12/2/2015

To Whom It May Concern:

We all know that oral health is an important component to overall physical health and well-being. One of the primary goals of the dental profession is to increase access to care for dental patients. It is of equal importance the state dental board regulates the profession in the interest of the public. As members of the dental profession, we should strive to shape our profession in a manner that allows for both goals to be achieved.

It is feasible to institute regulations that protect the patient and allow for all dentists to practice to the full scope of their qualifications. Unfortunately, a significant portion of the proposed regulations undermines both aspects of patient safety and means of cost effective access to care.

Please refer to the indexed sections of the proposed regulations along with subsequent comments below.

Section 1.38

(c) “Direct visual supervision” means supervision by a dentist or an oral and maxillofacial surgeon (with a permit to administer deep sedation and general anesthesia) by verbal command and under direct line of sight. (Gazzeri) In reliance on Part VI, Section 19.0 Administration of Anesthesia, 19.1 General Requirements, use of the word “Any licensed dentist licensed on the state of Rhode Island... Reliance on Section 19.2” Any licensed dentist permitted to administer general anesthesia/deep sedation, moderate sedation, minimal sedation... Section 15.2.3 (19.2.) “Those licensed dentists approved by the Board to engage in the practice of administering general anesthesia/deep sedation, moderate sedation, minimal sedation... Section 20.1.F Qualifications for Permit “For General Anesthesia/Deep Sedation: (a) be licensed as a dentist in this state of Rhode Island... Dr. Gazzeri believes that since this Section of the Rules and Regs specifically states and defines that the individual must be licensed and permitted DENTIST, the wording for 1.22 should be amended to read same.”

An oral and maxillofacial surgeon is a “dentist”. In the same manner a dentist anesthesiologist, or any other dentist who has fulfilled the education qualifiers to obtain a permit to administer sedation and/or general anesthesia, is a “dentist”, and overseen by Board of Registration. Why would said “dentist” be referred to as anything else in the state regulations? Any “dentist” who has obtained a minimal, moderate or deep sedation/general anesthesia permit should be required to adhere to the same regulations as any of their dentist colleagues.
Section 17.1.4 DAANCE-Certified Maxillofacial Surgery Assistant

17.1.4 **DAANCE-Certified Maxillofacial Surgery Assistant**

(a) Under direct supervision of an oral and maxillofacial surgeon with a valid general anesthesia/ deep sedation/general anesthesia permit, a DAANCE-certified maxillofacial surgery assistant may:

1. Discontinue an intravenous line for a patient who has received intravenous medications, sedation, or general anesthesia;

2. Adjust the rate of intravenous fluids infusion only to maintain or keep the line patent or open; and

3. Make medications readily available for review, inspection, and use by the oral and maxillofacial surgeon.

(b) Under direct visual supervision of an oral and maxillofacial surgeon with a valid general anesthesia/ deep sedation/general anesthesia permit, a DAANCE-certified maxillofacial surgery assistant may:

1. Follow instructions to prepare and assist in the administration of medications; and

2. Adjust the rate of intravenous fluids infusion beyond a keep-open rate;

3. Adjust an electronic device to provide medications, such as an infusion pump; and

4. Assist with preparation/delivery.infusion/administration of emergency medications to a patient in order to assist the oral and maxillofacial surgeon in an emergency.

• Why is the RI Dental Board willing to allow a minimally trained assistant (36 hour on-line course with no clinical training and without an academic degree) to essentially act in a role typically reserved for licensed healthcare providers with significantly greater training? RNs are not even allowed to do this without advanced training in addition to their advanced degree.

• Would any Rhode Island Hospital/Surgical Center allow someone with 36 hours of training act in the manner suggested by DAANCE? Would the educated public or other health professions consider this to be in the patients best interest regarding safety?

• Would the role of preparing/administering controlled substances with narrow therapeutic indexes (narrow margins of safety) be reserved for a licensed “doctor”, “nurse” or “paramedic” in any other healthcare setting outside the oral surgery office?

