


363. Reeves ST, Havidich JE, Tobin DP. Conscious sedation of children with propofol is anything but conscious.


449. Oksan D, Ayfer K. Powered intraosseous device (EZ-I0) for critically ill patients. Indian Pediatr. 2013;50(7):689–691


I would first like to introduce myself, Julie Galleshaw, Professor in Dental Health at the
Community College of Rhode Island. I am also a newly licensed Public Health Dental Hygienist.

I would like to specifically speak to section 2.9.1 Qualifications within the draft pertaining to 2.9
the Public Health Dental Hygiene Practice. I was at the original meeting of the draft as a public
member. I took part in several meetings in which lengthy discussion took place on the specifics
of this particular section of the regulation. The final version that was submitted has been changed
by this department in format, punctuation and intent. I am here because I feel these changes have
taken away the intent of producing safe and competent Public Health Dental Hygienists for the
community. 

The department's goal are to ensure that all dental professionals practicing in the
state of Rhode Island meet the requirements for licensure to protect the public. With that said, the
new version, in front of us today, has been changed from its original draft and in my opinion not
upholding the standard of creating competent Public Health Dental Hygienists.

The first error and change made by the Department of Health was the change in placement of the
colon. The colon was to be after the words (Public Health Fundamentals): (colon) in order to
start the enumeration of the courses to be taken, to meet the educational requirements, and not
placed after the word (issuance). I am submitting, with this statement, the original document’s
draft and a corrected version as evidence of what needs to be corrected to regain the original
document’s intent on what qualifications need to be met in order to obtain a Public Health Dental
Hygiene license.

The second change made, unilaterally by the Department of Health, without any discussion nor
recommendation by the Board, is in section 2.9.1 B 1-b. after the word Accreditation, the words
(, or by a program approved by the Board or the Department.) were added. I feel the Department
of Health has overstepped in its authority by placing these words and superseding the Board. The
Board in all areas of the rules and regulations is the determining entity for course approval for
the Department and not the Department itself. Nor is the word (Department) defined in these
Rules and Regulations to mean the Department of Health, specifically to Dentistry. Nor is it
stated, anywhere else in these rules and regulations, that the Department is to be able to approve
any course for licensure or license renewal. If the intent, of whomever added these words, was
to reflect that the Board (as defined in these Rules and Regulations) has the ability to approve a
course. Then I recommend that the words (or an accredited course approved by the Board.) be
the only submission and the words (, or by a program approved by the Board or the Department.)
be removed and replaced by this statement. (or an accredited course approved by the Board.). I
submit the following sections within these rules and regulations that specifically state that it is by
the approval of the Board and not the Department. Examples throughout these rules and
regulations is evident in the following sections: Section 2.4.6 A- 3, Sections 2.6 B, F, and G,
Sections 2.7.5 C, and Section 2.8.4 D. It is with great hope that this committee will do is due
diligence and correct these errors.

Respectfully Submitted,

Julie A. Galleshaw, CDA, RDH, PHDH, MA, M.Ed Professor of Dental Health
The below needs correction with the two punctuation errors.

1. The removal of the colon highlighted in green and substitute with a period.
2. The substitution of the comma for a colon highlighted in yellow.

2.9 Public Health Dental Hygiene Practice

2.9.1 Qualifications

A. A public health dental hygienist may provide dental services which are educational, preventive, therapeutic, prophylactic and intra-oral in nature as may be authorized by the Board and may perform all tasks as set forth under the Act and these Regulations.

B. Educational requirements for the Public Health Dental Hygiene Practitioner

1. Prior to practicing as a public health dental hygienist a dental hygienist shall complete a minimum of twelve (12) hours of continuing education as follows:

   a. A minimum of six (6) hours of hands-on experience in a public health setting.

   b. Successful completion of the following courses within twenty-four (24) months prior to license issuance:

- Public Health Fundamentals
- CDC Guidelines (Infection Control)
- Risk management for practice in a public health setting
- Management of medical emergencies, which are offered by an educational institution with a program accredited by the Commission on Dental Accreditation, or an accredited course approved by the Board.

Statement below reflects the above corrections.

1. Successful completion of the following courses within twenty-four (24) months prior to license issuance. Public Health Fundamentals: CDC Guidelines (Infection Control), Risk management for practice in a public health setting and Management of medical emergencies, which are offered by an educational institution with a program accredited by the Commission on Dental Accreditation, or an accredited course approved by the Board.
Public Health Dental Hygiene Practice:

1) A public health dental hygienist may provide dental services which are educational, therapeutic, prophylactic and preventive in nature as may be authorized by the Board and may perform all tasks as set forth under rules and regulations.

2) Educational requirements for the Public Health Dental Hygiene Practice
   a) Prior to practicing as a public health dental hygienist, the dental hygienist shall successfully complete a minimum of 12 hours in a CODA approved course in the following area:
      i) Public Health Fundamentals:
         (1) Infection Control (CDC Guidelines)
         (2) Risk management for practice in a public health setting and
         (3) Management of medical emergencies
      ii) In addition a minimum of 6 hours of hands on experience in a public health setting
      iii) Successful completion within twenty-four (24) months prior to registration issuance as a public health dental hygienist
b) The public health dental hygienist shall permanently retain documentation demonstrating compliance of continuing educational requirement including a signed affidavit that confirms successful completion.

3) A public health dental hygienist practicing in a public health setting may perform those services which are authorized by the Board to be provided in a public health setting, pursuant to a written collaborative agreement (WCA).

4) A registered dental hygienist practicing in a public health setting may provide dental hygiene services including placement of sealants, without first having a dentist examine the patient, either pursuant to a written collaborative agreement (WCA).

