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**AB 2235 (CALEB'S LAW)
AND THE FUTURE OF THE OMS
TEAM MODEL OF ANESTHESIA**



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ORAL & MAXILLOFACIAL SURGERY**

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EDITORIAL



The Importance of Purpose

by Jeffrey A. Elo, DDS, MS, FACS

The two most important days in your life are the day you were born...and the day you find out why. ~ Mark Twain

Why were you born? What do you live for? Work... family...money...materials? What gets you out of bed each morning? An alarm clock...or a calling? Is there anything that gets your heart racing with excitement?

I know the answers to these questions...for myself. But what about each of you? Even if we haven't yet met, I know this much about you. You have a purpose. Everybody lives for something. I think it's important to stop and think about *why* you do *what* you do. This is your purpose. Some might say their purpose is to have fun while they chase after pleasure. For others, life is all about the pursuit of success. Or perhaps it's about making money. I know many people who live for sports and

politics—I see these people each morning screaming at the radio in their cars on the drive in to work. Some live for emotional experiences, while others live for being in, or having, a relationship. The point is everyone lives for something.

As surgeons and leaders in our homes, offices, and communities, we should be seeking more than just the simple (or complex, really) pursuit of happiness. Typically, I've found that the most unhappy people are those who live solely to be happy. It seems that those who seek only after

happiness most often end up being miserable people. But I think if we seek to be moral and ethical in our professional and personal affairs then we will discover that happiness comes into our lives as a byproduct. Don't seek pleasure; seek purpose. Don't seek success; seek significance.

Your family, your colleagues, staff, and perhaps even patients are watching you. Are you a thermostat or a thermometer? Do you set the tone for your home or office with your leadership, or do you just go with the flow?

As the leader of your office, you are charged with communicating your office's purpose to your staff. When the purpose is clear and everyone understands it and is on the same page, the office moves forward in the right direction. Think of it like building a house and first laying down a solid foundation—this is the critical first step in creating a successful and purposeful practice.

Your practice is a system, just as any individual or family is a system. When you know how to optimize the system, you're then able to bring the best components of it into your world. A major component of this is in knowing and understanding why your practice exists. Having a clear purpose is one of the key foundational elements that you can build your practice on... and your life, too. When an office or business is not in touch with its purpose, it could be lost.

Do you have a purpose statement for your office? A purpose statement is like a compass—guiding you on the path to reach your destination. You might have a purpose or mission statement well defined, but the important question to ask is this: Is it a purpose that will inspire those around you to take positive action? If not, it's probably not the bigger purpose. You can lift your office's purpose to a much higher level just by asking "and why do we do that?" several times until you discover that higher purpose for being. Knowing the purpose then becomes the guiding light and motivation for everyone's working toward a common goal. The same is true on a personal level. A clearly defined purpose statement is the foundation to building a purpose driven life and a purpose driven practice.



Saturday, January 14, 2017::

"Medicine and Anesthesia for the Oral and Maxillofacial Surgery Patient: A Case Based Discussion"

speaker: **Norman Betts, DDS, MS**

panelists: **Kathryn Rouine-Rapp, MD and Gurpreet Dhaliwal, MD**

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PRESIDENT'S MESSAGE



A Review of the Year & Look to the Next: The Good, the Bad, & the Ugly

by Leonard M Tyko II, DDS, MD, FACS

2016 has been a busy and challenging year. From an evolving anesthesia crisis, through our organization's name change, to the successful election of Dr. Tom Indresano to AAOMS Vice President, the CALAOMS Board has worked hard on your behalf.

Knowing that most people only read the first few paragraphs of any story, let's start with the **good**. At this year's AAOMS Annual Meeting, Dr. Tom Indresano, long-time educator, Chair of OMS at The University of the Pacific/Highland Hospital residency program, past president of CALAOMS, and former AAOMS District VI trustee, was elected AAOMS Vice President. I've long admired Dr. Indresano—his vast experience, intelligence, and knowledge of OMS issues are all wrapped up in the soul of a true gentleman. Congratulations & good luck in Chicago, Tom!

Onto the **bad**. As previously reported, the CALAOMS Board hired Elmetts Communication to run a California informational campaign paralleling that of AAOMS. After a period of research, Elmetts suggested a variety of strategies. The group stated that "*maxillofacial*" was a word that nobody could define and that few could pronounce. To make our profession easier to pronounce and remember, *maxillofacial* was recommended to be shortened to *facial*, and the Board adopted a new name and image. A new logo was developed, our webpage reworked, and our newsletter renamed. Unfortunately, this new branding was not well received by the CALAOMS membership.

In retrospect, the Board recognizes the significant mistake we made in moving so quickly on our organization's re-branding and not seeking membership input. This time, we solicited your feedback. Recently, we sent out a survey of the membership regarding the name change. 303 members voted on their name preference; and the results were clear: 85% supported keeping the name CALAOMS, while 15% supported OFSOC. With these results in mind, what's old is new again, and we're back to CALAOMS officially. With that behind us, it gives us time to focus on our *most pressing concern* – anesthesia, the **ugly**.

Though the passage of AB 2235 is a success for OMS, the anesthesia issue is nowhere near complete.

For those of you not following the anesthesia issue, here's a quick recap. In February 2016, California Assembly Member Tony Thurmond introduced AB 2235 ("Caleb's Law,") in response to the death of a 6-year old undergoing office-based oral surgery under anesthesia. As the bill worked through the California legislature, it evolved significantly, and at times, seriously threatened our scope of practice. The CALAOMS Board, closely allied with CDA, worked tirelessly to address each amendment and advocate for an evidenced-based, cost-effective bill. Over time, AB 2235 morphed into legislation directing the Dental Board of California (DBC) to review outcomes data, current laws, and professional regulations in order to make recommendations to ensure the safety of dental pediatric anesthesia. AB 2235 was signed by Governor Brown in September.

Though the passage of AB 2235 is a success for OMS, the anesthesia issue is nowhere near complete. The focus now rests on the DBC, whose AB 2235-mandated report is due by 1 January 2017. CALAOMS continues to promote evidence-based, reasonable anesthesia guidelines as the DBC drafts its recommendations. In the past, we've presented our data (*see CALAOMS' position paper presented here in The Journal*) and advocated for our OMS Team Model of anesthesia at multiple DBC meetings. CDA, in an effort to develop a united dental voice, hosted stakeholders meetings where CALAOMS was a vocal and active contributor. As we move forward, CALAOMS continues to collaborate in and outside the dental profession to educate and advocate for thoughtful anesthesia reform.

While considerations are ongoing, the DBC's initial recommendations include the following requirements (*which we*

have also included in this issue of The Journal): 1) continued anesthesia outcomes data collection; 2) an update of anesthesia definitions to delineate between minimal sedation, moderate sedation, deep sedation, and general anesthesia; and 3) capnography and a minimum two staff members (one must be dedicated to monitoring the patient) for deep sedation/general anesthesia. Additionally, providers treating patients under the age of 13 will need PALS certification, and providers administering deep sedation/general anesthesia to patients under age 7 will be required to obtain a specialized pediatric anesthesia permit. CALAOMS applauds the spirit of these recommendations as a framework for future discussions.

The final DBC report likely *will not* be the final chapter on dental anesthesia. We are preparing for a continued attack on our anesthesia model. The most likely site of this attack will be via the state legislative process. CALAOMS is poised to address these issues and with Dr. Indresano on the AAOMS Board, California should enjoy additional national support as we strive to further increase anesthesia safety.

Finally, I would be remiss if I did not take this opportunity to recognize the tireless efforts of our CALAOMS lobbyist, Gary Cooper. Throughout this year, Gary has been at the forefront of the legislative fight, guiding CALAOMS Board members as we defended our practice model. His strategic approach, personal connections, deep knowledge of the legislators and their staff, and professional demeanor set the course for success. CALAOMS is better due to his efforts and, personally, I am indebted to him for guiding me through the political lion's den. Gary, we couldn't have done this without you!

Leonard M. Tyko II, DDS, MD, FACS
CALAOMS President

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CALAOMS Position Paper on AB2235

Introduction

In response to the Dental Board of California's (DBC) 1 June 2016 invitation to participate in the Dental Board of California's Anesthesia Project, the Oral & Facial Surgeons of California (OFSOC) respectfully submit this report that describes the Oral & Maxillofacial Surgery Team Model of out-patient anesthesia delivery.

