

STATE OF NORTH CAROLINA

OFFICE OF THE STATE AUDITOR

BETH A. WOOD, CPA



NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS

MORRISVILLE, NORTH CAROLINA

FINANCIAL RELATED AUDIT

MARCH 2015



NCOSA
The Taxpayers' Watchdog

EXECUTIVE SUMMARY

PURPOSE

The purpose of this audit was to determine whether the oversight of the practice of dentistry by North Carolina State Board of Dental Examiners (Board) could be improved to better protect public health and safety.

BACKGROUND

The Board was established in 1879 to ensure that only qualified persons be permitted to practice dentistry and dental hygiene in the state of North Carolina. As of March 2014, the Board regulates more than 4,500 dentists and 5,500 dental hygienists. The Board has eight members and its activities are mainly supported by fees.

KEY FINDINGS

- The Board allows dentists to provide sedation services before it inspects the dental facilities to ensure that the proper skills, equipment, drugs, support personnel, and procedures are in place to safely perform dental sedation and respond to medical emergencies.
- The Board does not conduct periodic inspections after it issues the initial sedation permits to ensure that dental facilities maintain the ability to safely perform dental sedation and respond to medical emergencies.
- The Board does not verify that dentists complete the continuing education hours that are required as a condition for renewal of anesthesia and sedation permits.

KEY RECOMMENDATIONS

- The Board should reconsider its policy of issuing temporary anesthesia and sedation permits prior to an inspection of the dental facilities.
- The Board should set up a risk-based schedule for inspecting dentists and dental facilities.
- The Board should develop standardized checklists, guides, or other documents covering the areas of compliance/requirements to be checked during the inspection and the level of reporting involved.
- The Board should verify continuing education hours that dentist report when renewing anesthesia and sedation permits.

The key findings and recommendations in this summary may not include all findings and recommendations in this report.



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AUDITOR'S TRANSMITTAL

March 4, 2015

The Honorable Pat McCrory, Governor
The General Assembly of North Carolina
North Carolina State Board of Dental Examiners
Bobby D. White, Chief Operations Officer

This report presents the results of our financial related audit at the North Carolina State Board of Dental Examiners. Our work was performed as authorized by *North Carolina General Statutes*, Chapter 147, Article 5A and was conducted in accordance with the performance audit standards contained in *Government Auditing Standards*, issued by the Comptroller General of the United States.

Our audit identified matters that are considered reportable under *Government Auditing Standards*. These items are described in the *Findings, Recommendations, and Responses* section of this report.

North Carolina General Statutes require the State Auditor to make audit reports available to the public. Copies of audit reports issued by the Office of the State Auditor may be obtained through one of the ways listed in the back of this report.

A handwritten signature in cursive script that reads 'Beth A. Wood'.

Beth A. Wood, CPA
State Auditor

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State Auditor

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Article V, Chapter 147 of the North Carolina General Statutes, gives the Auditor broad powers to examine all books, records, files, papers, documents, and financial affairs of every state agency and any organization that receives public funding. The Auditor also has the power to summon people to produce records and to answer questions under oath.



BACKGROUND, AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The North Carolina State Board of Dental Examiners (Board) was created in the public interest by *Chapter 139, Public Laws 1879* and by *Chapter 178, Public Laws 1915* and is governed by *North Carolina General Statute 90-22*. The Board's purpose is to regulate, license, and control the practice of dentistry in the state of North Carolina. As such, the Board establishes criteria for licensing dentists and dental hygienists.

The Board consists of eight members: six (6) licensed dentists, one (1) licensed dental hygienist, and one (1) consumer member. The Board employs nine staff members who are responsible for collecting fees, issuing and renewing licenses, and investigating complaints.

The Board's activities are mainly supported by fees collected. For the period of July 2013 through March 2014, the Board had total revenues of \$2,470,887 and total expenses of \$1,763,267.

During the audit, the Board started a series of public forums to solicit feedback from the public and professionals concerning possible changes to the rules and protocols for sedation permitting based on recent occurrences.

