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**OPEN HEARING TESTIMONY SUNSET COMMISSION
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**OFFICE-BASED SEDATION / GENERAL ANESTHESIA
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Mr. Chairman & Sunset Commission Members, my name is Roger Byrne and I am an OMS practicing in Houston, Texas. I am speaking today representing the TSOMS to express their concerns for patient health and safety during dental office-based sedation.

Dental Office Deaths Related to Office-Based Sedation

Media reports of recent deaths in the dental office note that TDB stats show a total of 85 deaths occurring since 2010 with only 5 prosecutions.

Sunset Staff Report indicates a TDB study by a staff DH of 100 case complaints over the previous 4.5 years related to sedation. Of these cases there was 41 deaths with 13 (31.7%) that showed violations in the standard of care. The Staff report also cites two example cases: 1) a 4 y/o child who suffered irreversible brain damage following moderate enteral sedation by a general dentist. As a civil expert witness on this case privy to her records, in my opinion the dentist had no clue what she was doing in the sedation procedure; 2) an adult patient died after deep parenteral sedation as the dentist exercised his portability permit. Unfortunately he left his emergency equipment in his car!

Unfortunately the TDB study does not provide critical data on provider type, a breakdown of the deaths to location, and the type of standard of care violations.

Facts on TDB Sedation Permits

- Morbidity and mortality in dental office-based sedation most commonly associated with permit level 2, 3, and 4
- TDB issues these permits based on two areas of evidence for competency:
 - 1) Proof of specialty postgraduate residency completion (only DA & OMS approved for level 4)
 - 2) Certificate of completion of continuing education course which is supposed to meet the ADA Guidelines on Teaching Pain Control and Sedation to Dentists
- ADA Minimal Guidelines on Teaching Pain Control and Sedation to Dentists
 - 1) Moderate Enteral Sedation (Level 2)
24 hours of didactic instruction, 10 adult case experiences (at least 3 live patients) no larger than groups of 5
Competence in airway management
 - 2) Moderate Parenteral Sedation (Level 3)
60 hours of didactic instruction, at least 20 supervised cases of IV sedation per participant
Competence in airway management
- ADA Disclaimers
Minimal Moderate Sedation Courses do not qualify a dentist to become competent in children less than 12 years of age or medically compromised adults (ASA PS II-IV)

Why We Are Seeing Increasing Sedation Morbidity and Mortality in Texas Dental Offices

Since I am limited in time to make this presentation, I will only be able to tell you the opinions of the TSOMS on our 5 issues of WHY? The TSOMS suggestions for correcting these issues are included in today's "Handout" to the Sunset Commission.

- 1) Increasing number of office-based sedation permits by TDB
 - Level 4 (425 OMS, 25 DA)
 - Level 3 (1,110- GP, Perio, Pedi)
 - Level 2 (1,407- GP, Perio, Pedi)

- 2) The TDB does not investigate or "certify" any proprietary moderate sedation course or approve the content for such a course to confirm the course meets the ADA recommended "Guidelines"
Therefore: TDB has no proof of compliance

- 3) The TDB ignores the "ADA Disclaimers" associated with their minimal competency guidelines
Therefore: The TDB allows the most minimally trained to treat all patients (children , 12, ASA II-IV adults)

- 4) The TDB allows the minimally trained dentists to have "portability" of their permit
Therefore: The TDB implies competency of dentist to public than are able to treat all patients

- 5) The TDB ignores the "high-risk" dental patients regardless of the increased incidence of deaths in this group of patients by their failure to set appropriate standards of care
Therefore: the extremes of age (< 5 or > 75 years of age) and the medically compromised population

Thank you for your attention and I welcome any questions.

