 Regulations. 13 (EXHIBIT 5, OFFICE OF REGULATORY 14 REFORM LETTER, MARKED) 15 HEARING OFFICER ROBERTS: 16 Αt. this time, I would like to call the first 17 speaker. Charles J. Cote. 18 DR. COTE: So, my name is 19 Charles J. Cote, I'm a Board certified 20 21 pediatrician and pediatrician anesthesiologist. 22 I have been the primary author of the American Academy of Pediatrics Association Guidelines 23 since the first publication in 1985 and every 24

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

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8 those reports. Obtained about 700. We also 9 got reports from the United States Pharmacopeia 10 and a survey that we sent to members of the 11 Academy of Pediatrics. Two anesthesiologists, 12 one ER physician and one ICU physician debated 13 the causes of the adverse health problems and 14 we ended up with 95 cases where we felt we 15 could agree on what happened. And of those 95 16 cases, 60 had death or neurologic injury as the 17 end point and 29 of these were related to 18 dental care. 80 percent of these children seem 19 20 to present with a desaturation, meaning that 21 they turn blue and should have been able to be 22 rescued, but the practitioners involved did not have the necessary skills to rescue the child. 23 Interestingly, there was a 2.4

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1	three-fold greater instance of cardiac arrest
2	associated with these non-hospital events
3	compared with hospital events with a 93 percent
4	mortality. So, when something went wrong in
5	the dental office setting, the outcomes were
6	dismal. Parenthetically, eleven of these
7	dentists were described as oral surgeons,
8	although we really couldn't tell what their
9	true education or training was. I can say had
10	I known that this dentistry was going to be so
11	highly represented, I would have invited an
12	oral surgeon or pediatric dentist or both to
13	help us analyze the data.
14	I have grave concerns about the
15	current bill, because at the beginning it
16	states that this bill is consistent with the
17	guidelines of the American Academy of
18	Pediatrics, and I take, I have a lot of
19	concerns about that, because it clearly does
20	not have anything at all related to the Academy
21	of Pediatrics. And I have detailed a whole
22	bunch of different areas where this is a
23	problem, but we don't have time to talk about
24	that.

1	What I'm concerned about, though,
2	is this independent practice of an oral
3	surgeons who can direct sedation with a dental
4	assistant, who's, the dental anesthesia
5	assistant certification exam DANCE, D-A-N-C-E,
6	which is fulfilled by taking 36 hours of an
7	Internet course and taking an examination. In
8	these 36 hours, they are supposed to learn
9	basic science, how to evaluate and prepare
10	patients, understand anesthetic drugs and
11	anesthetic techniques, anesthesia, anesthesia
12	equipment and monitoring and office anesthesia
13	emergencies. It took me three years to learn
14	that, and yet, these people are expected to
15	learn this in 36 hours of Internet time.
16	The other thing that's of
17	interest, there doesn't seem to be any
18	educational requirements for these
19	DANCE-trained individuals. It doesn't even say
20	they have to have a high school certificate.
21	It appears that they have on-the-job training
22	with an oral maxillofacial surgeon, and then
23	they take this test, and then they are DANCE
24	certified. So, it says that, in their

guideline, that there has to be either basic 1 life support or CPR certified, and it doesn't 2 mention PAL certified; and if they are going to 3 be taking care of children, obviously I think 4 they need to be PAL certified. 5 I think you know all know that 6 7 when something hatches, push comes to shove, you want to have medically trained people there 8 to assist with the emergency; and these 9 individuals have no real life experience that 10 could provide them with the medical knowledge 11 to assist an oral surgeon with any 12 life-threatening emergency, such as a child who 13 stopped breathing due to the effects of the 14 medication. The child developed spasms of the 15 muscle of the voice box. Seizure from a local 16 anesthetic. Drug overdose or allergic reaction 17 18 or other medical emergencies that can arise. These can happen in anybody's hands. Certainly 19 I have had these happen to myself over the 20 21 years. Is there a timer? HEARING OFFICER ROBERTS: 22 Yes. DR. COTE: How much time do I 23 have left? 2.4

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13 HEARING OFFICER ROBERTS: 1 That was your five minutes. 2 DR. COTE: You didn't give me a 3 warner. 4 HEARING OFFICER ROBERTS: 5 Τf 6 you're unable to complete your testimony in the 7 time allotted, you may have an opportunity to speak after the other speakers who are signed 8 up complete their testimony. Thank you. The 9 next speaker is Cynthia Johnson. 10 MS. JOHNSON: Good morning. 11 Good morning, I'm Cynthia Johnson. I am a 12 professor at the Community College of Rhode 13 Island, and I am speaking to the 2.9 Public 14 Health Dental Hygiene Practice Act. The reason 15 why I'm speaking on this is because in the new 16 quidelines it has spoken about not having the 17 courses come from an accredited institution. 18 CCRI and myself and a few of the faculty were 19 20 contacted by the Department of Health once this 21 Practice Act was put into place last, excuse 22 me, summer of 2017. So, when we were contacted, we were asked to create some courses 23 based upon the Practice Act. One was medical 2.4