For more than 60 years, California Oral & Maxillofacial Surgeons (OMS's) have held the practice authority to provide deep sedation/general anesthesia in an out of hospital setting. During short, potentially painful, and anxiety provoking procedures, it is common for OMS's to provide deep sedation and general anesthesia for in-office surgery via the Oral & Maxillofacial Surgery Team Model. Professional outcomes data show that the OMS anesthesia model delivers care that is safe and cost-effective. This model increases access to necessary oral health care for individuals who otherwise are unable to afford hospital-based surgical care.

What is an Oral & Maxillofacial Surgeon?

Oral & maxillofacial surgeons are the surgical specialists of dentistry. There are two paths to becoming an OMS. The first route requires the completion of 4 years of dental school and a 4-year, hospital-based residency program. The second route includes the completion of both dental school and medical school and a 4-year residency program. Oral Maxillofacial surgeons have between 8-12 years of post-graduate clinical training.

Procedures within the OMS's scope of practice include: surgery to correct maxillofacial trauma (e.g. motor vehicle accidents, gunshot wounds, industrial accidents, interpersonal violence); corrective jaw surgery for developmental deformities of the face and jaws; surgical treatment of head, neck and oral pathology, including benign lesions and cancer; cosmetic surgery; reconstructive surgery, including bone and skin grafts and dental implants; jaw joint surgery; and dental extractions. OMS's operate in both hospital and outpatient settings. While major and lengthy surgeries are carried out in a hospital setting, minor surgeries, on otherwise healthy individuals, are typically performed in an office setting. To facilitate office-based surgery, OMS's are trained to administer all forms of anesthesia.

OMS Team Model of Anesthesia

The OMS Team Model of anesthesia delivery is a core clinical competency taught throughout the residency program and requires post residency specialty licensure. This specialized training during residency includes a 5-month medical anesthesiology rotation. While in this rotation, the OMS functions as an anesthesiology resident, along side the other medical anesthesiology residents. The OMS Resident is supervised by medical anesthesiologists and performs a minimum of 300 general anesthetics. This anesthesia training includes: evaluation of patients for anesthesia, risk assessment, diagnosis and treatment of complications, appropriate patient monitoring and post-anesthesia care, and techniques to administer of all levels of anesthesia. As the anesthesiology resident, the OMS trainee performs local anesthetic techniques as well as general anesthesia for all types of major, hospital based surgical procedures.

In addition to their anesthesiology rotation, OMS residents continue their anesthetic training in the OMS outpatient clinic under faculty supervision in their clinical specialty. Throughout training, the OMS performs hundreds of office-based surgeries delivered under all forms of anesthesia while directing the anesthesia team.¹ In addition, OMS

residents must complete Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) training.

In order to provide deep sedation and general anesthesia, the practicing OMS must secure and maintain a separate General Anesthesia Permit issued by the Dental Board of California. California regulations require this General Anesthesia Permit in addition to (and separate from) their medical and/or dental license. As part of the anesthetic permit maintenance, the Dental Practice Act requires the OMS to obtain on-going anesthesia-related continuing education as well as completing Basic Life Support and Advanced Cardiac Life Support every two years. California regulations also require anesthesia permit holders to undergo regular, in-office evaluations by the Dental Board of California. These evaluations include a site inspection, observation of the OMS and his/ her team during a surgery with general anesthesia delivery, and the successful completion drills of 13 medical emergency scenarios.

OMS Team Members

The Oral & Maxillofacial Surgery Anesthesia Team consists of the surgeon and at least two trained assistants. The first assistant monitors the patient and maintains the airway as his/her only duties during the procedure. The second assistant assists the OMS in performing the surgery. Assistants achieve certification via completion of the California's Oral & Maxillofacial Surgery Assistants (OMSA) Program or the Dental Anesthesia Assistant National Certification Examination (DAANCE). Assistants are trained in the use of anesthesia monitoring equipment equivalent to the monitors found in many hospital surgical suites and are trained in the latest medical anesthesia protocols. Monitoring patients' vital signs, anticipating, and if needed, reacting to emergency situations are a major focus of the assistants' training and on-going performance evaluation.

Growing Role of Sedation out of the Operating Room

OMS's have a long history of administering anesthetics to patients undergoing short, interruptible, minor surgeries. However, OMS are not the only practitioners who provide out-of-operating-room anesthesia without an anesthesiologist.²⁻³ The delivery of sedation has become common, and as many providers argue, is the standard of care for uncomfortable or painful diagnostic and treatment procedures. Sedation helps patients tolerate lengthy MRI or nuclear medicine scans. Cardiologists and emergency department physicians provide procedural sedation and analgesia. Gastroenterologists routinely provide sedation for endoscopy. In fact, a survey by the American College of Gastroenterology found more than 98% of providers in the United States routinely administer sedation.⁴ Providers cite difficulty obtaining operating room time, excessive costs for in-patient care, and reimbursement challenges as reasons for providing more outpatient anesthetics. Multiple studies have demonstrated the safety of anesthesia in the above situations when administered to appropriate patients by well-trained providers. Furthermore, many studies report decreased patient anxiety and increased patient satisfaction with procedures performed under outpatient anesthesia. Together, these factors provide the basis for a multi-specialty practice of providing safe and affordable single-provider, outpatient anesthesia.

OMS Safety Record

All surgical procedures and all forms of anesthesia in every healthcare setting carry risks. The overall estimated mortality rate from hospital-based anesthesia in the United States is approximately 1 in 100,000.⁵⁻⁶ In comparison, the overall estimated mortality rate from office-based OMS anesthetics is 1 in 648,794.⁷⁻²² This difference is striking, but not surprising. One would expect a lower mortality rate with the OMS Team Model. Unlike other operating room surgeries, the typical, office-based anesthetic is less deep, the surgeries are minor, short and interruptible, and the patients are relatively healthy individuals. Multiple academic papers published in peer-reviewed, scientific journals attest to this safety record.

Repeatedly, retrospective and prospective studies, individual case studies, surveys, and closed claims reports report very low morbidity and mortality rates for OMS anesthesia delivery.⁷⁻²² In a 2003, prospective, cohort study of more than 34,000 patients, Perrott et al., reported an overall complication rate of 1.3% for office-based ambulatory anesthesia by the OMS Anesthesia Team Model.²⁰ Most complications were minor and self-limiting, and no complication resulted in long-term adverse sequelae. There were no deaths reported in this study of more than 34,000 patients.

Most recently, Inverso et al., 2016, published a multi-center, prospective study of 29,548 adolescent patients undergoing moderate sedation or deep sedation/general anesthesia in an outpatient setting.²² They reported overall complication rates for moderate sedation of 0.5% and 0.9% for deep sedation/general anesthesia. The most common complications were vomiting and prolonged emergence from anesthesia. Multivariable logistic regression analysis showed no increase in risk between deep sedation/general anesthesia and moderate sedation in an outpatient setting. As in earlier studies, Inverso reported no deaths in this large, multi-center trial. Inverso's findings are particularly relevant to discussions surrounding AB 2235, as all of the 29,548 subjects were pediatric patients less than 21 years old.

Large, randomized, cohort studies are expensive and difficult to conduct. As such, closed case claims reviews are an established method to look for low incident events. The American Society of Anesthesia used closed case reviews to help lower complication rates by identifying scenarios that led to poor outcomes.²²⁻²³

In a similar fashion, the OMS National Insurance Company (OMSNIC) recently completed its own closed case claims review of pediatric, anesthesia claims. OMSNIC is the largest OMS malpractice insurance company in the country, insuring approximately 80% of the United States 9,500 OMS's. They evaluated California claims from 2005 through 2015 for patients less than 21 years old and found 5 claims related to the delivery of anesthesia. Four claims were related to anesthesia care in an office setting and one claim involved a patient treated in a hospital. During the period of review, 2005 through 2015, there were no claims of a pediatric patient anesthetic death (see Appendix A).

It is important to note that in a detailed review of the OMS literature, no study demonstrates an increase in anesthetic complication rates in appropriately screened individuals, including pediatric patients, with the OMS Team Model of Anesthesia. As multiple researchers explain, office-based oral surgeries are minor procedures, performed on carefully screened, low risk individuals in an area that allows for direct monitoring of the airway. Given these findings, it is reasonable to conclude that for relatively healthy patients undergoing brief, interruptible surgeries in the head and neck region, the OMS Anesthesia Model provides a safe and effective standard for outpatient anesthesia.