**TSOMS Standard of Care Recommendations
To Improve Patient Safety in Office-Based Anesthesia**

- 1) The Texas Legislature pass a new Chapter in the DPA that provides certain “guidance” to the TDB regarding certain “Standards of Care”
- 2) A new section defining the “high risk” dental patient and the standards of care
- 3) A section to require the TDB to only issue a specific permit when they have confirmed competency under the ADA Guidelines with recognition of the “Disclaimer”
- 4) A section repealing all sedation permit portability except for the CODA approved residency graduates in dental anesthesiology
- 5) A section requiring certain standards for on-site office and dentist evaluations before new issue or renewal of an existing sedation permit
- 6) A section requiring all moderate and deep sedation permit holders to employ a nationally certified dental anesthesia assistant in their performance of dental office-based sedation
- 7) A section requiring the TDB to maintain a permanent electronic data base for dental morbidity and mortality cases associated with sedation or general anesthesia

**TEXAS SOCIETY OF ORAL & MAXILLOFACIAL SURGEONS
RESPONSE TO SUNSET COMMISSION STAFF REPORT ON TSBDE
APRIL 22, 2016**

The TSOMS appreciates the opportunity to respond to the Sunset Commission Staff Report regarding the State Board of Dental Examiners.

The body of work compiled in the Sunset Commission Staff Report was very thorough and complete and we generally are in support of the entire report. However, we do not agree with several Staff findings utilized to justify their suggested statutory changes. We also have several suggestions for additional statutory change for the Sunset Commission to consider.

***ISSUE #1
DECREASE SIZE OF DENTAL BOARD***

The TSOMS supports this Sunset Commission Staff Recommendation as an end result but has some reservations on several of the findings posited by the Sunset Commission Staff as justification for their recommendation.

1.1 STAFF FINDING

The Staff posits extreme concern for Board interest in areas that have not focused on their primary goal to protect the public. They cite their effort to “push business-oriented matters without clear evidence of patient harm.” Specifically the Staff state on page 12, “One set of proposed rules, regarding dental office ownership, purported to address patient care relating to non-dentist owners of dental offices, although the board lacks data to suggest that practice models or ownership arrangements are associated with a higher incidence of complaints alleging compromised patient safety or demonstrated harm.”

1.2 TSOMS CONCERN

We believe the non-dentist ownership model of a dental practice alters the motivation of the parties which often results in less than quality patient care.

We understand the Board does not have clear evidence of this issue at hand because the Board does not maintain data on which dental licensees are employed by non-dentist practice owners which could be readily available if they simply asked that question on license renewal applications and enter it in their electronic database. Therefore, as the Board receives complaints against dentists they are unable to review the number and type of complaints filed against the employee dentists nor are they able to look at claims, as a group, against non-dentist practice owners.

The TSOMS is aware of significant civil litigation against non-dentist practice owners (corporations) that have been successful. The TSOMS members are also aware of standard of care violations that occur in this practice model. While the Board may lack the data to verify one model of practice to another for patient safety, the practicing dentists are most certainly aware of such differences.

1.3 TSOMS SUGGESTED CHANGE

The Sunset Commission require the Board of Dentistry to develop and maintain electronic data points on disciplinary cases which would allow the Board to study and report the difference between dentists employed by a non-dentist owner model versus a dentist owner practice model on an annual basis.

2.1 STAFF FINDING

The Staff continued to posit extreme concern for Board interest in areas that have not focused on their primary goal to protect the public. They cite the result of Board rules that recognize a national dental association definition of dental specialty recognition. They also note the result of a federal lawsuit that was lost by the Board because no evidence was presented to the court that inappropriate specialty recognition was harmful to the public and a limitation on specialty designation damaged some dentist's first amendment rights.

2.2 TSOMS CONCERN

The TSOMS agree that no evidence was actually presented by the defendants of this case that showed an unbridled release of a dentist referring to them self as a specialist would be harmful to the public.

The TSOMS, as specialists in oral and maxillofacial surgery, were the only dental specialty to join the lawsuit with a representing attorney as a defendant with the Texas Dental Board who was defended by the Office of the Attorney General. In this process we spent approximately \$80,000.00 through membership assessment.

We want the Sunset Commission to have the opportunity to understand the total picture of the lawsuit. The same group of plaintiffs filed similar litigation in California and Florida. Both of these States prevailed ultimately in their defense of specialty recognition by developing data that did, in fact, prove the public would be harmed if any dentist is free to identify themselves as a specialist to the public without proving evidence to the Board their training was appropriately certified.