1	emergencies. Another was infection control.
2	Another was being investigated for risk
3	management. With the we met several times
4	with Dr. Zwetchkenbaum, and we had come up with
5	two courses that we were going to run, which
6	was the medical emergencies for the public
7	health dental hygienist and also the infection
8	control for the public health dental hygienist.
9	These classes are web-based courses. They run
10	for five weeks; and from the feedback we have
11	gotten from the people that took the course,
12	and it was very positive; and I do have their
13	evaluations with me here today.
14	The reason why I'm speaking upon
15	this is because now they are trying to make
16	these courses come from a non-accredited site.
17	We were told back in April that the risk
18	management course could be taken or another
19	course in the Rhode Island Dental Association.
20	So, myself and several of the dental hygienists
21	took that course. I, myself, am a public
22	dental hygienist. I also met with Dr.
23	Zwetchkenbaum and made another course, the risk

that I have created, again, is on line. It's 1 web-based. It run for five weeks, and it goes 2 over the all the collaborative agreement and 3 all of the tool kit they will need to become 4 dental public health hygienists. One of the 5 6 web sites that I could go to become a public 7 health hygienist and take the risk management course I went to and I noted that there was 8 some information that was lacking in those 9 particular web sites as well as the course that 10 I took with the Rhode Island Dental Association 11 in May. I have many people, health hygienists, 12 that have come to me that took that course and 13 wanting more guidance. I was happy to give 14 them that guidance within that; but within the 15 risk management course that we offer at CCRI, 16 we incorporated all of those questions and 17 18 answers. Also, within the risk management 19 20 course at CCRI, we incorporated a business 21 management plan as well and we also reviewed the rules and regulations of the public health 22 dental hygienists, which were very confusing 23 for some of the people in this program in the 2.4

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courses that we teach. From our courses and 1 from our evaluations, it has been noted that 2 every dental hygienist that took the course 3 felt that they had gained something. They had 4 felt that they had changed their practices 5 6 within our course work and had gained better 7 knowledge within our courses that we taught. So, I am here today seeking 8 support from the Department of Health, from Dr. 9 Zwetchkenbaum, from the Board to keep these 10 courses to be an accredited course, knowing all 11 the work and the consciousness that our college 12 puts forth in teaching our courses in general 13 and also with these public health hygiene 14 courses, we offer a lot of support to our the 15 students, and we offer a lot of guidance to our 16 students within these courses. Even once they 17 go out and they receive these credentialing, 18 they still come back and I'm still answering 19 20 their questions, which if they take some other 21 courses, they might not receive that support. 22 I am asking for the continued support of the Board and the Department of Health considering 23 that you had come to us first within these 2.4

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17 Thank you so much. 1 courses. HEARING OFFICER ROBERTS: Thank 2 The next speaker is Julie Galleshaw. 3 you. MS. GALLESHAW: Hi, can you hear 4 5 me? AUDIENCE: 6 Yes. 7 MS. GALLESHAW: All right. I, first, would like to introduce myself. I'm 8 Julie Galleshaw, J-U-L-I-E, G-A-L-L-E-S-H-A-W, 9 professor of dental health at the Community 10 College of Rhode Island. I am also a newly 11 licensed public health dental hygienist. 12 Ι would like to specifically speak to Section 13 2.9.1, gualifications within the draft 14 pertaining to 2.9, the Public Health Dental 15 Hygiene Practice. I was at the original 16 meeting of the draft as a public member. 17 Ι 18 took part in several meetings in which lengthy discussion took place on the specifics of this 19 particular section of the Regulations. The 20 final version that was submitted has been 21 22 changed by this Department in format, punctuation and intent. 23 I am here because I feel these 2.4

changes have taken away the intent of producing 1 safe and competent public health dental 2 hygienists for the community. The Department 3 and Board are here to ensure that all dental 4 professionals practicing in the State of Rhode 5 6 Island meet the requirements for licensure to protect the public. With that said, the new 7 version in front of us today has been changed 8 from its original draft; and in my opinion, not 9 upholding the standard of creating a competent 10 public health dental hygienist. The first 11 error and change made by the Department of 12 Health was the change in placement of the 13 The colon was to be after the words colon. 14 public health fundamentals, colon. In order to 15 start the enumeration of the courses to be 16 taken to meet the educational requirements and 17 not placed after the word insurance. 18 I am submitting with this statement the original 19 documents draft and the corrected version as 20 evidence of what needs to be corrected to 21 22 regain the original documents intent of what qualifications need to be met in order to 23 obtain a public health dental hygiene license. 2.4

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The second change made by the 1 Department of Health is in Section 2.9.1B1-B 2 after the word accreditation, the words, comma, 3 or by the program appointed by the Board or the 4 Department were added. I feel the Department 5 6 of Health has overstepped its authority by placing these words and superceding the Board. 7 The Board in all areas of the Rules and 8 Regulations is the determining entity for 9 10 course approval for the Department and not the Department itself. Nor is the word Department 11 defined in these Rules and Regulations to mean 12 the Department of Health, specifically to 13 dentistry. Nor is it stated anywhere else in 14 these Rules and Regulations the Department is 15 to be able to approve any course for licensure 16 or license renewal. If the intent of whomever 17 added these words was to reflect that the 18 Board, as defined in these Rules and 19 20 Regulations, has the ability to approve a 21 course, then I recommend that the words or an 22 and accredited course approved by the Board be the only submission in words not, comma, or by 23 a program or approved by the Department. 24 That