Efforts to Establish California Complication Rates

Currently, the DBC is compiling a report of adverse clinical events in pediatric patient between 2011 and 2016. In order to calculate complication rates for California OMS practicing under the current OMS Anesthesia Team Model, investigators need to know the number of anesthetics given by a practicing provider. There have been a number of past surveys in the United States and Canada attempting to estimate this denominator.⁶⁻¹⁹

In order to obtain the most current number of deep sedations/general anesthetics provided by an average California OMS, CALAOMS is conducting a survey of its active membership. Including residents, candidates, affiliates, and active members, CALAOMS has a total membership 953 OMS's. Out of the total membership, there are 725 active members. We assume that the vast majority of active members have general anesthesia permits. As of this report's submission date, 284 active members of OFSOC responded to the survey, for an overall response rate of 39%. CALAOMS members were asked to provide the number of pediatric (less than 21 years old) and adult

(21 years old and older) anesthetics. Members were requested to obtain the data from their practice management software by searching for anesthesia codes CDT 9220 and CDT 9223. Tables 1-5 summarize this data.

Table 1: Number of Deep Sedation/General Anesthetics Per Year

Year	Pediatric Patients Deep Sedation/General Anesthetics	Adult Patients Deep Sedation/General Anesthetics	Total Deep Sedation/General Anesthetics
2011	68,290	77,398	145,688
2012	71,070	82,445	153,515
2013	76,606	85,561	162,167
2014	78,639	86,613	165,252
2015	83,737	88,694	172,431
2016 (partial year)	53,003	56,210	109,213

Table 2: Number Of OMS Reporting By Year

Year	Number of Responders
2011	234
2012	244
2013	258
2014	268
2015	279
2016 (partial year)	270

Table 3: Average Number of Pediatric Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	292
2012	291
2013	297
2014	293
2015	300
2016 (partial year)	196

Table 4: Average Number of Adult Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	331
2012	338
2013	332
2014	323
2015	318
2016 (partial year)	208

Table 5: Average Number of Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	623
2012	629
2013	629
2014	617
2015	618
2016 (partial year)	404

Data collection is on-going, but thus far, OFSOC survey results correlate closely with previously published papers.⁶⁻¹⁹ OFSOC anticipates that the results of this survey will be combined with the DBC's data to generate OMS anesthesia morbidity and mortality rates during the period of 2011-2016.

Legal & Professional Standards to Ensure Patient Safety

The California Dental Practice Act defines the legal standards of practice for dentists in California. The requirements for obtaining and maintaining an anesthesia permit are contained within the Act. Permit holders are required to undergo office anesthesia evaluations (OAE) by the Dental Board of California as previously discussed. These evaluations of the OMS and his/her team include a site inspection, observation of a surgery with anesthetic delivery, and medical emergency scenario drills. The purpose of the OAE is to assess the OMS's ability to gauge a patient's anesthetic risk and to ensure the facility is prepared for emergencies associated with the administration of anesthesia in all types of patients, including pediatric individuals.

In order to give clear direction to the practicing OMS beyond the legal dictates of the Dental Practice Act, state and national professional societies define the standards of care for OMS. Beyond a general ethic of "do no harm," oral and maxillofacial surgeons are professionally bound to the specific principles outlined by the mission, actions, and publications of the OFSOC and AAOMS. Of the nearly 1,000 California OMS's, 953 are members of OFSOC and AAOMS.

The purpose of OFSOC is to contribute to the public welfare by advancement of the profession of dentistry and in particular the specialty of oral and maxillofacial surgery; to foster programs of education, research, standards of practice and scientific investigation in the specialty of oral and maxillofacial surgery; to provide a means of self-government relating to professional standards, ethical behavior and responsibilities of its fellows and members; to provide opportunities for social and professional development.²⁵ In order to qualify for membership in OFSOC and AAOMS, OMS's must undergo a professional evaluation. Once a member, the OMS is required to adhere to a code of professional conduct and a code of ethics; and to submit to peer review and to an ongoing evaluation of their office, staff and office procedures related to the anesthesia team model. Through their membership in the professional organization, OMS commit to following evidence-based standards of practice to insure safe anesthesia delivery.

Two AAOMS publications set the standards for OMS office-based anesthesia: AAOMS Parameters of Care for Anesthesia in Outpatient Facilities and the Office Anesthesia Evaluation (OAE) program.²⁶⁻²⁷ More rigorous than the California Dental Practice Act, the AAOMS Parameters of Care describes criteria and parameters for pain and anxiety control in the ambulatory surgery setting. Subjects covered within this document include: informed consent, proper documentation, facility attributes and required equipment, pre-anesthetic physical and laboratory assessment, perioperative complications and emergencies, general therapeutic goals, general risk factors that may exclude a patient from office-based surgery, desired outcomes, and risks and complications of anesthesia. This publication also outlines special considerations for pediatric, pregnant, and obese patients.

Each subject within the AAOMS Parameters of Care outlines what is expected of the OMS. For example, the operating theater must be large enough and equipped to allow for ACLS. Readily available mobile auxiliary sources of light and suction that can be used in a power failure must be present. Back up oxygen that can be delivered under positive pressure is required. Further, during deep sedation and general anesthesia, the Parameters call for the use of anesthesia monitoring equipment that is similar to those used in the operating room: blood pressure readings every 5 minutes, evaluation of the heart rate and rhythm by ECG, continuous evaluation of the patient by observation, pulse oximetry, and end-tidal CO₂ by capnography. Of note, OFSOC and AAOMS require monitoring devices that exceed those mandated in the California Dental Practice Act. The Parameters of Care for Anesthesia in Outpatient Facilities is regularly updated (at more frequent intervals than that of the Dental Practice Act) to ensure that the document reflects current, evidenced-based standards of care.

Both OFSOC and AAOMS require continuing education courses specific to anesthesia. OFSOC offers to its members and allied staff six to seven educational opportunities per year, with subjects ranging from medical emergencies, to anesthesia, to ACLS, to surgical updates, to the Oral & Maxillofacial Surgery Assistance (OMSA) program.

Finally, the AAOMS promotes many practices originally promulgated by the aviation industry to foster a culture of safety. The AAOMS publication Culture of Safety in the OMS Office defines policies and actions to ensure patient safety. Adopted by JCAHO and numerous healthcare entities, the pre-surgical “time out,” promotion of the team concept, cross training, collaboration, transparency, accountability, and systematic evaluation are all tools endorsed by AAOMS to help prevent potential errors. A full description of the Culture of Safety in the OMS Office is available on the AAOMS website. In March 2017, AAOMS will host a Patient Safety Summit to highlight their efforts in this arena.

Future Pathways to Increase Patient Safety

Despite outcomes data demonstrating extremely low complication rates, OFSOC and AAOMS strive to increase safety in the delivery of anesthesia. To that end, OFSOC and AAOMS continuously review, revise, and develop standards, policies, and educational opportunities for their members. Though rare in their occurrence, research points to airway problems as a major component of poor anesthesia outcomes. To further improve outcomes and to help its members better manage rare airway emergencies, AAOMS developed an emergency airway management simulation program, BEAM (Basic Emergency Airway Management), to be implemented in 2017.

Also, AAOMS is in the final stages of β -testing a national registry to prospectively track rare anesthetic adverse events. This anesthesia registry will interface directly with OMSs’ practice management systems to provide needed prospective data. Commonalities gleaned from the registry will be helpful in further reducing anesthesia morbidity and mortality.

Access to Care

According to the statistics above, requiring patients to receive care in the hospital would transfer approximately 452,000 patients (average number of 623 deep sedation/general anesthetic per OMS per year (Table 5) X 725 active OMS’s) per year to hospital operating rooms. California’s hospitals are ill-prepared to absorb this increase in patient utilization. California lacks a sufficient number of anesthesiologists, dental anesthesiologists, and nurse anesthetists to accept this load. Already, providers cite problems with obtaining OR time and the subsequent delay in care as a reason for needing alternatives to inpatient procedures.

Additionally, moving these cases to the hospital will increase the cost of basic oral health care dramatically. Insurance coverage for dental care is already a challenge, and patients who risk out of office-based procedures struggle to obtain adequate coverage for hospital surgeries. It is unclear if insurance companies will cover the cost of hospital care simply because of the patient’s age. Of note, Denti-Cal currently requires pre-authorization for office-based anesthesia; this authorization is not guaranteed and already delays services. Furthermore, one 2015 (post Affordable Care Act) study estimates 31% of Californians delay or decline care due to cost-concerns. The same study reports that 9% of Californians have deductibles that are $\geq 5\%$ of their annual income.²⁸ More expensive treatment plans will force Californians to delay or decline more care. Currently, untreated dental patients seeking care comprise 1% of all emergency department visits in the United States.²⁹ This number certainly will increase if dental care becomes more expensive, causing further negative effects on already understaffed and over-taxed hospital systems.