Unfortunately, our attorney and the Attorney General's office failed to enter the California and Florida data into our lawsuit as a defense exhibit which possibly could have enabled the Federal Judge to enter a different verdict. However, the fact remains that the public perception of a designation of "specialist" or "Board Certified" implies the practitioner using those terms have been vetted by the state and as such, is endorsed by the state. To that degree, the state should have clearly established rules for specialty advertising.

The Texas Medical Practice Act has addressed the issue of specialty identification by developing certain standards that provide a mechanism for those physicians who are not certified by the American Board of Medical Specialties to gain TMB approval. The State of Florida has passed similar legislation in their Dental Practice Act.

2.3 TSOMS SUGGESTED STATUTORY CHANGE

The TSOMS encourages the Sunset Commission to consider legislation similar to that contained in the Texas Medical Practice Act or the Florida Dental Practice Act. At a minimum, the new statute should require any dentist wishing to request recognition and status as a dental specialist from the Texas Dental Board to have completed a minimum of twenty-four (24) consecutive months of dental post-graduate residency training in an area that provides special expertise greater than that obtained in a primary dental school education.

3.1 STAFF FINDING

The 2013 Legislature created the Expert Review Panel of dentists to assist the Dental Board in review of "standard of care" cases before the Board.

The Sunset Commission Staff are critical of dentist Board members (Quality Control Committee) because of their continued involvement in the case resolution processes which reflects the difficulty they have had accepting the Board's diminished role (page 14).

3.2 TSOMS CONCERN

The TSOMS believe the “Expert Review Panel” is composed of approximately 130 dentists including general dentists and currently recognized dental specialists.

The TSOMS believe the case referral by the Dental Board Dental Officer, a general dentist, to an expert panel member is based on the respondent dentist’s area of practice (i.e., a general dentist has a complaint so that complaint is evaluated by a general dentist panel member). This referral limitation may create issues that prevent an appropriate case recommendation and resolution of the case.

The TSOMS believe that certain circumstances in a case may warrant a specialist opinion that a general dentist possibly could not be qualified to address appropriately.

It is important for the Board to remember that all dentists, regardless of general practice or specialty practice are held to the same standard of care legally.

3.3 TSOMS SUGGESTED CHANGE

The Sunset Commission should encourage the Dental Board to develop a referral algorithm that would address certain types of cases that would involve referral to an expert specialty panel member in addition to a general dentist.

4.1 STAFF FINDING

The Sunset Commission Staff believe a reduction in the size of the Dental Board to four (4) member dentists, two (2) dental hygienists, and three (3) public members will force the dentist members to allow rulemaking development to stakeholder groups rather than multiple self-interest dentist members and force a greater dependence on the expert review panel in standard of care violations in the disciplinary process.

The TSOMS support the reduction in Dental Board size from fifteen (15) to nine (9) members but we have concern over the composition of the four dentist members.

4.2 TSOMS CONCERN

The TSOMS believe the intent of this recommendation is to have a potential composition of four dentist board members who do not represent any dental specialty.

The TSOMS have always had the belief that at least one (1) oral and maxillofacial surgeon should be a dentist member of the Dental Board. This position has, in the past been supported by the Texas Dental Association. While this position will now be argued by some to be only self-serving to protect a special interest group, the TSOMS believe that the intense medical education and training their members possess make them different from the general and other specialty dentists. Their education, training, and skill enable them to be an asset to the Dental Board which other dentists cannot always provide in the interest of public health and safety.

4.3 TSOMS SUGGESTED STATUTORY CHANGE

The TSOMS therefore encourages the Sunset Commission to consider a statutory requirement, regardless of the number of dentist members of the Dental Board, that at least one (1) Texas licensed oral and maxillofacial surgeon be a sitting member of the Texas Dental Board.

ISSUE #2
DISCONTINUE BOARD DENTAL ASSISTANT CERTIFICATION PROGRAMS

The TSOMS supports this Sunset Commission Staff Recommendation with reservation on one issue.

