## BEFORE THE NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS

In The Matter of:

ANDREW W. KELLY, D.D.S.

(License No. 7350)

) FINAL ORDER DENYING SUMMARY

SUSPENSION OF MODERATE

SEDATION PERMIT

Andrew W. Kelly, D.D.S. ("Dr. Kelly") is the Respondent in a formal contested case hearing commenced by the filing of a Notice of Hearing ("NOH"), dated October 28, 2014. An amended NOH was filed on April 1, 2015. The amended notice alleges that Dr. Kelly engaged in negligence in the practice of dentistry relating to the treatment he provided to three patients ("PM," "BM" and "RD"). The amended NOH further alleges that these acts of negligence constitute violations of a 2011 Consent Order that should result in the activation of the one-year suspension of Dr. Kelly's dental license that was stayed in the 2011 Consent Order. A hearing on the merits of this contested case is set for August 7, 2015.

During the course of this contested case proceeding, the Investigative Panel ("IP") of the Board became aware of circumstances that led it to believe that summary suspension of Dr. Kelly's moderate sedation permit may be necessary. The Board has the authority, pursuant to G.S. 150B-3 (c), to summarily suspend an occupational license or permit if it finds that the public health, safety or welfare requires the Board to take emergency action. On March 26, 2015, the Board issued a notice of hearing to determine whether the Board should summarily suspend Dr. Kelly's moderate conscious sedation permit pending the hearing on the merits of his contested case. The summary suspension hearing was held on April 10, 2015, and an interim Order was entered on April 14, 2015.

In its April 14, 2015 Order, the Board found that the IP had introduced ample evidence to make a <u>prima facie</u> showing, which Dr. Kelly failed to rebut or refute, that he may not be practicing safe sedation dentistry and consequently that the Board was required to take immediate action to protect the public. The Board concluded it should briefly suspend Dr. Kelly's moderate sedation permit until a more definitive determination could be made and to give Dr. Kelly ample opportunity to show that no emergency existed because he currently is practicing safe sedation dentistry. In making this determination the Board balanced the need to protect the public health,

safety and welfare and the need to treat Dr. Kelly fairly. Dr. Kelly's license to practice general dentistry without sedation of his patients was not affected by the brief suspension of his moderate sedation permit.

The April 14, 2015 Order included four provisions. First, Dr. Kelly's moderate sedation permit was suspended until the Board's next scheduled meeting on May 13, 2015. Second, Dr. Kelly was required to submit to inspection of pertinent patient records and of his office by a qualified sedation inspector appointed by the Board. Third, the Board would resume the hearing on May 13, 2015, to make a final determination whether to continue the summary suspension until the August 2015 hearing on the merits. Fourth, the IP was directed to have an evaluation of the information obtained pursuant to the order made by an independent evaluator who had not yet participated in review of the matters at issue in this contested case.

On April 20, 2015, a judge entered an <u>ex parte</u> order temporarily staying the Board's summary suspension order, and on April 30, 2015, Superior Court Judge L. Todd Burke stayed enforcement of the Board's summary suspension until the Board made its final determination following the Board's May 13, 2015 meeting.

On May 13, 2015, the Board resumed the summary suspension hearing. The IP introduced the affidavit [IP Exhibit 4] of Dillon Atwood, D.D.S., the independent evaluator who reviewed a representative sample of Dr. Kelly's sedation dentistry patients treated during the past year and who inspected Dr. Kelly's office on May 12, 2015. Based on his background and experience, the Board finds Dr. Atwood to be a highly credible expert witness in sedation dentistry. His professional knowledge and skill are well known to the Board, and he currently is a member of the Board's Sedation Review Committee. [IP Exhibit 8, Dr. Atwood's curriculum vitae].

Included as attachments to Dr. Atwood's affidavit were: (a) a summary of his findings [IP Exhibit 4 (A), 2 pages]; (b) summaries of his evaluation of treatment records of twenty (20) of Dr. Kelly's patients [IP Exhibit 4 (B), 27 pages]; and (c) a completed on-site evaluation form of Dr. Kelly's office. [IP Exhibit 4 (C), 7 pages]. The Board found Dr. Atwood's summary and evaluations to be detailed, through and credible.