It is evident that the ability to provide out-of-hospital deep sedation/general anesthesia reduces the volume of patients treated in operating and emergency rooms. This, in turn, decreases cost, increases access to care and improves oral health of Californians.³⁰

Summary & Recommendations

Oral & Maxillofacial Surgeons provide deep sedation/general anesthesia because head and neck surgery is painful, and because there is a societal wide fear of surgery in the mouth, on the face, and in the neck. The alternatives to anesthesia are limited. Physically restraining a child is unacceptable and would cause both physical and emotional suffering. Lighter levels of sedation are inadequate for sensitive patients and painful surgeries. Lightly sedated patients often lose inhibitions and, correspondingly, their ability to tolerate the noises, pressures, and pain that accompany surgery. This typically results in a combative patient, which increases overall risk both to him/herself and to their providers. Appropriate level anesthesia is critical to the delivery of safe oral and maxillofacial surgical care.

According to the Dental Board of California’s working document, there were nine pediatric deaths during the study period of 2011-2016; only one of these was attributed to an OMS. During this period of study, it is estimated that 1,069,375 (average of 295 pediatric anesthetics (Table 3) multiplied by 725 active California OMSs times 5 years) pediatric anesthetics were administered. These data establish an office-based, mortality rate of less than 1 in a million for the OMS Anesthesia Team Model when applied to pediatric patients.

When properly performed, the OMS Anesthesia Team Model is a proven safe and effective method to provide care for patients who meet the specific risk criteria for office sedation and surgical procedures. OMS education, professional standards, and staff preparation establish an environment of safety. Multiple studies demonstrate safety of the OMS Anesthesia Model, and legal and professional systems exist to ensure individual providers are practicing within these safety standards. Current outcomes data validate the effectiveness of the current method.

Despite the proven safety record, every system can be improved. Patient safety is our paramount concern. To that end, OFSOC recommends the following enhancements to the Dental Practice Act’s section on deep sedation & general anesthesia.

1. Adopt the standards outlined in *AAOMS Parameters of Care for Anesthesia in Outpatient Facilities*

OFSOC feels strongly that no professional organization’s name should be codified into the California Dental Practice Act. However, OFSOC suggests changing the California Dental Practice Act’s section on deep sedation/general anesthesia to parallel the AAOMS Parameters of Care. These standards are the most complete and most rigorous, in all of dentistry. This change would update California law to the current standards of outpatient anesthesiology, and require all dentists who provide sedation or general anesthesia to abide by the same rigorous standards.

2. Require the presence of 2 trained assistants during moderate sedation and deep sedation/general anesthesia

OFSOC recommends the presence of two, certified assistants where one assistant is tasked solely with providing continuous, direct observation and monitoring of the patient’s status.

3. Add Capnography to the required monitoring equipment during moderate sedation and deep sedation/general anesthesia.

In dentistry, airway complications are the most common pathway to an anesthetic complication. As such, OFSOC advocates for the use of operating room level patient monitors during all moderate and deep sedation/general anesthesia procedures. The currently required monitors include an ECG, blood pressure, and pulse oximetry. OFSOC and AAOMS suggest the addition of monitoring exhaled carbon dioxide via capnography. Capnography provides immediate and constant data on an anesthetized patient's respiratory status. Monitoring exhaled carbon dioxide is the standard of care in the hospital operating room. The American Society of Anesthesiologists and American Heart Association include this level of monitoring in their parameters of care. OFSOC understands that the use of capnography is somewhat limited in patients who are not intubated. However, implementation of capnography would provide another layer of patient safety.

Respectfully submitted,

Leonard M Tyko II, DDS, MD, FACS

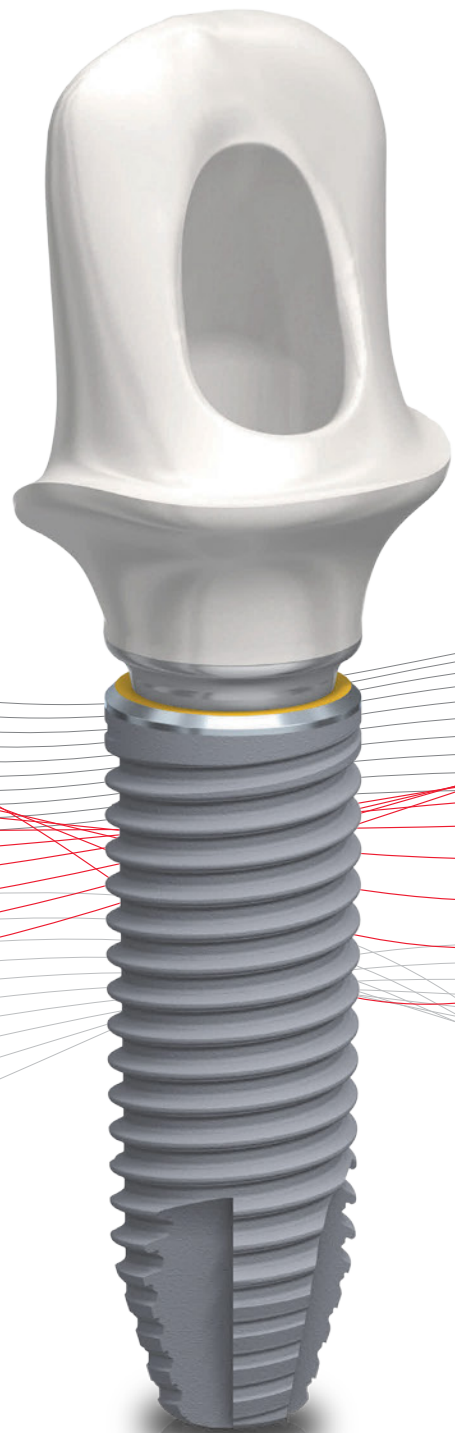
President, Oral & Facial Surgeons of California

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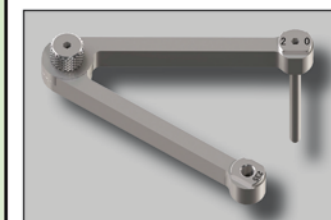
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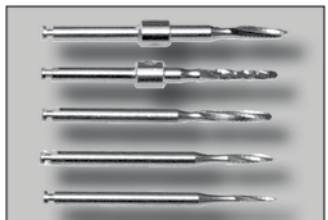
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Appendix A



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August 6, 2016

Dr. Leonard Tyko II
President
Oral and Facial Surgeons of California
950 Reserve Drive, Suite 120
Roseville, CA 95676-1351

Dear Dr. Tyko:

The following outlines the results of a review performed by OMSNIC earlier this year on its closed claim data on pediatric anesthesia related claims in California. This information is provided per the request of Ms. Pamela Congdon, Executive Director of OFSoC.

We reviewed OMSNIC's claim statistics based on the following criteria:

- Claims closed from 2005-2015
- Patient age range: 21 years or younger

A query of the Company's database of all closed claims of individuals under 21 years of age in California for the period from 2005 to 2015 was made. This query revealed a total of fifty four (54) claims involving patients age 21 or under. These claims were reviewed by experienced risk management personnel overseen by the Company's Chief Operating Officer, who herself has thirty years of insurance experience, to determine which claims were due to the administration of anesthesia. Five (5) of the fifty four claims identified were found to be related to the administration of anesthesia. Of these five, four (4) claims involved patients treated in an office setting and one (1) claim involved a patient treated in a hospital. We note that none of the claims resulted in a patient's death.

The time period reviewed covers an estimated 2,682 mature equivalent exposures (MEEs). The MEE is calculated as follows. A full-time OMS who is mature for purposes of claims-made liability coverage (i.e., practicing for five years or more) is equal to 1.00 for each year and cumulatively as 11.00 over the full period under review. Part-time or new-to-practice OMS are included at a fraction of 1.00 based on OMSNIC's claims-made factors. For example, an OMS practicing part-time would be included as .50 MEE for each year and 5.50 cumulatively. Put differently, each MEE approximates a full year of an OMS's practice.

On this basis, the incidence of closed pediatric anesthesia related claims for the period under review was 5 claims divided by 2,682 MEEs, or 0.2%. The incidence of pediatric anesthesia related death claims was Nil as there were no closed claims of this nature during the period under review.

Information regarding Mature Equivalent Exposures ("MEE") was prepared by me from proprietary Company actuarial data. I am a certified public accountant with twenty-four years of experience with OMSNIC and over thirteen years of public accounting experience. The MEE represents a more refined calculation of the risks insureds for the time period the claims were reviewed.

OMSNIC insured an average of 316 OMS in California for the time period between 2011 and 2015 based on the year-end policyholder counts for those years. The number can fluctuate during any given year but this average is a reasonable approximation.