According to local media, the Board is "looking for suggested improvements for the state's system for regulating dentists."¹ Topics may include "ways to better train North Carolina's dentists, methods for dentists to respond to emergencies and ways dentists should select patients for various treatment."

At the time of the completion of fieldwork for the audit, all of the forums had not been completed.

¹ www.newsobserver.com, "NC dental board seeks public help with new rules after suspected sedation deaths," March 9, 2014

The audit objective was to determine whether the North Carolina State Board of Dental Examiners (Board) effectively identifies substandard practices through its oversight process and ensures problems are corrected.

The audit scope included Board operations for the period of July 2013 through March 2014. Auditors conducted fieldwork from March 2014 to June 2014.

To accomplish the audit objective, auditors reviewed state laws, interviewed personnel, observed operations, examined internal documentation, and reviewed the North Carolina State Board of Dental Examiners' website.

As a basis for evaluating internal control, auditors applied the internal control guidance contained in professional auditing standards. As discussed in the standards, internal control consists of five interrelated components: (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

We conducted this audit in accordance with generally accepted government auditing standards applicable to performance audits. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.



FINDINGS, RECOMMENDATIONS, AND RESPONSE

ADDITIONAL OVERSIGHT OF SEDATION DENTISTRY² NEEDED

Although the potential consequences of improperly administered anesthesia and sedation drugs can be significant, the North Carolina Board of Dental Examiners (Board) does not provide adequate oversight of dentists who provide sedation services.

Specifically, the:

- Board allows dentists to provide sedation services before it inspects the dental facilities;
- Board does not conduct periodic inspections after it issues the initial sedation permits; and
- Board does not verify that dentists complete required continuing education hours.

Potential Consequences Make Proper Board Oversight A Necessity

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.

Although rare,³ deaths have occurred from the use of dental sedation. For example, incidents of sedation-related deaths in North Carolina and other states include:

- In North Carolina, a 71-year-old male died in 2013 of an overdose of drugs used to sedate him while his remaining teeth were extracted and replaced with dentures. The North Carolina Board of Dental Examiners later found that the dentist “failed to properly consider his 71-year-old patient’s medical and physical condition, failed to properly dose the patient with a sedative, and failed to give the patient a rescue drug.”⁴

² **Sedation dentistry** refers to the use of pharmacological agents to calm and relax a patient prior to and during a dental appointment. The pharmacological agents usually belong to a class of drugs called sedatives which exert their action by depressing the central nervous system, specifically those areas concerned with conscious awareness.

³ An American Association of Oral and Maxillofacial Surgeons White Paper states, “The OMS National Insurance Company (OMSNIC) Anesthesia Morbidity and Mortality Data (2000-2010) examined a total number of 29,975,459 in-office anesthetics (conscious sedation, deep sedation and general anesthesia) administered by oral and maxillofacial surgeons and found the ratio of office fatalities /brain damage per anesthetics administered to be 1:365,534.”

⁴ www.newsobserver.com, “NC dentist’s license suspended following patient’s sedation death,” September 19, 2014

- In North Carolina, a 57-year-old female died in 2012 of an overdose of drugs used to sedate her during a tooth extraction. The North Carolina Board of Dental Examiners later found that the dentist failed to recognize that the patient was in distress and failed to take appropriate rescue action.⁵
- In Hawaii, a 3-year-old girl died in 2014 “after losing consciousness and suffering massive brain damage following sedation” that she received during procedures to fill 10 cavities and perform four root canals.⁶ The parents filed a negligence lawsuit that was settled, and the state is investigating the dentist.⁷ The lawsuit alleged that the dentist administered “improper medications with incorrect doses” and “had no plan in place to respond to medical emergencies.”⁸
- In Illinois, a 5-year-old girl died in 2007 after being “over sedated during a routine dental procedure.”⁹ The Illinois Department of Financial and Professional Regulation found that the dentist “demonstrated a complete lack of understanding of conscious sedation after 9 years of practice in the area of conscious sedation, and after performing some 32,000 procedures involving conscious sedation.”¹⁰ The Department also found that the dentist “failed to ensure that his staff was adequately trained to provide preoperative, intra-operative, and post-operative care to the patient.”