In the summary of his findings, Dr. Atwood identified numerous "deficiencies that have created and could continue to create dangerous scenarios for patients if not corrected." [IP Exhibit 4 (A), Dr. Atwood's summary of findings, pages 1-2]. Dr. Atwood set forth the details substantiating these findings in his evaluation of each of the individual 20

patient records he examined. [IP Exhibit 4 (B), pages 1-27]. Of particular significance to the Board was Dr. Kelly's use of an anesthetic drug, Propofol, in sedating at least six (6) of his patients within the past year. For example, in his evaluation of patient #1 (treated on May 5, 2014), Dr. Atwood stated in his report that:

"[t]he greatest error in this doctor's management was with the decision to use Propofol. Propofol is a general anesthetic designed to render unconsciousness and a level of surgical anesthesia. It also causes cessation of breathing. It reads on the box, 'Propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical procedure.' The doctor [Dr. Kelly] is not trained in general anesthesia and is directly involved in the surgical procedure. The State Board also prohibits its use by doctors with moderate sedation permits. According to Board rules, medications used by doctors with moderate sedation permits should have a wide enough margin of error to make unintended loss of consciousness unlikely. Propofol is designed for loss of consciousness, so unintended loss of consciousness during a moderate sedation is very likely. It is even more likely with an obese patient such as this. The drug causes profound respiratory depression and soft tissue relaxation . . . both of which would be amplified in an obese patient."

[IP Exhibit 4 (B), Dr. Atwood's Evaluation of Patient 1, page 2].

Dr. Atwood reiterated this concern in his evaluations of Patients 6 (treated on June 24, 2014), 13 (treated on October 2 and 16, 2014 and December 10, 2014), 15 (treated on October 7, 2014), 18 (treated on January 6, 2015) and 20 (treated January 20, 2015 and February 10, 2015). The seriousness of this deficiency is so great that Dr. Kelly voluntarily agreed "that he will not administer Diprivan (also known as Propofol) with any patient until after a final agency decision is issued in this matter following the completion of the contested case hearing, which is scheduled for August 2015." (Stipulation, copy attached, signed by Dr. Kelly and dated May 20, 2015).

Among the other serious concerns that Dr. Atwood identified in his review of the patient records were concerns related to poor management of sedated patients' blood pressure and oxygen saturation levels. [IP Exhibit 4 (B)]. In his on-site evaluation report, Dr. Atwood also found that Dr. Kelly had insufficient knowledge needed to manage clinical emergencies of broncho-

spasms, allergic reactions, bradycardia and cardiac arrest. [IP Exhibit 4 (C)].

During the May 13, 2015 hearing, Dr. Kelly introduced three exhibits: (1) the affidavit of Bertrand Bonnick, D.D.S. (Dr. Kelly Exhibit G); (2) the affidavit of Candice Hebra, a dental assistant formerly employed by Dr. Kelly (Dr. Kelly Exhibit H); and (3) an audit report, dated March 2015, prepared by State Auditor Beth A. Wood relating to the Dental Board's oversight of sedation dentistry in North Carolina. (Dr. Kelly Exhibit I).

In his affidavit, Dr. Bonnick reviews Dr. Sullivan's affidavit (IP Exhibit 1) and challenges some of Dr. Sullivan's conclusions. Dr. Bonnick's expertise in sedation dentistry also is well known to the Board, and he too currently serves as a member of the Board's Sedation Review Committee. However, the Board finds that in this case, Dr. Bonnick is less credible because he has not done an evaluation of the same scope, breadth and detail as either Dr. Atwood or Dr. Sullivan. In addition, there are some inconsistencies between statements in Dr. Bonnick's affidavit and Dr. Kelly's patient records which make his conclusions less credible. (See, Dr. Sullivan's follow-up affidavit, IP Exhibit 7).

Candice Hebra was Dr. Kelly's employee from November 2010 until June 2014. In her affidavit she describes her recollections of BM's physical condition when BM was discharged from Dr. Kelly's office following her treatment on April 20, 2012. Ms. Hebra states that BM appeared to meet the criteria for discharge and did not appear to be incoherent when she helped BM and her granddaughter to her car following her treatment.

The State Auditor's report encourages the Board to be more proactive in its oversight of dentists who practice sedation dentistry. The Report states that "State dental board inspections must ensure that dentists have the proper skills, equipment, drugs, support personnel, and procedures to safely perform dental sedation because the potential consequences from improperly administered dental sedation can be significant and tragic." (Dr. Kelly Exhibit I, Auditor's Report, page 3). The Report then goes on to say that "[a]lthough rare, deaths have occurred from the use of dental sedation," citing the recent deaths of two patients in North Carolina and deaths in Hawaii and Illinois. (Dr. Kelly's Exhibit I, Auditor's report, pages 3-4).