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those words be removed and replaced by this 1 statement or and an accredited course approved 2 by the Board. 3 I submit the following sections 4 within these Rules and Regulations that 5 6 specifically state that it is by approval of 7 the Board and not the Department. Examples throughout these Rules and Regulations is 8 evident in the following sections: Section 9 2.4.6 A-3. Section 2.4.6, B, F and G. 10 Sections 2.7.5 C and Section 2.8.4 D. 11 It is with great hope that this 12 committee will do its diligence and correct 13 these errors. Respectfully submitted. Thank 14 15 you. HEARING OFFICER ROBERTS: Thank 16 you. The next speaker is Russell Chin. 17 18 DR. CHIN: My name is Russell Chin, C-H-I-N. I'm a general dentist in Rhode 19 Island, and I'm here as a private dentist. 20 Ι would like to make some recommendations to the 21 Rules that we are talking about. 22 First one is 2.10.3, Number 4. 23 I want to strike, "plus medication." Number 5, 2.4

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

insert "successful completion of a on-site 1 office evaluation performed by a Board member 2 and a Board memoranda appointed by an advisory 3 consultant." On 2.11.7A, first line, insert 4 the word "calibrated." On 2.11.9, C1, B, 5 insert "ACLS and PALS, if needed," and strike, 6 "BLS." Going out to D2B, insert "and." On C, 7 insert "DANCE," D-A-N-C-E. Going on to 5C, 8 insert with "BLS" and on Number 7, insert "and 9 PALS." Number 8, insert "PALS if treating 10 children." Section 2.13.2, A1, remove "the 11 American Dental Association." 12 (INTERRUPTED BY TIMER) 13 HEARING OFFICER ROBERTS: Thank 14 you. Your allotted time is up. If you are 15 unable to complete your testimony in the time 16 allotted, you may have an opportunity if any 17 18 time is available. The next speaker is Steve 19 Brown. 20 DR. BROWN: Good morning. I'm 21 Dr. Steve Brown. I'm an oral surgeon in the State of Rhode Island, and I am -- today I'm 22 representing the Rhode Island Society of Oral 23 and Maxillofacial Surgery. Generally, we are 24

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thankful for the Board for putting such an 1 effort into these new Regulations. I think 2 they are long overdue. It's been a process 3 that I know has taken a few years for this to 4 These new and Rules and Regulations 5 happen. 6 are consistent with the new ADA policy as well as the American Association of Pediatric 7 Dentists and most recent AMS Guidelines for 8 Sedation and Anesthesia by Dentists. The new 9 Regulations significantly increase the 10 educational requirement for the administration 11 of minimal and moderate sedation for the adult 12 patients by dentists. Deep sedation and 13 general anesthesia administration are reserved 14 for oral and maxillofacial surgeons, dental 15 anesthesiologists, medical anesthesiologists or 16 licensed practitioners with equivalent training 17 approved by the Board. These new Regulations 18 significantly encompass anesthesia services 19 provided by dental anesthesiologists and 20 21 acknowledges the vital service they for 22 identification to the public. The administration of sedation 23 and anesthesia to pediatric patients has been 24

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1	separated and the requirements to administer
2	these services to pediatric patients has been
3	strengthened. This is because the
4	physiological and anatomical make-up of
5	pediatric patients is much different than the
6	adult, and additional training and simulation
7	is required. Office inspections have been
8	streamlined. Office inspections for moderate
9	deep and general anesthesia are being conducted
10	by a team. Post permits and portable dental
11	facility permits will address the need for
12	dental anesthesiologists.
13	Having said that there are a
13 14	Having said that there are a number of typographical errors, omissions,
14	number of typographical errors, omissions,
14 15	number of typographical errors, omissions, problems with the Regulations as they are now
14 15 16	number of typographical errors, omissions, problems with the Regulations as they are now written, and I would recommend, and I, we agree
14 15 16 17	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
14 15 16 17 18	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
14 15 16 17 18 19	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
14 15 16 17 18 19 20	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
14 15 16 17 18 19 20 21	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
14 15 16 17 18 19 20 21 21	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,

sedation must meet the following criteria: 1 The word one must be removed. It says have 2 fulfilled one of the following educational 3 training requirements. The first two, A and B, 4 are correct; but the third, C, having completed 5 a Board approved simulation course that uses 6 7 high fidelity simulation is not appropriate. That section needs to be removed. There are 8 other examples, and I think Dr. Chin made a 9 good statement as to those problems. 10 I think another thing that the 11 Board should look at are the definitions 12 exactly of what a qualified dentist is and what 13 a qualified provider. Maybe we ought to put 14 examples of each. I think in the Regulation 15 it's not clear as to what practitioner can do 16 and what his responsibilities are. There are 17 other problems with these that we will submit 18 in writing, but generally, we concur with these 19 20 new Regulations. Thank you. 21 HEARING OFFICER ROBERTS: Thank 22 you. HEARING OFFICER ROBERTS: 23 The next speaker is William A. McDonald. 2.4