Appendix A



Dr. Leonard Tyko II
August 6, 2016
Page 2 of 2

Finally, the findings outlined above were reviewed by the five OMS directors of OMSNIC. Each of these directors is a practicing OMS with twenty or more years in practice and related activities.

In summary, the information was accumulated by very experienced Company personnel and was overseen and reviewed by individuals at the highest levels of our organization.

We understand this information will be used for the purpose of study and potential advocacy efforts by the California Dental Board. The data outlined above is provided solely for this purpose. Also, please note OMSNIC is providing this information without any position for or against any current or pending California legislation.

Sincerely,

William C. Passolt
President and CEO

cc: Ms. Pamela Congdon, CAE, IOM – Executive Director, Oral and Facial Surgeons of California

Dental Board of California
Subcommittee on Pediatric Dental Sedation
Preliminary Recommendations for Discussion
Published October 3, 2016

Since spring 2016, the Dental Board of California (Board) has been conducting research into whether or not California's present laws, regulations, and policies are sufficient to provide protection of pediatric patients during dental sedation.

The Board released its working document July 21, 2016, and conducted outreach to stakeholders and the public, including a public workshop held on July 28, 2016 in Sacramento, an invitation to submit comments, and opportunity for comment at a full board meeting held in Sacramento on Friday August 19, 2016.

Since that time, the Board has received numerous comments on the issue of pediatric sedation and anesthesia. The subcommittee has now received sufficient input to make preliminary recommendations.

After carefully weighing the available options, the subcommittee recommends the following:

1. The board should continue to research the collection of high quality pediatric outcomes data to inform decision making.
2. Update definitions of general anesthesia, conscious sedation, pediatric and adult oral sedation for consistency with the definitions of minimal sedation, moderate sedation, deep sedation, and general anesthesia.ⁱ
3. Restructure the dental sedation and anesthesia permit system.

a. General anesthesia/deep sedation

- i. Educational requirements for a general anesthesia permit: – completion of a minimum of one year of Commission on Dental Accreditation (CODA) approved advanced residency training that provides competency in the administration of general anesthesia. (existing)
 1. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography. (done, but not required)
 2. A minimum of two staff members shall be present, with at least one trained in monitoring and resuscitation of sedated patients, who shall be dedicated solely to monitoring the patient. (done, but not required)
 3. Completion of training in adult advanced life support or an equivalent course as determined by the board, plus additional hours of anesthesia related continuing education per renewal. (existing)
 4. Permit holders treating patients under the age of 13 shall be required to complete education in pediatric advanced life support as determined by the board. **(new)**

ii. Additional requirements for a general anesthesia permit holder to treat patients under age 7: (new)

1. Completion of an appropriate number of hours of education related to pediatric anesthesia as determined by the Board.
2. Documentation of a sufficient number of cases for children under age 7 for an initial application and for each permit renewal.
3. The holder of an age restricted (no patients under age 7) general anesthesia permit, may administer general anesthesia to patients under the age of 7 under the supervision of the holder of an unrestricted general anesthesia permit.
4. Supervised cases shall be submitted to the board as documentation to allow an age restricted anesthesia permit holder to qualify for an unrestricted general anesthesia permit.

b. Moderate sedation (new)

i. Adult moderate sedation permit requirements for administration of moderate sedation by any route to patients age 13 or older.

1. Education – completion of course of instruction plus a sufficient number of clinical cases consistent with ADA Guidelinesⁱⁱ. (existing)
2. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography when feasible.ⁱⁱⁱ
3. minimum of one staff member trained in the monitoring and resuscitation of sedated patients must be present.
4. Completion of continuing education related to sedation for renewal.

ii. Pediatric moderate sedation permit requirements – for the administration of moderate sedation by any route to patients under age 13. (new - adds requirements for patients under age 13)

1. Education – completion of a course of instruction plus a sufficient number of clinical cases for pediatric patients under age 13, or completion of equivalent training (i.e. a pediatric dental residency or other advanced residency program) as determined by the board.
2. Monitoring to include P/BP/pulse oximetry/precordial stethoscope/ECG and capnography whenever feasibleⁱⁱⁱ.
3. A minimum of one staff member trained in the monitoring and resuscitation of pediatric patients must be present.
4. Continuing education related to pediatric sedation for renewal, including pediatric advanced life support training or equivalent as determined by the board.

c. Pediatric Minimal Sedation – required for oral minimal sedation of patients under age seven (7). (new section)

- i. Education – similar to current pediatric oral conscious sedation permit requirements- (instruction in pediatric sedation plus one clinical case; training in airway management and patient rescue from moderate sedation.)
 - ii. Administration limited to a single dose of a single sedative drug, plus nitrous oxide and oxygen that is unlikely to produce a state of unintended moderate sedation.
 - iii. A single additional dose of the initial drug may be necessary for prolonged procedures. The additional dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed.
 - iv. Monitoring to include BP/P/pulse oximetry/precordial stethoscope (existing)
 - v. A minimum of one staff member trained in the monitoring and resuscitation of pediatric patients must be present. (existing)
 - vi. Continuing education related to pediatric sedation per renewal period, plus basic life support training. (existing)
4. Update requirements for records and equipment to include the following:
 - a. Age and size appropriate equipment must be available for all patients.
 - b. Body mass index (BMI) should be recorded as part of the preoperative evaluation.
 - c. Documentation that pre operative instructions, including fasting instructions appropriate for the planned level of sedation, have been given to the patient, escort, parent, or guardian.
 5. Collect data that will allow the future study and reporting of dental sedation and anesthesia outcomes.
 - a. 680 (z) reports should include detailed information in a format suitable for an electronic database.
 - b. Require sedation and anesthesia permit holders to report, at time of permit renewal, their annual number of administrations of minimal, moderate, and deep sedation/general anesthesia, and other parameters to be determined.
 6. Improve the Dental Board's onsite inspection and evaluation program.
 - a. Use a single evaluator (rather than current two) under specified circumstances for routine renewal evaluations.
 - b. Seek authority to require completion of specific remedial education prior to reissuance of a permit following an evaluation failure.

The subcommittee recognizes that few topics generate more controversy than the use of anesthesia, especially in children, and that no proposal will satisfy all interested parties. Although patient safety is always the foremost concern, the effects of regulatory change on healthcare can be fraught with unintended consequences. Any proposal should, therefore, strike a balance between established practice and evidence based changes that have a reasonable chance of improving outcomes.

The Board will be discussing these preliminary subcommittee recommendations at the October 13, 2016 meeting being held in Sacramento. All persons are encouraged to comment in person and/or in writing. Written comments should be directed to the Board at 2005 Evergreen Street, Suite 1550, Sacramento, CA 95815 or via email Karen.Fischer@dca.ca.gov and should be received before close of business on October 28, 2016 in order to be considered in the final report.

i Definitions for levels of sedation and anesthesia:

- a. **Minimal Sedation:** a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, breathing and cardiovascular functions are unaffected.
- b. **Moderate Sedation:** a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- c. **Deep Sedation:** a drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully after repeated verbal or painful stimulation. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may readily pass from a state of deep sedation to the state of general anesthesia.
- d. **General Anesthesia:** a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilation is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required. Cardiovascular function may be impaired.

ii American Dental Association. (2012). Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. In ADA (Ed.), (pp. 1–18). Chicago. Retrieved from http://www.ada.org/en/~media/ADA/Member_Center/Files/anxiety_guidelines

iii Continual monitoring of ECG and for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. When not used, it should be so stated (including the reasons) in a note in the patient's medical record.



AAOMS White Paper on Prescription Drug Abuse and Prevention.

As many of you know and are witnessing, federal and state agencies, insurance companies, third parties, and the media have focused their attention on the growing diversion, misuse, and abuse of opioid pain medications, particularly by younger patients. Oral and maxillofacial surgeons, by virtue of the fact that we are primary prescribers of opioids to post-surgical patients, have found ourselves in the eye of this particular storm. From the beginning, AAOMS has worked closely with the FDA, DEA, and CDC, as well as the media and other healthcare organizations to identify solutions that will help stem the abuse while protecting the well-being of post-surgery patients who need effective and appropriate pain management therapy in order to heal. CALAOMS is grateful to the AAOMS Committee on Governmental Affairs (CGA) for their assistance in this area. The CGA's revised Advocacy White Paper on Prescription Drug Abuse and Prevention offers sensible, effective guidelines that support provider education, encourage the development of realistic prescribing guidelines and protect the role of the practitioner as the most appropriate and knowledgeable decision-maker when it comes to prescribing pain medication. This is an important issue for our specialty, and I encourage you to use this white paper as a resource in communications with your legislative representatives, regulatory boards, patients, and others.