At the end of the May 13, 2015 hearing, the Board allowed both parties seven (7) days to supplement the record with any additional evidence and briefs supporting their positions. The IP submitted three additional exhibits and a position statement. Dr. Kelly submitted a formal response and detailed statement with supporting documents that addressed Dr. Atwood's evaluation

report. Dr. Kelly also submitted a written stipulation in which he agreed not to use Propofol during the pendency of this contested case and a motion asking the Board to enlarge the time for further post-hearing submissions, which the Board denied.

In his response and statement Dr. Kelly pointed out that a substantial majority of Dr. Atwood's criticisms involved the use of Propofol for sedation. Dr. Kelly stated that use of Propofol has been a controversial issue not isolated to dentistry, and there are divergent views as to its use. Dr. Kelly said that Propofol has a good safety record when administered by a properly trained professional such as himself. He said that he has successfully completed over 900 sedation procedures since 2007 when he obtained his moderate sedation permit in North Carolina and has never had a patient injured as a result of his sedation procedures. Dr. Kelly further stated that he stopped using Propofol in April 2015 "because of the current climate and the controversy associated with the administration of Propofol for procedural sedation by a non-anesthesiologist it is in the best interest of the public and myself to stop using this drug in my practice."

In his response and statement Dr. Kelly also disputed some of Dr. Atwood's conclusions regarding the management of some of Dr. Kelly's sedated patients' blood pressure and oxygen saturation levels. For example, he said that he relied on capnography, rather than pulse oximetry, readings to measure respiratory status because capnography is more reliable. Dr. Kelly also pointed out that under the Board's present sedation rules, specifically 21 N.C.A.C. 16Q .0301 (h), a dentist who holds a moderate sedation permit shall not intentionally administer deep sedation "although deep sedation may occur briefly and unintentionally."

The IP's exhibits included two additional affidavits by Dr. Sullivan. In the first (IP Exhibit 6), Dr. Sullivan stated that he reviewed the same 20 patient records that Dr. Atwood reviewed. Dr. Sullivan said that he reached the same or similar conclusions that Dr. Atwood reached and that "of the twenty cases reviewed, six certainly had the potential to end very badly." (IP Exhibit 6, page 4). In his second affidavit (IP Exhibit 7), Dr. Sullivan responded to statements in Dr. Bonnick's affidavit. Finally, IP Exhibit 8 is a copy of Dr. Atwood's <u>curriculum vitae</u>.

Whether the Board should suspend Dr. Kelly's moderate sedation permit pending the August hearing on the merits of his contested case depends on whether the Board finds that emergency action is required to protect the public health, safety or welfare. Based on all of the evidence submitted during the summary suspension hearings on April 10, 2015 and May 13,

2015, and later supplemented by the parties, there is substantial evidence indicating a troubling pattern of unsafe sedation practices that is of great concern to the Board and that should be reviewed at the August hearing on the merits, even if that may necessitate amending the NOH to accomplish this review. However, there is evidence that conflicts with the conclusion that Dr. Kelly is practicing unsafe sedation dentistry. Three members of the Board's Sedation Review Committee, whom the Board recognizes as experts in sedation dentistry, have conflicting views on this question with Dr. Bonnick's opinion versus the opposing those of Dr. Sullivan and Dr. Atwood.

The Board concludes that these conflicts should be resolved in a contested case proceeding based on a full evidentiary record, including the testimony from witnesses subject to cross examination, rather than by a summary procedure based on affidavits. Dr. Kelly has addressed the Board's principal concern for patient safety by agreeing not to use Propofol until the final agency decision has been rendered following the August 2015 hearing on the merits of his contested case. No evidence was presented of actual harm to any of Dr. Kelly's recent patients. Under these circumstances, the Board cannot conclude that there is an emergency situation requiring the Board to take immediate action to summarily suspend Dr. Kelly's moderate sedation permit to protect the public, health safety or welfare, pursuant to G.S. 150B-3 (c).

NOW, THEREFORE, it is ORDERED that Dr. Kelly's Moderate Sedation Permit (No. 348) shall not be summarily suspended prior to resolution of the merits of his pending contested case.

This is the  $4^{th}$  day of June, 2015.

Dr. Stanley L. Allen, Presiding Officer