• Why is the RI Dental Board considering allowing a minimally trained assistant (DAANCE consists of 36 hours of self study / quizzes without a degree exceeding a high school diploma) to essentially act in a role that requires a professional degree and/or far significant training/licensure in any other healthcare setting outside dentistry?
**Part VI Administration of Anesthesia in Dental Offices**

**Section 19.0 General Requirements**

19.1 Any dentist licensed in this state Rhode Island who is administering, permitting the administration of, or intending to administer general anesthesia/deep sedation/general anesthesia, moderate sedation, minimal sedation, or nitrous oxide analgesia in his or her dental office, must meet the statutory and regulatory requirements herein, and must hold an Administration Anesthesia Permit granted by the Board to administer or to permit the administration of general anesthesia/deep sedation/general anesthesia, moderate sedation, minimal sedation or nitrous oxide analgesia in a dental office in the State of Rhode Island. Said permit is site specific and the applicant must be evaluated by the Board, or its designees, at each facility at which the dentist intends to administer anesthesia in his or her dental office.

19.4 Any licensed dentist permitted to administer deep sedation/general anesthesia, moderate sedation, minimal sedation or nitrous oxide analgesia who intends to do so in a dental office in this state Rhode Island that does not have a facility permit allowing the administration of these anesthesia services on the premises, as required by § 27.3 of these Regulations, shall be allowed to do so only with prior written approval of the Board.

19.5 A licensed dentist who has been issued a valid anesthesia permit to administer deep sedation/general anesthesia, moderate sedation, minimal sedation and/or nitrous oxide analgesia shall only administer said anesthesia to his or her own dental patients. A licensed dentist is prohibited from acting as an independent anesthesia provider to other dental or medical providers either within the same facility or elsewhere.

- “Analgesia” old term not currently used for Nitrous Oxide minimal/moderate sedation. The term should not be in the RI Regulations.

- Why would the RI Dental Board prohibit a licensed dentist with valid anesthesia permit from acting as an independent anesthesia provider (Section 19.5)?
  - Mobile dental anesthesia is available in both Massachusetts and Rhode Island dentists without sedation/anesthesia training will be limited in the patients they can safely treat. Since 1844, dentists such as Horace Wells (credited with discovery of anesthesia) have provided anesthesia for other dentists and physicians. For years, oral surgeons and dental anesthesiologists have helped other dentists treat patients by collaborating together to offer sedation/anesthesia. This is a mechanism for patients in need of restorative dental treatment to access care under sedation or anesthesia.

- Would a licensed doctor formally trained in anesthesia focused solely on the practice of anesthesia and patient monitoring improve patient safety? Would
there be any reason to disallow a proven model of improving patient safety and treatment efficacy?

- If the intent of the anesthesia regulations is in the best interest of the dental patient population, why are there considerations to allow a dental oral surgery assistant to prepare/administer anesthesia medications, yet preventing a licensed dentist/doctor from doing so?

- Considering the practice model of most “Dentist Anesthesiologists” is to provide sedation/anesthesia in collaboration with a dentist who focuses solely on the dental procedure, should this be considered a “restraint of trade”? This is the medical model standard of care as practiced throughout the country. The dental board would need to look no further than a drug package insert for an anesthesia induction agent (for example propofol or brand name Diprivan) to see the support of a model of care than divides surgical and anesthesia responsibility between two licensed, educated and qualified providers.

- Why is the RI Dental Board considering proposed wording that essentially eliminates the most qualified sedation/anesthesia providers within the dental profession (Dentist Anesthesiologists) from increasing patient safety, access to care, and efficacy of treatment for all facets of dentistry? Dental Anesthesiologists are the most highly trained sedation/anesthesia providers within the dental profession.

- The revision draft also implies inhibiting “board eligible” anesthesiologists from providing office based dental anesthesia. Are there any such limitations on any over dental practitioner? Are “board eligible” but not “board certified” oral surgeons, periodontists or endodontists prevented from providing care within their scope of practice? Would this be another example of “restraint of trade”?

20.1.1 For Deep Sedation/General Anesthesia:

(a) be licensed as a dentist in this state Rhode Island; and

(b) hold current certification in Advanced Care Life Support (ACLS) or Pediatric Advanced Life Support (PALS);

(c) have completed (or 40) hours of continuing education in anesthesia related subjects at the time of license renewal. The course must be accredited by the American Dental Association’s Continuing Education Program (CERP), the Academy of General Dentistry’s Program Approval for Continuing Education (PACE) or other nationally recognized entity approved by the Board; and

(d) 1) have completed an advanced training program in anesthesia and related subjects beyond the undergraduate dental curriculum that satisfies the requirements described in the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (October 2007, 2012) [Reference 7];

2) have completed an American Dental Association accredited post-doctoral training program (e.g., oral and maxillofacial surgery) which affords comprehensive and appropriate training necessary to administer and manage deep sedation/general anesthesia, commensurate with the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (October 2007, 2012).
• Is this an attempt to limit deep sedation and general anesthesia to utilization by oral surgeons only and deny access to care?