Final Draft 12-11-2015
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E. Public health dental hygienists shall maintain current malpractice insurance.
Good morning my name is William A. MacDonnell, D.D.S. I am a graduate of Providence College, Georgetown University School of Dentistry and completed an Anesthesiology Residency as well as a Fellowship in NeuroAnesthesia at the University of Pittsburgh. I served as a staff anesthesiologist at the University of Connecticut John Dempsey Hospital for several years and have provided pro bono anesthesia for UCONN School of Dental Medicine patients for more than thirty years. I have held faculty appointments at both the UCONN Schools of Medicine and Dental Medicine teaching anesthesia, sedation and medical emergencies. Currently I teach and supervise the training of periodontal dental residents intravenous moderate sedation at the University of Connecticut School of Dental Medicine. I have a clinical appointment at Tufts University School of Dental Medicine teaching Nitrous Oxide minimal sedation. Since 1983, in my mobile dental anesthesia practice I provide only
sedation/anesthesia for dental patients in the offices of their dentists. Over the years I have provided anesthesia for more than 200 dentists in Connecticut, Massachusetts and New York. Last year I provided anesthesia for dental patients in more than sixty (60) different dental offices.

In 1984/5 I attended the meetings with Connecticut Department of Public Health (DPH), Connecticut Society of Oral and Maxillofacial Surgery (CSOMS) and the Connecticut State Dental Association (CSDA) that created the original Connecticut Dental Anesthesia Regulations. I am serving on the Connecticut State Dental Association Ad hoc Sedation/Anesthesia Regulation Committee. I am a past President of the Connecticut State Dental Association, the American Society of Dentist Anesthesiologists and the Past editor of the American Dental Society of Anesthesiology (ADSA) newsletter “The Pulse”.

I am very concerned that these newly proposed Rhode Island Dental Sedation/Anesthesia Regulations will not benefit the safety of the citizens of Rhode Island, limit access to dental care for patients, and limit dentist anesthesiologists from providing sedation/anesthesia because of the difficulties in obtaining anesthesia and facility permits.

These proposed regulations would limit the ability of non-oral surgeon Rhode Island dentists to provide
dental care in their offices with sedation/anesthesia.

Rhode Island patients and dentists will be harmed if these proposed dental sedation/anesthesia regulations are approved as written.

First, a separate fully trained anesthesia provider should be mandated for children having deep sedation/anesthesia in Rhode Island. The current American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) recommendations* call for a separate distinct fully trained anesthesia provider who is not also providing the surgery/dental treatment. The AAP and AAPD are opposed to the operator/anesthetist model where a single physician/dentist is administering both the patient’s anesthesia and dental care.

Based on the AAP/AAPD Recommendations for patient safety the single operator/anesthetist model should be eliminated for children eighteen (18) years and younger).

The age of eighteen (18) under rather than twelve (12) and under should be used for pediatric patients because the Commission on Dental Education (CODA) requirements for oral surgeon training define children as eighteen (18) years and younger. Oral surgeons are required to provide 50 cases of deep sedation/general anesthesia of children eighteen and under.

Therefore, on Page 2: Definitions 2. “Adult means a
person nineteen (19) years or older”. On page 36 Pediatric should read “under the age of 19 years.” On page 44 C.1.A should read “nineteen (19) years old”.

According to the Commission on Dental Education (CODA) there are two dental specialties that are trained to administer deep sedation/general anesthesia (oral surgeons and dentist anesthesiologists).

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Dentist anesthesiologists according to CODA have thirty-six (36) months of anesthesia training and consider children as 12 years of age and under and under. The dental anesthesia residents have to anesthetize 125 children seven (7) years of age and under.

Dentist anesthesiologists practice according to the medical anesthesia model and provide only anesthesia. They do not provide both anesthesia and dental procedures at the same time.

Is there a hospital in Rhode Island that allows physicians to provide both medical procedures/surgery
as well as patient’s anesthesia at the same time? If Rhode Island physicians are not allowed to administer anesthesia and perform surgical/medical procedures simultaneously how can dentist be allowed to do two things a once in their offices?

The proposed Rhode Island Dental Anesthesia Regulations allow for a third anesthesia provider the Dental Anesthesia Assistant National Certification Examination (DAANC) dental assistant who has 36 hours of on-line training to administer anesthesia. The regulations licensed these dental assistants to administer anesthetic agents such as propofol. Michael Jackson died as a result of the administration of propofol by a board certified cardiologist. Cardiologists have years of hospital residency training after graduating from medical school. Rhode Island DAANACE assistants can also administer opioids such as fentanyl, which was implicated in the 100 plus overdoses on New Haven Green last month. If a cardiologist can have a bad outcome with propofol how can a high school graduate with thirty-six (36) hours of on line training be allowed to administer anesthetics and other potentially life threatening medications to Rhode Island patients?

According to Dr. Cote et al the 36-hour online DAANCE course does not qualify participants to draw up or independently administer medications.

Will any Rhode Island hospital, surgical center or physician office allow medical assistants, nurses, or non-physician anesthesiologists administer propofol? If
only anesthesiologists or nurse anesthetists can administer anesthetic agents how can dental assistants with thirty-six hours of on line training administer these agents in a dental office?

For the record dental assistants are not allowed to administer anesthetic or any medication in Connecticut.

Is there a need for a “Facility Host Permit”? If the anesthesia provider is permitted and the facility is permitted why is there a need for a “facility host permit”? This only creates more bureaucracy, increases patient costs, and limits access to dental care. It also prevents dentists from caring for their patients who need/want anesthesia in their office. If a patient wants anesthesia in their dentist’s office now they are forced to have restorable teeth extracted and implants placed by oral surgeons who provide both the surgery and anesthesia at the same time.

Why is “Direct visual supervision” limited to only oral surgeons? This needs to be clarified before being approved.

What exactly is “practice of a certified maxillofacial surgery assisting”?