The TSOMS supports the Sunset Commission Staff opinion when they state, “Existing credentialing programs and private market forces already offer consumers and employing dentists standards and oversight for dental assistants training and practice, rendering the states certification programs redundant.” Clearly the Sunset Staff supports national certifications of certain dental assistant groups as long as Texas Dental Board resources are not spent to maintain these programs.

TSOMS CONCERNS

The TSOMS, in their presentation to the Sunset Commission Staff, supported a position to improve patient health and safety in office-based sedation and/or anesthesia by requesting legislative guidance of the Sunset Commission to require that each Texas Dental Board permit holder in enteral moderate sedation (Level 2 permit), parenteral moderate sedation (Level 3 permit), or deep sedation/general anesthesia (Level 4 permit) have a certified dental anesthesia assistant present for any sedation or anesthesia procedure as an employee of the permit holder.

We cited the Dental Anesthesia Assistant National Certifying Examination (DAANCE) offered by the American Association of Oral and Maxillofacial Surgeons as an entity to provide certification for this category of assistant.

At that point we assumed the Sunset Staff was well aware of the other certification levels required of Texas dental assistants by the Board of Dental Examiners and certainly we were unaware of their interest to discontinue all dental assistant certification programs by the Board.

TSOMS SUGGESTED STATUTORY CHANGE

Therefore, we suggest the Sunset Commission consider the following wording in their effort to improve patient health and safety by making it part of a proposed statute to grant authority of the Dental Board to regulate office-based dental sedation or anesthesia:

Every dentist who holds a permit from the Texas Board of Dental Examiners to perform enteral moderate sedation (Level 2 permit), parenteral moderate sedation (Level 3 permit), or deep sedation/general anesthesia (Level 4 permit) shall employ a dental anesthesia assistant certified by the Dental Anesthesia Assistant National Certifying Examination or other national entity with comparable course preparation and psychometric testing.

ISSUE #3
REQUIRED OFFICE EVALUATIONS FOR ANESTHESIA PERMITTING

The TSOMS supports this Sunset Commission Staff Recommendation. However we are concerned not about the intent of the recommendation, but the use of words that may be construed differently from what we believe and understand the intent to be.

STAFF RECOMMENDATION WORDING

3.1 Statutory change to authorize the Board to conduct inspections of dentists administering **parenteral anesthesia** in office settings (page 31).

The Sunset Staff also states that, “as a management action, the Board should adopt rules to support a risk-based inspection schedule, detailing the framework and procedures for inspections of the offices and documents of licensed Texas dentists holding **any level of anesthesia permit.**”

TSOMS CONCERN

The TSOMS believe the intent of this recommendation is to improve public health and safety by recognizing the import of an office evaluation for those dental providers who apply for, and ultimately receive, a sedation/ anesthesia permit from the Board to perform moderate enteral sedation (Level 2 permit), moderate parenteral sedation (Level 3 permit), or deep sedation/general anesthesia (Level 4 permit). The Staff point out the most sedation/anesthesia complications occur in these three (3) permit groups.

The TSOMS believe the use of the term ***parenteral anesthesia*** is an incorrect description of the intent of the recommendation. First the term ***anesthesia*** in the Board permitting process refers to a general anesthetic state which requires the education and training of a Level 4 permit holder. The term parenteral usually refers to an intravenous route to obtain sedation or general anesthesia while ignoring other routes of drug administration.

The TSOMS believe it is unnecessary for the Sunset Commission to require the Board to require office inspections on nitrous oxide inhalation conscious sedation or Level I minimal sedation permit applicants or holders but ***should require*** the Level 2, 3 and 4 permit holders to have office inspections.

TSOMS SUGGESTED STATUTORY CHANGE

The TSOMS therefore recommend the change in statute to read: Authorize the Board to require and conduct inspections of dentists and their office(s) who administer enteral moderate sedation, parenteral moderate sedation or deep sedation/ general anesthesia.

ISSUE #4
BOARD TO CONFORM TO LICENSING REGULATIONS

The TSOMS supports this Sunset Commission Staff Recommendation.

ISSUE #5
CONTINUING NEED FOR DENTAL BOARD

The TSOMS supports this Sunset Commission Staff Recommendation.