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1	DR. McDONALD: Good morning. My
2	name is William McDonald. I am a dentist
3	anesthesiologist. I'm a Providence College
4	graduate. And I practice dental anesthesia,
5	mobile anesthesia in Connecticut. I have been
6	on the facility at the University of
7	Connecticut Medical School and Dental School
8	for many years. I teach sedation, general
9	anesthesia and medical emergencies to medical
10	and dental students; and over the years, I have
11	provided anesthesia for more than 200 dentists
12	in Connecticut, Massachusetts and Rhode
13	Island I'm sorry, Connecticut, Massachusetts
14	and New York. Last year I provided anesthesia
15	for dental patients in more than 60 offices.
16	I came this morning because I'm
17	very concerned about the safety that is being
18	jeopardized in these proposed Regulations.
19	Also, it appears that there's a limit of access
20	to care for patients in Rhode Island because of
21	these Regulations. Also, the dentist
22	anesthesiologists are having great difficulty
23	in being inspected. And also, general
24	practitioners and non-oral surgeons would have

difficulty in getting permits so that they 1 could have anesthesia provided for their 2 3 patients. Most importantly, the thing that 4 should be addressed is that, for children, 5 there should be a separate, trained anesthesia 6 7 provider, whether it is a physician anesthesiologist or an oral surgeon, nurse 8 anesthetist or dental anesthesiologist. The 9 Academy of Pediatric Dentistry and the American 10 Academy of Pediatric Dentistry both make that 11 recommendation. CODA states that for oral 12 surgery training, children are considered 18 13 and under; so, everyplace that children are 14 mentioned in this document it should be 18. 15 There should be a separate person trained to do 16 the anesthesia. Oral surgeons have five months 17 18 of anesthesia training during their programs. They are supposed to do 50 cases of deep 19 20 sedation with general anesthesia during their 21 training for eight children 18 and under. 22 Dentist anesthesiologists have 36 months of training and they have to treat 125 children 23 ages seven and under. Dentist 2.4

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1	anesthesiologists practice like physician
2	anesthesiologists where one person provides the
3	surgery and one person provides the dentistry.
4	The oral surgeons in general practice doing two
5	things at once. Is there a hospital in Rhode
6	Island that would let a physician or surgeon do
7	surgery and anesthesia at the same time? I
8	doubt that. Dr. Cote mentioned the issue of
9	the DANCE where somebody has 36 hours of
10	training administering anesthesia. Michael
11	Jackson, as we all know, died as the result of
12	the administration of Propofol. That was
13	administered by a Board certified cardiologist.
14	In Rhode Island, the DANCE
15	assistant appears to be able to administer
16	opioids such as Fentanyl. In New Haven last
17	month there were a hundred overdoses in New
18	Haven Green as a result of Fentanyl. Is there
19	any hospital in Rhode Island that would allow
20	somebody with 36 hours of training to
21	administer Propofol or an anesthetic agent?
22	For the record, no dentist assistants in
23	Connecticut are allowed to administer any
24	anesthetic or medications. Is there really a

need for a host permit? If the anesthesia 1 provider has an anesthesia permit, the facility 2 is permitted, why would you have to have an 3 anesthesia host permit? Why would there have 4 to be an agreement between that dental office 5 6 and the hospital? Would Rhode Island Hospital 7 or any other hospital in the state turn down a patient in medical emergency? Why should a 8 dentist have to have a hospital appointment? 9 In one point, nitrous oxide is considered an 10 inhalant, therefore, dental assistants may not 11 be able to do that. I think that has to be 12 readdressed. In the wording for inspections, 13 it states surgery. If a general dentist office 14 to be inspected, fillings, root canals, 15 cleanings are not considered as being surgery. 16 I worked, as I said, in 60 17 different offices last year. Would I have to 18 be inspected 60 different times? We have had 19 20 difficulty in Connecticut where those people 21 that control the inspections have made it very difficult for non-oral surgeons to be 22 inspected. A dentist anesthesiologist was told 23 there was no one who could do inspections for 2.4

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	50
1	him. A periodontist's office was cancelled at
2	the last minute. Reschedule has taken more
3	than eight months to get inspected.
4	And then the question of the
5	evaluators. Oral surgeons have five months of
6	training. Dental anesthesiologists have six
7	months of training. Those trained in moderate
8	station have to do 20 cases. Also, in this
9	comment it talks about nitrous oxide analgesia.
10	That term hasn't been used in 40 years. There
11	are no CODA approved nitrous oxide analgesic
12	courses, so the terminology has to be
13	corrected.
14	HEARING OFFICER ROBERTS: Your
15	allotted time is up. If you are unable to
16	complete your testimony in the time allotted,
17	you may have an opportunity to speak if any
18	time is remaining after the other speakers who
19	have signed up complete their testimony. The
20	next speaker is Sam Zwetchkenbaum.
21	DR. ZWETCHKENBAUM: Good
22	morning. I'm Sam Zwetchkenbaum,
23	Z-W-E-T-C-H-K-E-N-B-A-U-M, dental director in
24	the oral health program. The following changes