Prescription Drug Abuse and Prevention - White Paper reprinted here, with permission by and courtesy of AAOMS

Prescription Drug Abuse and Prevention

America is in the midst of a prescription opioid epidemic. It is estimated that 6.5 million Americans and 2.5% of the population age 12 years and older are current nonmedical users of psychotherapeutic drugs. Of these, 4.3 million, or 66.2%, reported the use of pain relievers for nonmedical purposes.¹

As oral and maxillofacial surgeons (OMSs) and lawful prescription drug prescribers, we know that when used as prescribed, prescription opiates enable individuals with acute and chronic pain to lead productive lives and recover more comfortably from invasive procedures. We also recognize, however, that acute pain medication prescribed following oral and maxillofacial surgery is frequently the first exposure many American adolescents have to opioid prescriptions, and that roughly 12% of all immediate release opioid prescriptions in the US are related to dental procedures.² Dentists, including OMSs who primarily manage acute pain, have a responsibility to ensure we do not exacerbate a growing public health risk while ensuring our patients receive the relief they need following complex dental procedures.

Over the past decade, a number of approaches have been proposed to address this issue. The AAOMS provides the following positions in response to several of these proposals.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs), if properly funded, implemented and updated by dispensers, are valuable tools for detecting a practice known as "doctor-shopping" and preventing the diversion of prescription opioids. AAOMS believes that federal and state efforts to develop these programs should be supported and properly funded. AAOMS further believes that in order to prove useful in preventing abuse and diversion, dispensers should enter data into a PDMP in real time. In addition, if the prescription is for a period of less than 7-days, it should not be mandatory to check a PDMP for acute pain patients who receive an opioid following an invasive surgical procedure, as the risk of abuse and diversion is low in these instances. Furthermore, because checking the PDMP is an administrative task, the AAOMS believes that approved auxiliary personnel should be authorized to access the system on the doctor's behalf.



American Association of Oral and Maxillofacial Surgeons

White Paper

Continuing Education

The training received during their residencies implicitly qualifies OMSs to manage their patients' pain and in particular acute pain following invasive procedures. Nevertheless, AAOMS encourages our members to be aware of public health trends that may impact patient care and supports voluntary provider participation in continuing education (CE) programs that focus on drug abuse and responsible prescribing practice. AAOMS is working with the National Institute on Drug Abuse (NIDA) to develop an education course to help prescribers, including oral and maxillofacial surgeons, talk to adolescents about substance use and abuse. We also helped develop and encouraged our members to participate in the Substance Abuse and Mental Health Services Administration's (SAMHSA) online training on "Safe Opioid Prescribing for Acute Dental Pain." Prescribing, while important, is but a small part of the overall care that is provided to each patient. A significant increase in CE requirements in this one topic would be overly burdensome and could possibly prevent a practitioner from obtaining needed CE in other critical areas of patient care. AAOMS believes that to be most effective, CE should be managed at the state level and be customized so that it is relevant to each type of prescribing situation. AAOMS further believes that provider specialty organizations, such as the AAOMS, should be included as accepted practitioner training organizations for CE requirements. Finally, there remains a need beyond prescriber CE to educate patients and the public at large about opioid abuse and diversion. AAOMS supports such collaborative education efforts that include governmental agencies, non-profit organizations and prescriber organizations.

Prescribing Guidelines

The AAOMS appreciates the development of prescribing guidelines, which may be helpful to some practitioners as they determine the proper course of post-operative treatment for their patients. AAOMS recognizes and encourages our members who provide chronic pain management to consider the CDC Guideline for Prescribing Opioids for Chronic Pain.³ AAOMS also supports efforts currently underway by several OMS residency training programs to develop and utilize acute prescribing guidelines. If government entities seek to develop prescribing guidelines, we encourage them to recognize the unique care provided by OMSs by involving them in the development process, and to avoid a

one-size-fits-all approach as patient pain management needs vary from patient to patient. AAOMS encourages provider and/or patient discretion by allowing them to partially fill a prescription with the option to acquire the remaining amount only when necessary. Implementation of such a practice will not only reduce the risk of a patient's over-dose or addiction, but also significantly lessen the risk of diversion of unused medications. AAOMS also supports additional pain management strategies, such as the use of long-acting local anesthetics during surgery of the dentoalveolar complex and nonsteroidal anti-inflammatory drugs (NSAIDs) either preoperatively and/or postoperatively for acute pain control in conjunction with the judicious use of opioids or as a substitute.

Supporting Practitioner Judgement

Only the treating practitioner, not subjective policy, can determine a patient's medical needs. It is the position of the AAOMS that the patient-practitioner relationship must be upheld, allowing the practitioner to have the final say regarding the management of a patient's pain including drug types, dosage and treatment duration. Practitioners should be informed of the latest public health trends, including possible alternatives to opioid pain treatment; but in the end, practitioners should be trusted to treat their patients according to their best professional judgement. As with any issue, should a practitioner be shown to be practicing contrary to the standard of care, the practitioner should be referred first for peer review, followed by prescription writing counseling/continuing education and then, if necessary, punitive remediation.

References:

- 1 Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration. September 2015.
- 2 JADA. July 2011; 142(7): 800-810.
- 3 CDC Guideline for Prescription Opioids for Chronic Pain. Recommendations and Reports. 65(1); 1-49. March 2016. June 2016, AAOMS Committee on Government Affairs

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LEGISLATIVE UPDATE



by Gary Cooper
Legislative Advocate, CALAOMS

Fall 2016 Update

The 2016 legislative year proved to be very active for the California Association of Oral and Maxillofacial Surgeons (CALAOMS). While our activities in 2015 centered on our own sponsored bill (AB 880), 2016 found us engaged in a protracted legislative debate on the safety of the oral and maxillofacial surgeon (OMS) team model that allows OMSs to perform indicated surgical procedures while providing the much necessary anesthesia. Assembly Bill 2235 by Assemblymember Thurmond was the genesis of the lengthy legislative discussion that will continue into 2017.

AB 2235 (Thurmond) was introduced by Assemblymember Thurmond in response to the tragic death of a six-year old in the office of an OMS. Sadly, because the young boy died under anesthesia, his family mem-

bers mounted a legislative/social media campaign to prohibit oral and maxillofacial surgeons from performing surgical procedures and administering the anesthesia on the same patient. Initially, the bill required the “dental” provider to inform the patient in writing that if ‘one provider was doing the procedure and administering the anesthesia there was a greater likelihood of death.’ We obviously disagreed heavily with that. CALAOMS was successful in having that unproven inflammatory section removed from the bill. Subsequently, language was added to the bill that mandated that the Dental Board of California (DBC) establish a statutory committee to determine best pediatric dental anesthesia practices in California. Unfortunately,

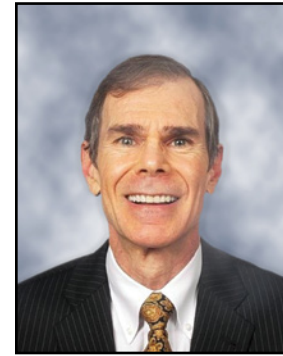
the composition of that committee would have included health care practitioners who have previously publicly

Because this issue still remains unresolved in the minds of many of those participants in the debate, CALAOMS remains highly engaged with all of the stakeholders, including the legislature and the Governor’s office.

stated that the OMS team model (‘operator/anesthetist’) is *unsafe*. CALAOMS was successful in eliminating that section, as well. Ultimately, the bill that was passed and sent to Governor Brown requires the DBC to complete a study of the current pediatric dental anesthesia statutes in California—and nationally—and requires a study of any adverse actions related to anesthesia. This language mirrored an official request of the DBC that was submitted by the Chair of the Senate Business and Professions Committee. As of this writing, Governor Brown signed AB 2235 and the DBC has completed its study and is in the process of preparing final recommendations for the legislature (*initial recommendations by the DBC are included in this issue of The Journal*). Most likely, there will be several pieces of legislation introduced in the 2017-18 legislative session that resumes in January 2017. Because this issue still remains unresolved in the minds of many of those participants in the debate, CALAOMS remains highly engaged with all of the stakeholders, including the legislature and the Governor’s office. I suggest that all CALAOMS members continue to make themselves aware of all the activities and discussions surrounding this important issue relating to your practice.