• Is there any Rhode Island hospital or surgical center that would allow a physician or dentist to perform a procedure AND simultaneously administer deep sedation/general anesthesia?

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(2)be employed or practice in conjunction with a Board Certified or Board eligible anesthesiologist. Such permit is subject to permit applicant passing a facility inspection performed by the Board, or its designee. An applicant who qualifies for a deep sedation/general sedation permit under this provision will only be granted a Anesthesia Facility Permit and not an Anesthesia Administration Permit.

The availability of anesthesiologists in the dental office setting increases access to care. It allows patients to acquire dental treatment with sedation/anesthesia in the dental office setting without the need for hospital admission. Residency training of a physician or dentist anesthesiology residency far exceeds the training of any other dental specialty residency. Utilization of an anesthesiologist allows the patients of general dentists, pediatric dentists, periodontists, endodontists and all other dental specialties access to deep sedation/general anesthesia in the cost effective dental office setting. The mobile dental anesthesia model is currently available in almost every state, including Rhode Island.

By not welcoming a practice model of a mobile, office based anesthesia professional, it forces other dentists to compromise dental care when employing less effective levels of sedation and/or techniques that prevent their undivided attention to the dental procedure(s) they are entrusted with providing. This often leads to providers attempting to exceed the reasonable limitations of a given technique, their own abilities or the resiliency of a patient. This process is contributive to increased likelihood of morbidity or mortality. It is the advanced training of the caregiver that makes a difference in providing a safe and effective means of sedation/anesthesia.

Facility Inspection
In regards to the concept of a facility inspection to allow for utilization of sedation & general anesthesia, please reference statements derived from an article by dentist anesthesiologist Dr. Ronald O. Davies, DDS.

Are we wasting valuable time and resources by inspecting every dental “facility” where anesthesia/sedation is provided?

Which is documented to insure patient safety; the dentist administering anesthesia, or the “facility” where the anesthesia/sedation is provided?

The studies are clear: Facility inspections do not increase patient safety. Other common models in our daily lives all depend upon on the training of the operator, not location, as the primary safety parameter.

- Pilots must have a “check out” (rating) in a 757, but they certainly aren’t tested at every airport or if they fly a 757 with a different tail number. And these pilots have hundreds of lives under their control, not just one.
- Although over 50,000 people die on the highways in cars every year, no one expects to take another driver test when they buy a new car.

Review of the literature finds that in every instance the causes for anesthetic catastrophes were improper vigilance and human error. “Facilities” were not considered as the causative factor for the anesthetic mishaps and no recommendations for site visits/evaluations were advanced to improve patient outcome. Equipment failures were only an insignificant issue, demonstrating that site visits/evaluations probably have no scientific validity as to significantly improving patient safety.

In emergency medical care paramedics and EMTs are judged on their ability to provide emergency care and not the “facility” where they provide their patient care. Their emergency equipment is mobile/portable and not fixed to one “facility”. Since the introduction of state anesthesia regulations in the 1980s mobile Oral and Maxillofacial Surgeons and dentist anesthesiologists have been providing anesthesia in tens of thousands of dental offices without any reported anesthetic mishaps related to the “facility”.

“Facility” OR “Provider”? by Ronald O. Davies, D.D.S.
Pulse July/August 2007, pg 8 – 10

Independent periodic evaluation of a provider of sedation/anesthesia is justifiable. However, the focus on the facility is misguided and does little if anything to improve patient safety or outcome. There are a number of state dental practice acts that Rhode Island could look to in order to develop a means of evaluation of the individual provider of sedation/anesthesia.
**Facility Inspection Staff**

What are the qualifications of the staff inspecting each dental facility? Who manages this process? Is it an independent group? Are all dentists with a permit to administer sedation/general anesthesia subject to the exact same inspection process?

**Comparison of Dental Residency Training Requirements in Regard to Sedation/General Anesthesia**

CODA standards are for OMFS (pg 35) vs. DA (p18) programs.

- The clinical minimum requirements for OMFS programs: (4-9.1)
  - The cumulative anesthetic experience of each graduating resident must include administration of general anesthesia/deep sedation to a minimum of 300 patients.
  - A minimum of 150 of these cases must be ambulatory anesthetics for oral and maxillofacial surgery.
  - A minimum of 50 of the 300 patients must be pediatric (18 years of age or younger).