are recommended to the Regulations. Number 1 one, public health dental hygiene education 2 provider, Section 2.9.1B, B, changed to 3 successful completion of the following courses 4 within 24 months prior to license issuance. 5 6 Public health fundamentals, colon, CBC 7 guidelines, inspection control, comma, risk management for practice in a public health 8 setting and management of medical emergencies, 9 comma, which are offered by an educational 10 institution with a program accredited by the 11 Commission on Dental Accreditation, comma, or a 12 program approved by the Board or the 13 Department. Rationale, the current course 14 available is excellent, however, similar to 15 most continuing education is not subject to 16 CODA approval or evaluation. Fully closing the 17 door to any other opportunities such as can be 18 provided through other Rhode Island resources 19 inhibits the ability of other able 20 21 organizations to enter this area. For example, 22 for courses in medical emergencies or infection control, Brown School of Medicine, RIC College 23 of Nursing or Salve Regina may wish to be a 24

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provider. For a course in risk management, 1 organizations with significant experience such 2 as Rhode Island Dental Association, Eastern 3 Dentists Insurance Company and other 4 malpractice carriers offer comprehensive 5 training in areas truly in their wheelhouse. 6 Allowing these additional opportunities to be 7 reviewed as alternatives makes sense. 8 Number two, dental radiology 9 10 education provider. Section 2.10.3A, 11, lists as non-delegable procedures exposures of 11 radiographs without successful completion of a 12 course in dental radiography which is offered 13 by an education institution with a program 14 accredited by the Commission on Dental 15 Accreditation and which fulfills institutional 16 requirements as set forth in RIGL 40-20-1. 17 Recommended changes to the dental Regulations. 18 Exposures of radiographs without successful 19 completion of a course in dental radiography, 20 21 which complies with Commission on Dental 22 Accreditation Standards for radiological techniques and safeguards in dentistry and 23 approved by the Board or the Department and 24

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1	which fulfills institutional requirements as
2	set forth in the Rules and Regulations for
3	Diagnostic X-rays and an Associated Imaging
4	Systems in the Healing Arts. Rationale, the
5	current available course similar to most
6	continuing education is not subject to CODA
7	evaluation or approval. Opening the door to
8	opportunities that can be provided through
9	additional resources would increase
10	opportunities for future dental assistants.
11	Assuring the course meets CODA standards would
12	allow conformance with necessary training
13	components. Other states provide a mechanism
14	of board approval of radiology programs based
15	on guidelines established by the board. North
16	Carolina, almost ten times larger in population
17	than Rhode Island, has over 50 sites approved
18	by their board to provide radiology training.
19	In Massachusetts, their board assures that
20	programs based in their career and tech centers
21	comply with CODA standards and thereby approves
22	them.
23	Number three, inclusion of WREB,
24	W-R-E-B, as one of the acceptable Dental Board

exams. Recommend change 2.5.A.1C from having, 1 successfully passed the ADEX exam, including 2 the periodontal examination portion, within 3 five years from the date of application for 4 licensure in Rhode Island. 2, have 5 6 successfully passed the ADEX or Western 7 Regional Examination Board, WREB exam, including the periodontal examination portion 8 within five years from the date of application 9 for licensure in Rhode Island. Rationale, WREB 10 is accepted at multiple Northeast states and 11 offered at several of the largest regional 12 dental schools, including Tufts Dental. 13 Faculty from Tufts find the examination to be 14 of high quality and regularly subject to 15 evaluation. Unique to WREB is the CTP or 16 Comprehensive Treatment Planning exam which 17 tests fundamental and vital skills. 18 Including WREB as an acceptable examination increases 19 20 likelihood for recent graduates to apply for 21 positions in Rhode Island. HEARING OFFICER ROBERTS: 22 Are there any other persons present who would like 23 to continue their testimony or make a statement 2.4

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concerning their proposed Regulations? 1 Mr. Cote? 2 DR. COTE: I promise to take 3 less than five minutes. Dr. Charles Cote, 4 So, it's astonishing to me that these 5 С-О-Т-Е. DANCE certified individuals are allowed to 6 fulfill the position of an independent observer 7 to assist the oral surgeon with general 8 anesthesia and deep sedation. And it's 9 10 astonishing to me that dental hygienists require three years of training and over 4,000 11 hours of training to become a dental hygienist 12 but you can become DANCE certified and assist 13 with medical emergencies with 36 hours of 14 Internet training and no practical hands-on 15 experience. So, I'm going to finish, on 16 Page -- to summarize, the AAP and CAPD, 17 American Academy of Pediatric Dentistry 18 Guidelines, is very specific. If the intended 19 level of sedation is minimal sedation, you must 20 21 have the skills to rescue a patient from 22 moderate sedation. If your intended level of sedation is moderate, you must have the skills 23 to rescue from deep sedation; and if your 24

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1	intended level of sedation is deep, you must
2	have the skills to rescue from a state of
3	general anesthesia, because we all know that a
4	patient may easily progress from one to the
5	other. The independent observer wording in the
6	Academy of Pediatrics document is that the
7	independent observer whose only responsibility
8	is to continuously monitor the patient is
9	required. That's for deep sedation. This
10	individual must, at a minimum, be trained in
11	PALS and capable of assisting with any medical
12	emergencies. And that's the key phrase, and
13	capable of assisting with an emergency.
14	The single provider model where
15	the oral surgeon is performing the procedure
16	and directing the anesthetic sedation at the
17	same time is fraught with danger because when
18	something goes wrong with this practice model,
19	there's no other skilled medical or dental
20	professional present to assist with managing
21	the patient and rescuing the patient.
22	Caleb's Law in California was
23	proposed because of the death of a
24	five-year-old in an oral surgeon's office. His