MEANING IN ETHICS



by Richard Boudreau, MA, MBA, DDS, MD, JD, PHD

Clinical Judgment & Phenomenology

Phenomenology focuses on the essence of lived experience and the meaning of a particular aspect of experience. Contextually speaking, phenomenology is a useful tool for clinical decisions that can be specifically applied to the first person experience of illness in order to illuminate this experience and enable health care providers to enhance their understanding of it. This approach, described by phenomenologist Maurice Merleau-Ponty, distinguishes between the biological body and the body as lived, and considers notions of motor intentionality and ‘intentional arc’ used to capture the experience of illness. Clinical application includes providing physicians with a concrete understanding of the impact of illness on the lives of their patients.

Let us view, in brief, the interpretive nature of clinical judgment by focusing on the experience of illness and the physician-patient relationship. The task at hand consists of describing the phenomenon of medical judgment, so as to grasp the meaning of experience that leads the physician through a process of argumentation and reasoning to a particular therapeutic action on behalf of the patient. The thrust of my analysis takes the description of experience as the first step in the approach. The presumption underlying this approach is that phenomena speak to us only if we allow them to fully appear for what they are. Phenomenologists underscore the *a priori* nature of the experience so that everything and anything that is given rests on experience.

According to philosopher Max Scheler “He who wishes to call this empiricism may do so. The philosophy of phenomenology as its foundation is empiricism in that sense. It is based

on facts and not on construction of an arbitrary understanding. All judgments must conform to facts, and methods are purposeful only insofar as they lead to propositions conforming to facts.” The goal of phenomenological description is not to provide just a copy of things, but to uncover those fundamental structures that make things what they are. Hence, the act of phenomenological description is an ‘intellectual insight’ that transcends the realm of empirically verifiable factuality.

Within broader context, each moment relates to the next; each moment necessarily moves in a crescendo that culminates in the medical decision. This represents the focal point and situation of maximal ontic density to which the points of clinical action converge. The broader characteristic of clinical phenomenon under consideration is its intrinsic teleology; that is, all the elements of medical judgment acquire meaning in light of the final point, or telos, toward which they move.

Metaphysical problems historically raised against teleology impose a more nuanced reflection. In particular, the teleology underlying clinical action cannot be described as an ideal trajectory of unrelated points whose connection is being projected on the action itself by an act of synthetic apperception. Such a connection would not define the action into ontological consistency, but only a function of the observer’s mind. In Kantian terms, it would be only a transcendental condition on the side of the subject.

On the other hand, the presumption of phenomenological description is one of ontic realism. Something is seen as the objective correlate of intentional relation (intentionality), even if no conclusions are immediately drawn on the ontological nature of such intentional correlate. Yet, the process-like nature of clinical judgment is the reality of an action understood in relation to a situation of illness. If so, the clinical decision represents the closure of a process in which all the elements entailed by it are taken into account and synthesized around the final question, “What should be done for this particular patient?”

Suffice it to say that the reference to a decision that functions as the fulfillment of the clinical process is important: it clears the ground for understanding clinical rationality as a practical rationality, one in which the explanatory model implied by the scientific understanding of disease is not suspended or superseded, but rather integrated as a dimension, however essential and important, of the larger praxis of medicine.



OMS OFFICE & COSMETICS



Therapeutic Botox vs. Cosmetic Botox and the California Law

by Michael Morrissette, DDS

Wouldn't it be a nice benefit to your surgical staff to inject them with some neurotoxin after a full, hard day of work? A way to say more than just "thank you" for making your day run so smoothly and successful? What does the California Dental Practice Act allow concerning the use of neurotoxins (Botox, Dysport, and Xeomin)?

In 2011, in reference to the use of neurotoxins, the legal counsel for the Dental Board of California (DBC) stated that "if it's not for the 'diagnosis or treatment by surgery or other method, of diseases or lesions of the human teeth, alveolar process, gums, jaws, or associated structures...then it cannot be done.'"¹

What about the injection of patients with symptoms of TMD or facial pain? The injection of 45 units of neurotoxin to each masseter muscle to alleviate the symptoms associated with TMD, in other words, therapeutic neurotoxins injections, appears to fall within the scope and intent of the statute as it pertains to the Dental Practice Act. What if a dentist takes that same Botox injection needle and injects the lateral orbicularis muscle or "crow's feet" with 6 units to each side for purely cosmetic purposes? According to the Dental Practice Act, this would be a violation of the statute and therefore is NOT allowed in the state of California. It is that simple.

The Dental Practice Act does allow dentists with an Elective Facial Cosmetic Surgery permit to inject patients and their staff members with neurotoxins for strictly cosmetic purposes.

This permit, as you are aware, is limited to oral and maxillofacial surgeons (OMSs) who have completed an accredited residency in oral and maxillofacial surgery. Therefore, dentists, other than OMSs, are not permitted to inject patients with neurotoxins for strictly cosmetic purposes, and those OMSs must have the cosmetic permit.

How did we get to this point where in our state nurses, licensed nurse practitioners, and physician assistants can all inject cosmetic neurotoxins? Nurses require a physician to be present, but licensed nurse practitioners can inject patients without the presence of a physician. Do these practitioners, as part of their basic education, ever perform a complete dissection of the human face or skull? Which practitioners have been required through education to perform such intense training of facial anatomy, and which practitioners inject the face daily and should have the greatest knowledge of the nerves of the face? The answer becomes very evident. When public safety is concerned, I believe that the training, knowledge, and experience should determine policies concerning the scope of practice with public safety being the primary concern. Like medicine, dentistry is an evolving and changing profession and it is important to know that the DBC has been studying this issue.

Why would you want to add cosmetic Botox or dermal fillers to your practice of oral and maxillofacial surgery? In my area of California, I have found that more and more general dentists are performing their own implant surgeries. In my 25 years of experience, the number of dentists performing implant surgery has increased dramatically. Remember the days when you were reimbursed for what you billed to extract 3rd molars? Now, in many cases, reimbursement is 50% of what is billed. I don't think a discussion of reimbursement for orthognathic surgery or trauma is necessary by the number of surgeons no longer offering these services. The expansion of services that are well within the scope and training of an OMS is what makes our specialty so unique!

So how can you, as an OMS add simple cosmetic procedures to your practice? Yes, you must acquire an Elective Facial Cosmetic Surgery permit. Do you need to perform all types of cosmetic surgery to obtain a permit? Absolutely not! That is one of the unique features of the permitting process. If all that you want to do is perform Botox treatment, or Botox and dermal fillers, then apply for a limited cosmetic surgery permit for just those procedures. What about training and proctoring and getting cases to present to the committee? There are several of our members who are current permit holders who would be happy to assist you with this process. In some cases, since we are surgeons and all so well versed with facial injections, safely being proctored for injections and obtaining a few cases is a simple process. In fact, I would be willing to



guess that most of your staff members and a few relatives would be willing volunteers!

Lastly, what about office accreditation? Unfortunately, when we fought so hard in 2006 to pass California Senate bill SB 438 we could not anticipate the ensuing massive explosion of non-surgical cosmetic treatments like Botox, dermal fillers, Ultherapy, Pelleve, simple chemical peels, and non-ablative lasers for the face. These procedures, though non-surgical, fall under the same facility requirements as all cosmetic procedures. Though you may perform a therapeutic injection of neurotoxin to treat a patient suffering from TMD in your current office, in order to perform the same injection procedure for cosmetic purposes your office MUST be accredited.

If anyone is interested in obtaining further information about the Elective Cosmetic Facial Surgery permit process or facility accreditation, I recommend contacting one of the permit holders listed on the DBC website. You will quickly notice that there are many surgeons who are limited elective cosmetic facial surgery permit holders.

References

1. Meeting minutes, Dental Board of California meeting, November 8, 2011.

IN REMEMBRANCE

John T. Forte, DDS

Dr. John T. Forte, DDS, passed away on August 15, 2016 at age 84 from injuries following a bicycle accident.

Following his graduation from Temple University Dental School, he entered the U.S. Navy under the Dental Intern Scholarship program, where he spent three years on active duty. He completed his Oral and Maxillofacial surgery training at the University of Pennsylvania in 1963.

Dr. Forte was in practice for over 40 years in Huntington Beach. He spent his retirement years in Prescott, Arizona, with his wife Sharon. They were both very active and enjoyed many hobbies together; including hiking, biking, and photography.

Dr. Forte held memberships in many professional organizations including the American Association of Oral & Maxillofacial Surgeons, and the California Association of Oral and Maxillofacial Surgery. He was a diplomate of the American Board of Oral & Maxillofacial Surgeons.

Dr. Forte is survived by his wife Sharon, his son Jonathan, daughters-in law Audrey Forte and Jenna Hosier; daughter Susan and daughter and son-in law Kasey and Bret Russell; his seven beloved grandchildren, Jared and Jacob Forte, Chloe and Brock Hosier, Madyson, Brooke, and Maveric Russell.