There seems to be a conflict between 2.10.3 on page 33 non-delegable procedures: i.e. Administering general anesthesia/deep sedation, moderate sedation and/or minimal sedation, or nitrous oxide plus medication; and page 46 where DAANCE dental assistants are allowed to
administer anesthetic agents?

Nitrous Oxide is considered an inhalant and thus a dental assistant cannot administer Nitrous Oxide Sedation because that is an inhaled agent. (2.10.3 Administering inhalants; page 33)

The proposed regulations call for onsite inspections and the observation of “surgical cases”. There is no explanation of who will do the inspections? (Page 35 2.11.1 5C).

In Connecticut there has been a history of complaints that those controlling the inspection process making it very difficult for non-oral surgeons to get sedation/anesthesia permits. A dentist anesthesiologist was told there was no one who could inspect him in a certain location. A periodontist’s inspection was canceled the day before the inspection. It took three (3) months to reschedule the inspection.

The wording for inspections states “surgery” If a general dentist is doing fillings, root canals, cleanings, etc. those procedures are not considered “surgery”. Would the general practitioners be forced to do extractions? Will these regulations require patients to be put to sleep in each office? If I were practicing in Rhode Island I wouldn’t have to be inspected in each dental office and put patients to sleep sixty times in sixty offices?? How many patients would I have to put to sleep for testing purposes to be able to demonstrate that I can provide safe anesthesia care for patients? It
takes a half-day to be inspected. Then that would mean 30 plus days being inspected and not being able to work?

What are the qualifications/training of the inspectors/evaluators? (OMS 5 months; dentist anesthesiologists 36 months; moderate sedation 20 cases.

Why is there a need to have a written agreement with a hospital to accept emergency patients from that specific dental office (page 40 d4)? Would any Rhode Island hospital refuse a patient in an emergency situation? This is another example to prevent Rhode Island dentist from caring for their patients in their office. It is only going to decrease access to dental care. (D 4)? Why is there a need for the host dentist to have a hospital appointment? This just limits access to care.

It is my understanding that it is currently impossible for a dentist anesthesiologist to be inspected in Rhode Island. If I wanted to practice dental anesthesia in Rhode Island I wouldn’t be able to practice here?

Currently, how many Rhode Island dentists have hospital appointments? It will act to decrease competition. This regulation will only decrease access to care and increase patient costs.

The inspection team, inspection criteria and checks and balances need to be defined to avoid a different interpretation years from now. All these issues must be
clearly laid out so that there is no confusion and potential limitation of a dentist’s ability to treat patients.

Do Rhode Island surgical centers have their anesthetics inspected/observed?

The proposed regulations require dentist anesthesiologists to have a “Portable Individual Anesthesia Permit” (page 36) and a “Facility Permit”. Does the dentist anesthesiologist also have to have an “Individual Anesthesia Permit”?

Why should a “Facility Host Permit” be required if the facility is already permitted? It is yet another way to reduce competition.

There are no CODA approved Nitrous Oxide Analgesia training programs (page 37 “B”). The correct terminology is “nitrous oxide sedation” not “analgesia” or “anesthesia”. The intent is to administer sedation not general anesthesia.

Have satisfactorily completed a nitrous oxide analgesia training program from a CODA approved advanced education program and whose training program is consistent with the provisions of the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2016) incorporated by reference at § 2.2(J) of this Part, and which includes experience in the administration of nitrous oxide analgesia.
On page 38 #2 it should read, "Be a candidate or hold diplomate status of the American Dental Board of Anesthesiology. The regulations allow oral surgeons to be "candidates" so should be true for dentist anesthesiologists.

1. Be a candidate for or hold current board certification by the American Board of Oral and Maxillofacial Surgery (ABOMS), or

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2.13.A.1.3 (page 53) why should any Nitrous Oxide Sedation machine be able to administer a hypoxic mixture of Nitrous Oxide in a dental office?

If nitrous oxide and oxygen delivery equipment capable of delivering less than 25% oxygen is used, an in-line oxygen analyzer shall be used;

ADD: Nitrous Oxide systems should have the appropriate Pin Index Safety System or Diameter Index Safety System.

Thank you for the opportunity to present this morning regarding my thoughts this morning regarding the proposed dental anesthesia regulations. If you have any questions I will be happy to try to answer them.

Respectfully submitted,

[Signature]
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Past President Connecticut State Dental Association
158 Hunter Drive
West Hartford, CT 06107
860-561-1233
william.macdonnell@gmail.com

216-RICR-40-05-2

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 05 – PROFESSIONAL LICENSING

Testimony: William A. MacDonnell, D.D.S.

September 11, 2018

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West Hartford, CT 06107
860-561-1233
william.macdonnell@gmail.com

Hello my name is Patrick McCarty, D.D.S., and I am a board certified dentist anesthesiologist. I have been licensed in Rhode Island since 2007. I am a graduate of Boston College, the University of Southern California School of Dentistry, and completed an anesthesiology residency at the Mount Sinai Hospital. Since 2008, I have served as a staff anesthesiologist at Franciscan Children’s Hospital in Brighton, MA. I have held clinical appointments at the dental schools of Boston University, Tufts University and Harvard University providing didactic and clinical instruction regarding sedation/general anesthesia for pediatric dental residents, periodontology residents and continuing education courses for practicing dentists. Since 2007, I have maintained a mobile, office based anesthesia practice originating in Massachusetts and Rhode Island. The practice has grown to cover four states (including New Hampshire and Maine) while encompassing four anesthesia providers (all dentist anesthesiologists). In 2018, we have collectively conducted over 2400 anesthetics. Over the last eleven years, we have zero instances of morbidity or mortality. While inherent risk exists for any sedation/general anesthesia case, adherence to known standards of care can often mitigate risk to an appropriate level. For any football fans out there we can recall Coach Bill Parcells stating “you are only as good as your last game,” but we also know his best success came when surrounding himself with talented support staff like our friend, Bill Belichick.