- The clinical minimum requirements for Dental Anesthesiology programs: (2-6)
  - The following list represents the minimum clinical experiences that must be obtained by each resident in the program:
    - Eight hundred (800) total cases of deep sedation/general anesthesia to include the following:
      - Three hundred (300) intubated general anesthetics of which at least fifty (50) are nasal intubations and twenty-five (25) incorporate advanced airway management techniques. No more than ten (10) of the twenty five (25) advanced airway technique requirements can be blind nasal intubations.
      - One hundred and twenty five (125) children age seven (7) and under, and Seventy five (75) patients with special needs.
    - Clinical experiences sufficient to meet the competency requirements (described in Standard 2-1 and 2-2) in managing ambulatory patients, geriatric patients, patients with physical status ASA III or greater, and patients requiring moderate sedation; and
    - Exposure to the management of patients with chronic orofacial pain.

This comprises the minimal requirements for each residency (OMFS or Dental Anesthesia). It is without question that Dentist Anesthesiologists are the highest trained sedation/anesthesia provider, within the profession of dentistry. Many practicing Dentist Anesthesiologists have completed formal medical anesthesia residencies that far exceed the minimum criteria listed above. Dentist Anesthesiologists are the only dentists that are capable of obtaining hospital operating anesthesia privileges due to training on par with their medical colleagues.
Sedation and general anesthesia provides a tremendous asset to daily dental office based practice. The benefits of the ability of all appropriately trained dentists providing sedation/anesthesia consist of; increased access to care, cost effective means of patient care in comparison to the hospital operating room, better patient experience along with better working conditions for the operating dentist. Many years ago, oral surgeons realized these benefits and strived to organize parameters of care that would increase patient safety and efficacy of office based treatment.

In regards to safety of dental office based anesthesia administration, the most accurate statistics regarding morbidity and mortality would come from liability insurance companies. A review of Dr. Lewis Estabrooks Report on “Frequency of Office Anesthetic Deaths 2000 – 2011” would reveal a relatively safe model of care that does have room for improvement. Dr. Estabrooks is the Chairman of the Board of OMSNIC Risk Retention Group along with the Fortress Insurance Company. OMSNIC insures the vast majority of oral surgeons nationwide. According to the report, ninety-one (91) oral surgery office anesthesia deaths occurred within the eleven-year period of study. Dr. Estabrooks evaluated the number of patient deaths, estimated number of years of practice, and number of anesthetics performed by oral surgeons to derive a statistical basis of an oral surgeon experiencing an anesthesia related patient death in their office. Dr. Estabrooks concluded that statistically one (1) in every five hundred and forty five (545) Oral Surgeons would experience an office anesthetic death per year. Thus, one (1) in eighteen (18) Oral Surgeons will experience an office anesthetic death during their career.

Sedation and Anesthesia practice carries an inherent risk regardless of the qualifications of the provider. As a profession, we should be striving to mitigate the inherent risk associated with providing such care. Based on the current proposed Rhode Island regulations, would delegating aspects to a minimally trained DAANCE assistant while limiting the practice of a dentist with formal anesthesia residency training be a benefit to public safety or a potentially dangerous hazard?

The revisions found in the present draft undermine the culture of safety while also limiting patient access to qualified practitioners.

What is even more important to realize is that each type of dental provider (general practitioner, pedodontist, periodontist etc.) has a means to acquire training within the appropriate scope of practice. Whether that may be minimal, moderate, deep sedation or general anesthesia, there are defined education criteria throughout residency programs along with continuing education courses. As members of the dental profession, we should collaborate on methods to utilize the benefits of sedation/anesthesia while mitigating the inherent associated risks. This is more than feasible as long as all involved parties recognize the avenues on which we can improve practice parameters to assure for sufficient access to care in the safest manner possible. I urge the Rhode Island dental board to keep that at the forefront of their minds when considering revisions to the current guidelines.
Thank you for your time and consideration. Rhode Island currently has two practicing Dentist Anesthesiologists (Dr. Kristen Zitterell & Dr. Patrick McCarty). In addition, you can find two of the most accomplished Dentist Anesthesiologists in the nation in the neighboring states of Massachusetts (Dr. Morton Rosenberg) and Connecticut (Dr. William MacDonnell). We are all willing to help consult with dental providers of all disciplines to make sure we establish parameters of care that allow for all dentists to utilize the gift of anesthesia while allowing patients access to the safest and most effective means available. Thank you for your time and consideration.

Respectfully Submitted,

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