1	aunt, Annie, sent me the office records. It
2	was clear that this particular individual was
3	not skilled in rescuing the patient and did not
4	have anybody in the office who could assist him
5	with the rescue of this five-year-old child.
6	When Caleb's oxygen levels dropped and he
7	stopped breathing, he apparently panicked. No
8	reversal agents were given. No oral devices
9	were placed to clear the obstructed airway. He
10	could not perform basic bag-mask ventilation.
11	He attempted intubation and knocked out a
12	number of teeth, and he even attempted a
13	surgical airway from the side of the neck, but
14	he didn't understand the anatomy of the airway.
15	By the time 911 arrived, Caleb was pulseless.
16	So, if there had been an extra
17	skilled anesthesia trained person there, this
18	would have been something that we see every day
19	and would have been very easily taken care of.
20	But in this situation, obviously, they failed
21	to rescue Caleb; and had they had that person
22	there, I wouldn't be talking to you about
23	Caleb's Law. This is an extreme example of why
24	skilled anesthesia providers must be present,

1	but it's particular important in a non-hospital
2	environment; because when something happens to
3	me in the hospital setting, we press that code
4	button and help is coming out of the woodwork
5	in seconds. When something happens in an
6	office setting, the only backup is 911 and that
7	may I take five to 20 minutes for them to
8	arrive; and that's why one practitioner cannot
9	and should not perform two services at the same
10	time.
11	I guess I would ask each of you
12	if you would ever get on a commercial airline
13	flight where there was a polite and no copilot.
14	Well, instead of the copilot, we are going to
15	substitute with the flight attendant, and she
16	or he is going to fulfill the role of the
17	copilot. Obviously, that's very wrong. If
18	something happened, they certainly wouldn't be
19	able to assist the pilot with an emergency.
20	It's kind of like that GEICO ad, oh, yes,
21	that's a giant cavity. We can't do anything
22	about it. We are just here to tell you that
23	there's something wrong.
24	I think what this legislation is

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doing is it's asking you to cardify into law 1 and support this very dangerous, solo practice 2 where they are providing both anesthesia and 3 doing the procedure at the same time. There's 4 nowhere in medicine where this kind of practice 5 6 is allowed except perhaps in the emergency room where there's an urgent procedure that's going 7 to take a few minutes. And in that situation, 8 they have skilled nurses who are trained to 9 deal with medical emergencies on a daily basis, 10 and they fulfill that role as the independent 11 observer. 12 A DANCE certified person is, does 13 not have those kind of skills. They could even 14 be a high school dropout. There's no 15 requirement for education, as far as I could 16 tell, when I looked at that document. So, 17 think about if you would ever allow yourself, 18 your child or your grandchild to be put at that 19 kind of a risk. Think about that. Thank you 20 21 very much. 22 HEARING OFFICER ROBERTS: Thank you. Mr. Chin? 23 DR. CHIN: Continuing on, on 2.4

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1	Section 2.13.2, 1A strike the American Dental
2	Association. 1B, strike American Dental
3	Association. 2.13.2C, 1A, strike American
4	Dental Association. B, strike American Dental
5	Association. In Section 2.15.1, strike three
6	entirely and strike 4 entirely. And going back
7	to 2.2 H, strike American Dental Association.
8	In Section 2.3A, 30C, strike C entirely.
9	Number 31, insert "director" after mobile
10	dental facility. And 32 insert "permit
11	holder." 37, strike "non" on the first line
12	for nonfacility. On 2.4.3 on the second line,
13	insert CDA and DA. And 2.4.5A, 1A, insert
14	"dental". And 2.46, Number 3, insert "or
15	Canadian dental school" and strike "or its
16	designated agency approved by the Board." In
17	2.4.7A.2, insert "U.S. CODA or Canadian dental
18	school." On 4, insert "equivalent" on Line 2
19	and strike "organizations." On 5, insert "for
20	immediate past five years." On 2.5A1, C1,
21	insert "equivalent" on the first line as well
22	as "equivalent" on the second line and on the
23	third line strike "similar." And going down to
24	3, strike "a clinical exam," insert "an

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1	equivalent clinical exam." On 2.6B, that
2	should be stricken or modified to July 1. On
3	2.7.2A, 3, insert the word "equivalent." On
4	2.7.3A, 2, insert CODA. Section 4, insert the
5	word "equivalent" and strike out the word
6	"organizations", and on 5, insert "in the past
7	five years." Section 2.7.4B, 4, insert
8	"equivalent" on the first line and on the
9	second line insert "equivalent" and strike
10	"similar." On 2.8.4D, insert "ACLS" and strike
11	"basic life support, BLS." On 2.9.1B, 1B,
12	strike "or program approved by the Dental Board
13	or the Department." 2.92C, 1, insert "CODA."
14	On 3, insert "equivalent." Strike out
15	"organizations." On 2.9.3A, 6F, insert
16	"contact the MBO director or PDO director." On
17	B, "can provide emergency dental referral or
18	propofol referral." Thank you.
19	HEARING OFFICER ROBERTS:
20	Mr. McDonald?
21	DR. McDONALD: William McDonald
22	again. Just to continue, the question of the
23	inspections talks about surgery and the issue
24	is if the inspection were done in a non-oral