I have followed the Rhode Island dental anesthesia regulation revision process since late 2015. What I cannot follow is the logic of ignoring ASA, AAP and AAFP parameters of care regarding the qualifications of collaborative professionals, ignoring standards of care regarding utilization of a separate licensed anesthesia professional, or failing to surround oneself with staff that are truly qualified and experienced, and not just certified by a private organization.

Any panel of advisory consultants should include a diverse group of providers with various degrees of sedation/anesthesia training. The panel itself should be led by professionals who have completed formal anesthesia residency training (MD/DO, DDS/DMD or CRNA) who are also dedicated towards putting the public well-being and profession ahead of their own agenda. There is no question concerned professionals are willing/able to provide their time and efforts to improve safe, access to care with the benefit of the patients and profession in mind. This draft proposal falsely claims to adhere to guidelines set forth by ASA, AAP or AAFP. In reality, the document only does so when it fits the self-serving agenda of the Rhode Island oral surgery society.

Following today’s testimonies and subsequent written comments, I hope the Department of Health urges the dental board to revise numerous aspects of these proposed regulations. While I am sure everyone is eager to complete what has been a long process with a great deal of effort, it is far more important to make sure the regulations are capable of their intentions.

I hope it is clear that the regulations currently proposed require a great deal of revision. I also hope that the focus is on what is in the best interests of the patient/public and not individuals within the dental profession attempting to abuse board power for their own personal gain by inhibiting their perceived “competition”.
2.2 Incorporated Materials – Section I (pg 2 of 76)

H. These regulations hereby adopt and incorporate American Dental Association ASA Physical Status Classification System for Dental Patient Care (2017) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

I. These regulations hereby adopt and incorporate the American Academy of Pediatrics, American Academy of Pediatric Dentistry, Guidelines for Monitoring and Management of Pediatric Patients Before, During and After Sedation for Diagnostics and Therapeutic Procedures (2016), by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

2.3 Definitions

There seems to be a complete disregard for current (2018) American Society of Anesthesiology, American Academy of Pediatrics and American Academy of Pediatric Dentistry guidelines in regards to pediatric dental patients undergoing deep sedation & general anesthesia for dental procedures, within a dental office setting.

Attachment #1 is the 2018 American Academy of Pediatric Dentistry policy of selecting anesthesia providers for the delivery of office-based deep sedation/general anesthesia. The Rhode Island proposed guidelines grossly deviate from the standards set forth in this policy in regards to delivery of deep sedation/general anesthesia for pediatric patients. The Rhode Island dental board and legislation has an obligation to the safety of the public.

2018 AAPD Policy in Selecting Anesthesia Providers
http://www.aapd.org/media/Policies_Guidelines/P_SelectingAnesthesia.pdf
2.3 Definitions – Section A.3 (pg 2 of 76)

2.3 Definitions

A. Wherever used in this Part the following terms shall be construed to mean:


2. "Adult" means a person thirteen (13) years of age or older.

3. "Advisory consultants" means those individuals appointed by the Board to serve as advisory consultants to the Board in determining compliance with the statutory and regulatory provisions of this Part, of applicants seeking a permit to administer or to permit the administration of general anesthesia/deep sedation, moderate sedation, minimal sedation or nitrous oxide analgesia. Such consultants may be Diplomates of the American Board of Oral and Maxillofacial Surgery, Members or Fellows of the American Association of Oral and Maxillofacial Surgeons, or Fellows of the American Dental Society of Anesthesiology, and may include a Board Certified Anesthesiologist and a licensed dentist with experience in the administration of general anesthesia/deep sedation, moderate sedation, minimal sedation or nitrous oxide analgesia.

Advisory consultants should NOT predominantly consist of only oral surgeons as "2.3.A.3" is clearly directed towards. There is an implication that the requirements listed (ABOMS, AAOMS or ADSA) are somehow demonstrating a provider who is qualified to assess and judge how the profession as a whole should provide sedation/anesthesia care. Oral Surgeons are by no means experts in the field of dental anesthesiology. There are numerous professional resources available to the RI Dental Board with a far greater understanding of the intricacies and standards of both dentistry and anesthesia, along with the relationship between the two disciplines. Many aspects of this proposed draft are littered with attempts to push a self-serving agenda at the risk of the patient’s safety.

Any panel of advisory consultants should include a diverse group of providers with various degrees of sedation/anesthesia training. The panel itself should be led by professionals who have completed formal anesthesia residency training (MD/DO, DDS/DMD or CRNA) who are also dedicated towards putting the profession and the
public well-being ahead of their own agenda. There is no question concerned professionals are willing/able to provide their time and efforts to improve safe, access to care with the benefit of the patients and profession in mind.

This draft proposal falsely claims to adhere to guidelines set forth by ASA, AAP or AAPD. In reality, the document only does so when it fits the self-serving agenda of the Rhode Island oral surgery society.


2.3 Definitions – Section A.9 (pg 3 of 76)

8. "Continuous" means prolonged without any interruption at any time.

9. "DAANCE-certified Maxillofacial Surgery Assistant" means a person currently certified by the American Association of Oral and Maxillofacial Surgeons to provide supportive anesthesia care.

While I am aware legislation has passed regarding DAANCE assistants being able to prepare and administer anesthetic medications, it is never too late to correct a monumental mistake.

When we trust someone who does not have a respect for patient safety and the discipline of anesthesiology itself, we can expect more of this;

http://www.health.state.ri.us/discipline/DENMohammadBanki.pdf

http://www.health.state.ri.us/discipline/DENFrankPaletta.pdf

STATEMENT ON SAFE USE OF PROPOFOL Committee of Origin: Ambulatory Surgical Care (Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

The statement in the AANA-ASA Joint Statement Regarding Propofol Administration, dated April 14, 2004, reads, "Whenever propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. This restriction is
concordant with specific language in the propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death."