John was dearly loved by his family, friends and respected by his many patients and colleagues. He will be sorely missed.

by Sam J. Poidmore, DDS



RISK MANAGEMENT

Top 3 Patient Safety Tips: Reducing Technology Risks

by Carol Murray, RHIA, CPHRM, CPPS,
Patient Safety Risk Manager, The Doctors Company

The adoption of electronic tools in the patient care setting has grown exponentially in recent years. Although new technologies bring many benefits, they also bring new liability risks—and 2015 could be considered a high-water mark for both new risks and increased prevalence of previously identified risks. The top three patient safety tips of 2015 addressed these risks.

1. Telemedicine: Comply with HIPAA, HITECH, and state-specific laws when transmitting patient health information and follow state licensing requirements.

While the benefits of telemedicine are vast, its use and adoption must be tempered with caution. Physicians must be aware of the risks associated with access, such as patient and staff privacy, inaccuracies in self-reporting, and symptoms that may only be caught in person. Additional legal considerations for online interactions, such as licensure compliance and professional liability coverage for out-of-state interactions, must be addressed for the protection of the physician and the patient. According to the Federation of State Medical Boards, only 12 states have provided special-purpose licenses to allow for cross-border telemedicine, while most states require complete licensing if the patient is in their jurisdiction.

To reduce these liability risks and enhance patient safety:

- Comply with all laws when transmitting all personal health information. Train staff on how to protect and secure your data.
- Clearly define proper protocols for webcams and web-based portals.
- Use mechanisms to protect the privacy of individuals who do not want to be seen on camera (including staff members, other patients, or patients' families).

- Ensure robust and reliable high-speed broadband connectivity to support clinical functions.
- Check practice requirements and legal limitations in states where you anticipate providing care to patients.
- Understand reimbursement practices for telemedicine services.
- Make certain that your professional liability policy extends coverage to all jurisdictions where you provide services.

2. Medical equipment alarms: Enact policies to ensure alarms are never silenced.

Concerns about the adequacy and effectiveness of medical equipment alarms have been a focus for The Joint Commission's National Patient Safety Goals. Issues with alarms have also appeared frequently in analyses of unanticipated outcomes. A main patient safety risk is alarm fatigue, where too-frequent alarms cause providers to override or disable them.

When alarms are silenced or eliminated, a significant change in a patient's condition may go undetected. If there is a resultant harm to a patient, it is extremely difficult to mount an effective defense.

The Joint Commission emphasizes policies that can help reduce the risks:

- Policies should be in place and communicated to staff to never silence an alarm and should discourage the use of patient-owned medical equipment without alarms in clinical settings.
- Any medical device equipped with an alarm should be evaluated annually for preventive maintenance.

3. Electronic health records (EHRs): Ensure that implementation includes thorough staff and provider training.

More than 80 percent of doctors have adopted an EHR.¹ There is a lag time between adopting a new technology and identifying risks, but in 2015, EHR issues were increasingly apparent.

Weaknesses include inaccurate entries that are repeated throughout the record; faulty interfaces between companion



systems; greater potential for breaches, resulting in loss of patient privacy; over-reliance on the system by staff, leaving less time to spend with patients; changes in medical record information due to system updates; and difficulty in standardizing the legal medical record for consistency in response to requests for records.

Audit trails requested during litigation may not accurately reflect the activity or may be undecipherable. Some systems allow changes in record entries long after a patient is seen—if that is discovered, this could be interpreted as spoliation of evidence.

To reduce exposure to EHR risks:

- Ensure implementation includes thorough staff and provider training.
- Establish guiding policies and procedures, especially a policy defining the legal medical record, and designate an ongoing workgroup or individual to address problems in either support systems or the software itself.
- Maintain an ongoing relationship with the vendor to communicate software issues and to thoroughly understand the impact of each software update.
- Conduct a periodic review of metadata reports that identify name, date, and time of access—a useful way to monitor inappropriate access to the record by staff.
- Train staff to be observant and report any inconsistencies, including a near-miss or incident.
- Conduct medical record audits at least quarterly to look for any possible problems.

Increasing attention is also directed at the integrity (accuracy) of data entries in the EHR. Weaknesses in data integrity can and have resulted in erroneous treatment or delays in the discovery of new and vital information. More and more related systems have an interface with the EHR, such as laboratory or imaging information, other healthcare encounters, medication history, and even basic demographic information. It is not uncommon for data in the EHR to be inaccurate or missing. Problems such as errors in entering treatment regimens can have far-reaching outcomes. While there is a strong emphasis on interoperability of systems, there are also many problems in perfecting the interface.

As the assimilation of medical technology increases at a faster rate, all providers and organizations must closely scrutinize these systems to discover issues and problems before they reach the patient. Training staff and physicians and ensuring solid communication models are the most valuable ways to reduce patient safety risks.

Reference

¹More than 80 percent of docs use EHRs. *Healthcare IT News*. September 18, 2015. <http://www.healthcareitnews.com/news/more-80-percent-docs-use-ehrs>. Accessed November 23, 2015.



Contributed by The Doctors Company. For more patient safety articles and practice tips, visit www.thedoctors.com/patientsafety.

CALIFORNIA ASSOCIATION OF ORAL & MAXILLOFACIAL SURGEONS UPCOMING CE EVENTS

2017 Meetings

- **January Anesthesia Meeting** - The Claremont, Berkeley January 14 – 15
- **ACLS** - TBD March – TBD
- **OMSA Spring** - Irvine Marriott April 8 – 9
- **17th Annual Meeting** - Grand California Disney, Anaheim May 6 – 7
- **ACLS** - TBD October – TBD
- **OMSA Fall** - (Northern California) October – TBD
- **Medical Emergencies** - (Northern California) November 8



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INLAND EMPIRE: Immediate full-time oral maxillofacial surgeon wanted in Southern California's Inland Empire. We promote a workplace with a supportive and efficient staff, individual growth and personal achievement. The right individual should demonstrate creativity, interpersonal skill and have a team player attitude. We emphasize dentoalveolar surgery, dental implants and pathology but also practice orthognathic, TMJ and trauma surgery. Compensation includes competitive salary, incentive bonus system, health insurance stipend and relocation advancement. Interested applicants should call (909) 331-0227 or email MDudzziak@inlandempireomfs.com.

LOS ANGELES: Opportunity for full-time associate / future partner to join highly productive modern Los Angeles area OMS practice. Desired candidate is board certified/ eligible with motivation and interpersonal skills to complement surgical abilities. Interested parties please contact Scott Price of Brady Price & Associates @ 925-935-0890 or email CV to scott@bradyprice.net. All inquires strictly confidential.

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TUSTIN: We offer an excellent opportunity for a board certified/eligible surgeon to join our well-established, well-respected, full scope modern Oral and Maxillofacial surgical practice. We are seeking a full time, energetic and motivated surgeon, who is personable and caring with excellent communication and interpersonal skills, who wants to practice a full-scope of oral and maxillofacial surgery. Our practice, established over 20 years ago, has a very wide referral base and is considered a cornerstone in the dental community. For more information about our office, please visit our website at drjeffreyleemddmd.com. If you would like to be part of an elite OMS practice, please contact Beth Bushling @ hr@drlecoms.com.

PRACTICES FOR SALE

SF BAY AREA: East San Francisco Bay Area OMS practice available for sale with transition. Collections average >\$900K/yr. on 3.5 days of services per week of services. +/- 2,300 sq.ft. office contains 2 Exam, 2 Ops and digital radiography. Interested parties please contact Scott Price of Brady Price & Associates @ 925-935-0890 or email scott@bradyprice.net.

WOULD LIKE TO BUY

SOUTHERN CALIFORNIA: I am currently out-of-state and would like to relocate to California. I am looking for an OMS practice for purchase with transition. Southern California preferred (Greater Los Angeles, Inland Empire or Greater San Diego) / mid-size city or suburban community. 1,500-2,000 sq. ft. 2-3 operatories. Please email me @ surgeryoms@gmail.com

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ORAL SURGERY DENTAL CONSULTANT/PART-TIME: Delta Dental of California seeks California licensed oral surgeon to evaluate claims for the Denti-Cal program based in Sacramento. Excellent benefits included. Call Dr. Barry Dugger at (916) 861-2519.

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Photo: Sanford L. Ratner, DDS and Monty C. Wilson, DDS, oral and maxillofacial surgeons at Ratner & Wilson DDS, Orange and Santa Ana, California

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