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SURGEON'S office, a general practitioner that's 1 not considered surgery, so this terminology has 2 to be readdressed. The next question is does 3 each office have to be inspected, and the other 4 issue is does a patient have to be put to sleep 5 6 in each office. In my case, I would have to be 7 inspected 60 times to put 60 patients asleep. How many people do you have to put to sleep 8 that demonstrate that you're safe at doing 9 that? The other question is, is the host 10 permit. The question is why would there have 11 to be an agreement between any office, 12 physician office, dental office that Rhode 13 Island Hospital would accept their patients? 14 Ι don't understand that or the fact that there is 15 a need to have the dentists be on the hospital 16 staff. How many, how many Rhode Island 17 18 dentists are on hospital staff? The other issue is with the dentists anesthesiologists, 19 20 it appears they have to have a portable 21 individual anesthesia permit. There has to be 22 a facility permit, and do they have to have an individual anesthesia permit also? 23 The question is that being redundant? The facility 2.4

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host permit, what's the advantage to that other 1 than limiting access to care and restraint of 2 trade. It really makes it very difficult for 3 the host. I see no reason to have that. The 4 other thing I did mention before is there are 5 no CODA approved nitrous oxide analgesia 6 courses. The term nitrous oxide analgesia 7 hasn't been used in more than 40 years in 8 dental education. On Page 38, Number 2, it 9 should read "be a candidate or hold a 10 diplomatic status of the American Board of 11 Anesthesiology. The oral surgeons also refer 12 to candidates in the line before that. And 13 under 2.13 A1, 3, Page 53, why should any 14 nitrous oxide anesthesia machine in a dental 15 office be able to administer a hypoxic 16 mixture -- in other words, give a hundred 17 percent nitrous oxide. There's no reason to 18 have that. It mentions the fact that if a 19 machine can deliver less than 25 percent 20 21 oxygen, you have to have an in-line oxygen 22 analyzer. That would mean the machine could give a 100 percent nitrous oxide, which is 23 obviously a hypoxic mixture. 2.4

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I also notice in the Regulations 1 there's no mention for nitrous oxide systems to 2 have either the appropriate pin index safety 3 system or diameter index safety system. Thank 4 5 you. HEARING OFFICER ROBERTS: 6 Are 7 there any other persons presented who would like to make a statement concerning the 8 proposed Regulations? Please just state and 9 spell your name for the record. 10 DR. BROWN: Steve Brown, 11 S-T-E-V-E-N, Brown, B-R-O-W-N. I just wanted 12 to add in the very last section where we talk 13 about continuing education, what's considered 14 continuing education. The very last section, 15 Section 7 says cardiopulmonary information 16 resuscitation afford the person three hours of 17 continuing education. I would hope that the 18 Board would add in there as well ACLS training 19 and PALS training to apply toward to an 20 21 individual's annual or bi-annual continuing 22 education requirements. Thank you. HEARING OFFICER ROBERTS: Thank 23 Are there any other persons present? 2.4 you.

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THE WITNESS: Hello, my name is 1 Ray English, the third. I'm a new oral surgeon 2 in Rhode Island. I recently completed my 3 training and have come back to Rhode Island 4 because I'm a native of this state. The crisis 5 in Rhode Island is not dental anesthesia but 6 access to care. And one of the reasons for 7 this is that Rhode Island has made it difficult 8 for dentist specialists to practice here due to 9 10 reimbursement issues; and my fear is that if we continue to restrict our ability to practice, 11 that's only going to exacerbate the problem. 12 So, I'm thankful to the Board for putting 13 together new Regulations that increase training 14 because that's important, but I would keep 15 access to care in mind when we finalize these 16 Regulations because that's what matters. When 17 a patient comes to our office with an acute 18 dental abscess, it is important to treat them 19 in a timely manner. The hospital system cannot 20 accommodate all of our dental needs. Thank you 21 22 and that's it. 23 HEARING OFFICER ROBERTS: Thank you. Are there any other persons... 24

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

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1	anesthesiologist providers.
2	In 2018, to give you an idea of
3	our patient volume, we have conducted over 2400
4	general anesthetics. Over the last eleven
5	years, we have zero instances of morbidity and
6	mortality. And while an inherent risks exist
7	for any provider at any level of sedation or
8	general anesthesia, adherence to known
9	standards of care often mitigate risks to an
10	appropriate level.
11	For any football fans out there,
12	we all know Coach Parcells. And his saying of
13	you're only as good as your last game. One
14	thing that Parcells did was surrounded himself
15	with a talent that was experienced and
16	qualified in an expense of our new friend, Bill
17	Belichick.
18	I followed the Rhode Island
19	dental anesthesia regulation process since late
20	2015. What I cannot follow is the logic of
21	ignoring aspects of the American Society of
22	Anesthesiology, the American Academy of
23	Pediatrics or the American Academy of Pediatric
24	Dentistry and the parameters of care regarding