The Warnings section of the Diprivan’s package insert (Diprivan®, AstraZeneca 08/05, accessed 1-09) states that 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.” Patients should be continuously monitored, and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available.”

It is of grave concern that the proposed Rhode Island dental regulations would ignore American Society of Anesthesiology, American Academy of Pediatric Dentistry, the American Association of Nurse Anesthetists guidelines, and the package insert warning of Diprivan (propofol) regarding safe practice of sedation and anesthesia. It is inconceivable that the Rhode Island dental regulations would further reduce patient/public safety by allowing an unqualified provider (DAANCE assistant) to administer such medication of narrow therapeutic index. The oral surgeon acting as an “operator/anesthetist” while providing deep sedation or general anesthesia on their own is sub-standard of care in the eyes of these national authorities, within the discipline of anesthesia. It is almost unfathomable to think how these authorities would evaluate a DAANCE assistant as any kind of a viable solution.
2.3 Definitions – Section A.30

29. "Local anesthesia" means the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug; injection of a local anesthetic agent (e.g., Lidocaine) into and around the operative site to eliminate sensory perception in the area where a procedure(s) is to be performed. This type of anesthesia does not involve any systemic sedation.

30. "Minimal sedation" means a state of sedation in which the patient is at a minimally depressed level of consciousness. This state is produced through by a pharmacological method dose (MDR) along with nitrous oxide. Characteristics of minimal sedation include:

   a. which retains the Patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command;

   b. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

As written states "medically recommended dose," but should say "FDA Maximum Recommended Dosage."

2.3 Definitions – Section A.30.d (pg 6 of 76)

d. If more than one enteral drug is administered to achieve the desired effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply. Similarly, if more than one enteral drug is administered to achieve the desired effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

31. "Mobile Dental Facility" (MDF) means any self-contained facility where dentistry will be practiced which may be driven, moved, towed, or transported from one location to another. See related definition under Portable Dental Operation in §2.3(A)(32) of this Part.

As written, statement is repetitive, confusing and deviates from ADA Guidelines.
2.3 Definitions – Section A.39 (pg 7 of 76)

39. “Public Health Dental Hygienist” (PHDH) means a registered dental hygienist who holds a valid license to practice in the State of Rhode Island and who has a minimum of three (3) years of full-time or an equivalent **four thousand five hundred** (4500) hours of clinical experience and who has the fulfilled the necessary training requirements and who works in a public health setting pursuant to a written collaborative agreement with a local or state government agency or institution or a dentist who holds a valid license issued in the State of Rhode Island pursuant to this Part.

4500 hours of clinical experience is needed for a public health hygienist to provide dental hygiene treatment ... yet **36 hours** of online self-study for a dental assistant to prepare/administer medications with narrow therapeutic index, and to act as a vigilant monitor of general anesthesia and be called upon in to act as a primary caregiver of ACLS/PALS/airway management without having any relevant clinical experience or education is sufficient??

2.8 DAANCE – Certified Maxillofacial Surgery Assistant Licensing Requirements – Section 2.8.1.A.1 (pg 20 of 76)

2.8 DAANCE-Certified Maxillofacial Surgery Assistant Licensing Requirements

2.8.1 License Requirements

A. No person shall perform any act which constitutes the practice of certified maxillofacial surgery assisting in Rhode Island unless such person is duly licensed in accordance with the Act and this Part as a DAANCE-certified maxillofacial surgery assistant.

1. Furthermore, dental hygienists, public health dental hygienists, DAANCE-certified maxillofacial surgery assistants, DANB-certified assistants and dental assistants, shall perform only those auxiliary dental services, procedures/duties, and under the specified type of supervision, as set forth in § 2.8 of this Part. Those persons listed in R.I. Gen. Laws § 5-31.1-37 are exempt from these requirements.

2.8.2 Qualifications for Licensure- DAANCE-certified Maxillofacial Surgery Assistant
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 who happens to be unqualified, inexperienced and unlicensed to do so in any other healthcare setting is a concern for patient safety.

Are DAANCE assistants eligible for liability insurance in this role? As a state licensed provider, what are the malpractice liability concerns and/or coverage in the event of morbidity/mortality of a patient?

Will patients and/or parents/guardians be informed of their choices of an anesthesia provider along with information regarding the qualifications of the 2nd rescuer (DAANCE assistant) in the oral surgery dental office setting? This would be necessary when providing valid informed consent that they will undergo an oral surgery procedure with general anesthesia while one provider attempts to simultaneously perform both aspects of care. If a provider was unable to simultaneously bill for such care, would they be willing to take on such inherent risk? Would a provider voluntarily practice below national standards of care when it served no financial benefit to themselves? Would a patient provided with a valid informed consent allow such care to occur?

At the very least “no person ...” should be changed to something hopefully encouraging to consider the use of standard of care providers along with this ill-advised option of a DAANCE assistant.
2.10.3 Non-Delegable (Exclusionary) Procedures/Duties – 
Section A.4 (pg 33 of 76)

2.10.3 Non-Delegable (Exclusionary) Procedures/Duties

A. Notwithstanding the provisions of § 2.14 of this Part, nothing in this Part authorizes a dental hygienist, public health dental hygienist, DANB-certified assistant or dental assistant, to perform any of the following procedures or duties:

B1. Diagnosis and treatment planning;

B2. Surgical procedures on hard or soft tissue;

B3. Prescribing medications;

B4. Administering general anesthesia/deep sedation, moderate sedation and/or minimal sedation, or nitrous oxide plus medication;

B5. Administering inhalants;

Language implying it is acceptable for a DAANCE assistant to “administer general anesthesia/deep sedation, moderate sedation and/or minimal sedation, or nitrous oxide medication” should be changed to something at least pretending to adhere to acceptable safety guidelines.
2.11.2 Qualifications for Permit Professional Licensing Requirements

A. The Board shall issue the following permits to qualified Dentists and Facilities:

1. Individual Anesthesia Permit:
   a. Authorizes a Qualified Dentist, licensed by the State of Rhode Island, to administer one or all of the following levels of sedation, which shall be delineated on the permit: minimal and nitrous oxide-oxygen alone, or in conjunction with a local anesthetic, moderate, deep sedation and/or general anesthesia, in a dental facility that has the required Facility Permit for the type of anesthesia or sedation being administered in compliance with this Part.

2. Portable Individual Anesthesia Permit:
   a. Authorizes a trained Dental Anesthesiologist to perform sedation services at any dental facility with the appropriate Facility Host Permit.

I assume a “Portable Individual Anesthesia Permit” acknowledges the ability to transport appropriate equipment, supplies, staff etc. from office to office in a mobile capacity? It would be beneficial if the dental board recorded the requirements of obtaining this permit, within the final regulations. As currently drafted, there is nothing offering any information regarding equipment, medications, supplies, staff etc. I am personally weary of seeing this left open to interpretation. I request, specific requirements of any inspection process are documented in the final regulations.

On a side note. any reference to a “dental anesthesiologist” should be changed to a “dentist anesthesiologist.” Dentist anesthesiologists are not focused on just providing anesthesia for teeth as the term “dental anesthesiologist” infers.
2.11.3 Qualifications for Individual Anesthesia Permit – Section F.2
(pg 38 of 76)

c. Have completed a Board approved simulation course that uses high fidelity human simulation.

F. Applicants for a Pediatric Individual Anesthesia Permit to administer or to authorize the administration of deep sedation/general anesthesia to pediatric patients must meet all the foregoing requirements and:

1. Maintain current American Heart Association (AHA) Advanced Cardiopulmonary Life Support (ACLS)/Pediatric Advanced Life Support (PALS) certification;

2. Be a candidate for or hold current board certification by the American Board of Oral and Maxillofacial Surgery (ABOMS), or

3. Be a diplomate of the American Board of Anesthesiology (ABDA), or

4. Proof of education or training commensurate with the type of individual permit sought, as follows:

   a. Completed an education program accredited by the ADA's Commission on Dental Accreditation (CODA) that provides comprehensive training necessary to administer and manage general anesthesia and deep sedation.

The 2018 Commission of Dental Accreditation requirements of an oral surgery residency program define a pediatric patient as “less than or equal to the age of 18.” As a result, if the Rhode Island Dental Board is setting criteria to require a “pediatric anesthesia permit” as defined as patients under the age of 13, an oral surgeon should be required to provide written documentation of a case load consisting of such pediatric patients during their training residency. In addition, it should be determined as to whether they provided anesthesia as the primary provider or whether their role was observational in the presence of an anesthesiologist. In addition, it should be noted whether the patient was provided a protected airway through advanced airway instrumentation or if the technique utilized was leaving an airway unprotected during deep sedation/anesthesia (i.e., was it relevant to the methods employed by the oral surgeon in his/her dental office based setting). It should also be noted as to whether they were simultaneously performing the dental procedure for a pediatric patient under deep sedation and/or general anesthesia.

While completing the five (5) months of formal anesthesia training during the oral surgery residency, the standards of care are those of the American Society of Anesthesiology. The supervision, safety and standards of care employed during this training period are not adhered to in the proposed Rhode Island regulations when considering such aspects as simultaneously functioning as an “operator/anesthesiologist” or employing unqualified personnel to function as a physical administerer of
anesthesia medications, monitoring individual or active participant in emergency scenarios.

https://www.ada.org/~media/CODA/Files/oms.pdf?la=en

Let us review the 2018 American Academy of Pediatric Dentistry Policy for Selecting Anesthesia Providers for the Delivery of Office Based Deep Sedation/General Anesthesia (the same policy that Section 2.2 Incorporated Materials Section (1.) attempts to remove from consideration for these RI Dental Practice Regulations).

I ask any member of the Rhode Island dental board who prides themselves on holding a high value on ethics and what is in the best interest of the patients, public and the profession as a whole, to please take the time to read the referenced articles in their entirety.

"With the use of office-based deep sedation/general anesthesia, the primary dental provider takes on a 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

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 the 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. Close collaboration between the dentist and 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 patient care."

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 population or on a mobile basis.

The following table summarizes the educational requirements of various anesthesia professions;
<table>
<thead>
<tr>
<th>Anesthesia Provider</th>
<th>Permitted to Function Independent of Supervision by Anesthesiologist</th>
<th>Minimum Duration of Program Required for Certification</th>
<th>Minimum Number of DS/GA Cases</th>
<th>Minimum Number of Pediatric Cases</th>
<th>Definition of Pediatric Patient</th>
<th>Minimum Number of Special Needs DS/GA Cases</th>
<th>National Examination/Certification Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certified Anesthesiologist Assistant²</td>
<td>No</td>
<td>24 mon</td>
<td>400 GA cases</td>
<td>0-18</td>
<td>N/A</td>
<td>N/A</td>
<td>National Commission for Certification of Anesthesiologist Assistants</td>
</tr>
<tr>
<td>Certified Registered Nurse Anesthetist⁶</td>
<td>In some states</td>
<td>24 mon</td>
<td>25/400³</td>
<td>&lt; 2 yrs. 10</td>
<td>2-12 yrs. 30</td>
<td>≥12 yrs</td>
<td>N/A</td>
</tr>
<tr>
<td>Dentist Anesthesiologist¹</td>
<td>N/A</td>
<td>36 mon</td>
<td>800</td>
<td>125</td>
<td>≥7 yrs</td>
<td>75</td>
<td>American Dental Board Anesthesiology and/or National Dental Board of Anesthesiology</td>
</tr>
<tr>
<td>Medical Anesthesiologist¹</td>
<td>N/A</td>
<td>48 mon</td>
<td>N/A</td>
<td>100</td>
<td>≥12 yrs</td>
<td>N/A</td>
<td>American Board of Anesthesiology</td>
</tr>
<tr>
<td>Pediatric Medical Anesthesiologist⁴</td>
<td>N/A</td>
<td>12 month fellowship following medical anesthesia residency</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>American Board of Anesthesiology (Pediatric anesthesia examination)¹¹</td>
</tr>
<tr>
<td>Oral and Maxillofacial Surgeon¹¹</td>
<td>Yes</td>
<td>5 months</td>
<td>300</td>
<td>50</td>
<td>≥18 yrs</td>
<td>N/A</td>
<td>National Board of Anesthesiology for anesthesia training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>American Board of Oral and Maxillofacial Surgery for surgery training</td>
</tr>
</tbody>
</table>