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1	the qualifications of collaborative
2	professionals, ignoring standards of care
3	regarding utilization of the separate licensed
4	anesthesia professional or filing to surround
5	oneself with staff that are truly qualified and
6	experienced and not just certified by a private
7	organization. Any panel of advisory
8	consultants should include a diverse group of
9	providers with various degrees of sedation and
10	anesthesia training.
11	We had an anesthesia committee
12	set up for these Regulations and I'm not going
13	to make any contention comments, but I believe
14	there are people in this room that will state
15	that was an infective committee, and I'm sure
16	they will by right. Aside from that, you know,
17	the panel itself should be led by professionals
18	who have completed formal anesthesia training,
19	whether it be an MD or a DO, a DDS or a DMD
20	like some of the members here in this room, or
21	CRNs, who are also dedicated towards putting
22	the public well-being of the profession ahead
23	of their own agenda along with primarily the
24	welfare and the public safety of our patients.

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And I don't think that's happened with this 1 document. I really don't. 2 Aside from that, you know, 3 there's no question we have concerned 4 professionals willing and able to provide their 5 6 time and efforts to improve safety, access to care with the benefit of the patients and the 7 profession in mind. Charles Cote is end-all 8 authority on any of these national regulations, 9 and he came down today to speak, and I think, 10 honestly, we have a meeting. I understand 11 there's time constraints, but to tap out on 12 five minutes, which I understand is part of the 13 process, I'm sure, if asked, he would donate 14 his time. Bill McDonald came from Connecticut. 15 We know Mark Rosenberg has done so. There's 16 others that would gladly do it. I think when 17 we make regulations that, while I agree with 18 19 Dr. English, access to care is an issue and so 20 is safety. I think it's hard to put one above 21 the other, much like the practice of anesthesia itself. It's most in hindsight, and we have to 22 remember that with some foresight. 23 Following today's testimony, I hope 2.4

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the Department of Health urges the Dental Board 1 to revise numerous aspects of this proposed 2 Regulations. Although I'm sure everyone is 3 eager to complete what's been a long process 4 with a great deal of effort on all parts, it's 5 6 far more important to make sure those 7 Regulations are capable of their intention. Ι 8 hope it's clear that the currently proposed draft needs a great deal of revision, and I 9 10 think there's people in this room and people involved in the process up to this point that 11 are capable of that, and I hope that it's done. 12 Thank you for your time. 13 HEARING OFFICER ROBERTS: Thank 14 15 you. Are there any other persons present who would like to make a statement concerning the 16 proposed Regulations? 17 18 (PAUSE) HEARING OFFICER ROBERTS: 19 Thank 20 you all for your attendance and for the 21 information you have observed, and this hearing is now closed. Thank you. 22 (HEARING CLOSED AT 11:10 A.M.) 23 2.4

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1	<u>CERTIFICATE</u>	
2		
3	I, Mary Ellen Hall, hereby certify that t foregoing is a true, accurate and complete transcript's of my notes taken at the	he
4	above-entitled public hearing.	
5	IN WITNESS WHEREOF, I have hereunto set m hand this 24th day of September, 2018.	ıу
6	nand enits zeen day of september, zoro.	
7		
8		
9	MARY ELLEN HALL, NOTARY PUBLIC/ CERTIFIED COURT REPORTER	
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11	JOB DATE: SEPTEMBDER 11, 2018	
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Concerns Regarding the Single Operator Model of Sedation in Young Children

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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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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 anesthesiarelated 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 highrisk 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 \sim 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 348602 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 500000 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 FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

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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.

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 ⁸	< 2 yrs: 10 2-12 yrs: 30	≤12 yrs	N/A	National Board of Certification and Recertification for Nurse Anesthetists
Dentist Anesthesiologist ^z	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 ^y ;	300	50	≤18 yrs	N/A	National Dental Board of Anesthesiology for anesthesia training;
	Sederica/Conserved describes	48 months	and Marilla Casia				American Board of Oral and Maxillofacial Surgery for surgery training

Table. Anesthesia Education and Training Comparison

 $\label{eq:legend: DS/GA-Deep Sedation/General Anesthesia OMFS-Oral and Maxillofacial Surgery$

 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.

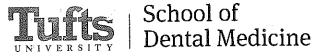
- 1. What is your experience with pediatric patient populations? ... special healthcare needs populations?
- 2. What is your background/experience in providing office-based deep sedation/general anesthesia care? ...and specifically for pediatric dental patients?
- 3. How do you evaluate a dental facility 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?

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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.

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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=2.128 993356.1947217376.1535839869-1295743337.1535839869

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.

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 endtidal 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

Morton.Rosenberg@Tufts.edu

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ь х 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



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, partiallary 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 DAANCEcertified 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 RIOMS President (401) 739-5500

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. <u>http://www.adha.org/resources-</u> <u>docs/7513 Direct Access to Care from DH.pdf</u>

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

I can be contacted by e-mail or cell.

stackkm@umich.edu

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