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

² = During the oral and maxillofacial surgery, training programs, a resident's assignment to the department of anesthesiology "must be for a minimum of 6 months; should be consecutive and one of these months should be dedicated to pediatric anesthesia."³⁵

³ Supereiated throughout the training program to ensure competency in deep sedation/general anesthesia on adult and pediatric patients.
2.11.3 Qualifications for Individual Anesthesia Permit – Section F.3

(pg 38 of 76)

c. Have completed a Board approved simulation course that uses high fidelity human simulation.

F. Applicants for a Pediatric Individual Anesthesia Permit to administer or to authorize the administration of deep sedation/general anesthesia to pediatric patients must meet all the foregoing requirements and:

1. Maintain current American Heart Association (AHA) Advanced Cardiovascular Life Support (ACLS)/Pediatric Advanced Life Support (PALS) certification;

2. Be a candidate for or hold current board certification by the American Board of Oral and Maxillofacial Surgery (ABOMS), or

3. Be a diplomate of the American Dental Board of Anesthesiology (ADBA), or

4. Proof of education or training commensurate with the type of individual permit sought, as follows:

   a. Completed an education program accredited by the ADA’s Commission on Dental Accreditation (CODA) that provides comprehensive training necessary to administer and manage general anesthesia and deep sedation.

5. Applicant’s written statement indicating special circumstances which justify the need for the permit.

If the RI Dental Board will issue a “pediatric anesthesia permit” to a board eligible (not board certified) oral surgeon, then there is absolutely no justifiable reason a board eligible (not board certified) dentist anesthesiologist should not also be eligible for a “pediatric anesthesia permit.” Referring to the above chart, a dentist anesthesiologist has a vastly greater education, training and experience in both pediatric and adult sedation/general anesthesia.

Successful completion of a dental anesthesia residency demonstrates a sound basis in training/experience in comparison to all qualified anesthesia providers. There is no reason to assume such for an oral surgery residency graduate in comparison to every alternatively licensed/educated anesthesia provider across all health care disciplines.
2.11.3 Qualifications for Individual Anesthesia Permit – Section G.3 (pg 39 of 76)

G. Applicants for a Portable Individual Anesthesia Permit:

1. Must hold a valid Rhode Island Dental License.

2. Must have completed an advanced post-doctoral program in anesthesia which is CODA approved and meets the requirements for board eligibility of the ADBA, or submits evidence of similar training and practice prior to establishment of these CODA approved programs and the ADBA, and

3. Current certification in ACLS.

2.11.4 Qualifications for a Facility Permit

If the mobile qualified provider is seeing pediatric patients, then they should also have updated PALS certification.

Without listing requirements of a “portable permit,” there seems very little purpose to the concept. The requirements of acquiring the portable permit should be written within these regulations.
that complies with the standards established by the Board.

C. Qualifications for a Moderate Sedation Facility Permit:


2. A moderate sedation individual permit in accordance with the requirements set forth in § 2-11.3(D) of this Part, and

3. Successful completion of an on-site office evaluation performed by a Board member or a Board appointed advisory consultant.
   a. An office evaluation team shall consist of two or more persons chosen and approved by the board. At least one of the evaluators must have administered general anesthesia in a dental practice setting for a minimum of three years preceding their application to be an evaluator, exclusive of any general anesthesia or conscious sedation training. At least one of the members of the evaluation team must have the same qualifications as the applicant. At least one member of the team must have substantial experience in the administration of the method of delivery of anesthesia or sedation used by the dentist being evaluated.
   b. The board may appoint a licensee member of the board to serve as a consultant at any evaluation.

4. An applicant for a Facility Permit to administer moderate sedation shall obtain written agreement from a hospital to accept emergency patients, or show evidence of membership on a hospital staff.

This is an attempt to undermine the ability of a moderate sedation provider to practice within their acceptable scope of practice. I cannot think of a single emergency situation where a patient is not readily accepted through the hospital emergency room at which point the treating dentist is no longer the primary provider of a given patient. The destination of any emergency patient is based on the acuity of a patient’s condition and transport occurs to the closest appropriate hospital (examples need for Emergent cardiac catch lab, pediatric care etc.).
Why is this being attempted to be tied to eligibility for a moderate sedation facility permit? How would any emergency situation differ if the dental patient was not sedated? They are just as likely to suffer an MI, stroke, anaphylaxis etc. whether sedated or not. Does every dentist in the state of Rhode Island need a transfer agreement for acceptance of conscious emergency patients?

It is vastly disappointing that a proposed document over three years in the making would attempt to ignore ASA, AAP & AAPD standards of care that do not fit certain author’s self-serving financial agenda, yet simultaneously attempt to inhibit their perceived competition from practicing their respective scope of practice. Instead of attempts of intimidation of providers, why not focus on ways to assure the provider of sedation/anesthesia is surrounded by not just “certified,” but actual qualified personnel. Sedation and general anesthesia in a non-hospital environment historically have been associated with an increased incidence of “failure to rescue” from adverse events, because bravado replaced appropriately trained/educated personnel.

2.11.4 Qualifications for a Facility Permit – Section D.4 (pg 40 of 76)

D. Qualifications for a General Anesthesia/Deep Sedation Facility Permit:

1. Rhode Island license to practice dentistry pursuant to R.I. Gen. Laws § 5-37.1-6;

2. A general anesthesia/deep sedation individual permit in accordance with the requirements set forth in § 2.11.3(E) of this Part; and

3. Successful completion of an on-site office evaluation performed by a Board member or a Board appointed advisory consultant.

4. An applicant for a Facility Permit to administer 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.

Membership on a Hospital Staff offers no confirmation of a provider’s ability to perform deep sedation/general anesthesia in a competent manner. Any dentist could become a member of a hospital staff yet lack any competency in sedation/anesthesia. If the RI dental board requires hospital credentials for the general anesthesia providing dentist, they should seek documentation stating the provider has privileges to perform sedation and/or general anesthesia within the hospital setting on both adult and pediatric patients as the primary provider without direct observation from an anesthesiologist or CRNA.
I do not follow the logic of ignoring ASA, AAP and AAPD parameters of care regarding the qualifications of collaborative professionals, ignoring standards of care regarding utilization of a separate licensed anesthesia professional, or failing to surround oneself with staff that are truly qualified and experienced (RN, EMT-P). To then turn around and attempt to insist on “red tape” of written documentation that a hospital emergency room will accept an emergency patient makes no logical sense. To attempt to require such under the guise of patient safety is insulting to any individual educated on the subject. In the face of blatant disregard for organizations not only more educated, but more qualified in the discipline of anesthesia, I am unsure how this board believes an emergency room providing written documentation of acceptance of patients will have any bearing on the outcome or well-being of an emergency patient. What emergency room across the country does not readily accept emergency patients originating from any location (be it a dental office, school, business, home etc.)? Let’s focus on adhering to known standards of care. To have the unmitigated gall to suggest such ill-advised methods on someone’s child is even more disingenuous.

Why not start with requirements of basic emergency drugs or an automated external defibrillator? If one opens any package insert for a dental local anesthetic carpule, you will find for example;

**BRIEF SUMMARY of PRESCRIBING INFORMATION (See Package Insert For Full Prescribing Information)** Articaine hydrochloride 4% and epinephrine 1:200,000 Articaine hydrochloride 4% and epinephrine 1:100,000

**WARNINGS AND PRECAUTIONS** Accidental Intravascular Injection Accidental intravascular injection of Orabloc may be associated with convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Dental practitioners who employ local anesthetic agents including Orabloc should be well versed in diagnosis and management of emergencies that may arise from their use. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use.


I hope it is clear that the regulations currently proposed require a great deal of revision. I also hope that the focus is on what is in the best interests of the patient/public and not individuals within the dental profession attempting to abuse board power for their own personal gain.
2.11.4 Qualifications for a Facility Permit – Section E.2 (pg 40 of 76)

E. Qualifications for a Facility Host Permit (H Permit):

1. An applicant pursuing a Facility Host Permit (H Permit) authorizing the administration of moderate or deep anesthesia and/or general anesthesia at the specific site named on the permit by a Qualified provider who is not the Operating Dentist must submit an attestation to the safety of all equipment used in connection with the administration of anesthesia.

2. An applicant for a Facility Host Permit to administer moderate sedation, 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.

Again, the Rhode Island Dental Board needs to decide if their intentions are based on the goal of improving safe, access to care for Rhode Island dental patients, or catering to the self-serving needs of individuals attempting to use their board authority to undermine their dental colleagues in a form of inhibition of competition or restriction of trade.

An applicant applying for a "host permit" would in all likelihood provide no level of sedation on their own (be it minimal, moderate, deep or general anesthesia). That individual looking to collaborate with a "qualified anesthesia provider" is demonstrating a respect and accordance with suggested standards of practice set forth by the ASA, AAP and AAPD. They intend to offer one hundred percent focus on the dental procedure(s) at hand while relying on a formally trained anesthesia provider to focus one hundred percent on the delivery of anesthesia and associated monitoring and well-being of a given patient. Any educated dental board would champion this model of care because it is simply common sense, free of sinister self-interest.
2.13 Physical Facility, Equipment and Safety – Section E.1.b (pg 55 of 76)

E. Qualifications for a Facility Host Permit (H Permit):

1. An applicant pursuing a Facility Host Permit (H Permit) authorizing the administration of moderate or deep anesthesia and/or general anesthesia at the specific site named on the permit by a Qualified provider who is not the Operating Dentist must submit an attestation to the safety of all equipment used in connection with the administration of anesthesia.

2. An applicant for a Facility Host Permit to administer moderate sedation, 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.

Equipment should be checked & calibrated according to manufacturer’s recommendations with subsequent documentation available for audit.

With the exception of a basic, rudimentary nitrous oxide / oxygen gas mixer (with or without a halogenated agent vaporizer), all anesthesia machines are capable of delivering less than 30% of oxygen by design. Anesthesia machines provide an audible alarm when oxygen supply pressure falls, while simultaneously cutting off flow from other gases thus preventing inspired oxygen concentration from falling below room air levels of 21%. In addition, during deep sedation/general anesthesia, it is an appropriate standard to monitor inspired/expired concentrations of all gases delivered to a patient (i.e oxygen, air, nitrous oxide, halogenated agents). If improvement in patient safety is the intent of the dental board, these requirements should be adopted.