The examples cited above demonstrate that state dental board oversight is necessary to ensure that dentists have the proper training, equipment, drugs, support personnel, and procedures to safely perform dental sedation.

In fact, the American Dental Association states, “State dental boards have the responsibility to ensure that only qualified dentists use sedation and general anesthesia.”¹¹

Board Allows Dentists To Provide Sedation Services Before It Inspects Facilities

The Board allows dentists to perform anesthesia and sedation services for up to three months before verifying through inspection that the dentist has the proper skills, equipment, drugs, support personnel, and procedures to safely perform dental sedation.

As a result, dentists could be following substandard practices that threaten public safety and health for up to three months without detection.

To obtain a temporary permit, a dentist completes an application and submits an application fee and documentation of training in anesthesia or sedation to the Board. The Board issues a 90-day temporary permit after the application is received and training is verified. The Board issues six types of temporary permits for anesthesia and sedation services. (See Appendix)

⁵ www.carynews.com, “Eleven months after a patient dies...”, November 11, 2013

⁶ www.cbsnews.com, “Hawaii investigating dentist after 3-year-old girl’s death”, January 8, 2014

⁷ www.timesfreepress.com, “Lawsuit settled over death of 3-year-old who died after suffering a heart attack while at dentist office”, September 3, 2014

⁸ www.cnn.com, “Hawaii girl, 3, dies after dental procedure”, January 5, 2014

⁹ www.chicagotribune.com, “Dentist, family settle for \$1million, 5-year-old died of oversedation”, July 18, 2007

¹⁰ State of Illinois Department of Financial and Professional Regulation Division of Professional Regulation, case no. 2006-12566

¹¹ American Dental Association Policy Statement: The Use of Sedation and General Anesthesia By Dentists As Adopted by the October 2007 ADA House of Delegates.

However, until an inspection is completed, the Board does not verify whether the dentist, dental staff, and dental facilities meet the relevant requirements for general anesthesia and sedation services described in the North Carolina Administrative Code (NCAC).

For example, until the inspection for the “minimal conscious sedation permit” (See Appendix) is completed the Board does not verify that the dentist can demonstrate competency in the following areas:¹²

- “Monitoring of blood pressure, pulse, pulse oximetry and respiration;
- Drug dosage and administration (by verbal demonstration);
- Treatment of untoward reactions including respiratory or cardiac depression (by verbal demonstration);
- Sterilization;
- Use of CPR certified personnel;
- Monitoring of patient during recovery (by verbal demonstration); and
- Sufficiency of patient recovery time (by verbal demonstration).”

The Board has recently improved its permitting policy by reducing the length of time that a temporary permit is valid. Prior to September 2014, a temporary permit could be valid for up to six months. Each temporary sedation permit could be issued for up to 90 days, and a 90-day extension could be granted if requested. Effective September 2014, however, the Board no longer allows extensions.¹³

Nevertheless, Board policy still allows dentists to practice sedation for up to three months before dentists demonstrate that they are able to meet the competencies and other requirements outlined in the North Carolina Administrative Code (NCAC).

Best practices require regulatory agencies to ensure that practitioners meet requirements before they are allowed to practice in the regulated industry. For example, the National State Auditors Association’s “Best Practices in Carrying Out a State Regulatory Program” states,

“As part of a good licensing/permitting process, the agency would be expected to take reasonable steps for the initial application and subsequent renewals to ensure that the **applicant meets all current requirements.**”
(*Emphasis Added*)

¹² 21 NCAC 16Q .0401(d)(2)

¹³ 21 NCAC 16Q .0303(a)

Board Does Not Conduct Periodic Inspections After It Issues Sedation Permits

The Board does not conduct periodic on-site inspections of the 618 dentists with sedation permits to ensure that they remain in compliance with Board policies. In fact, the Board does not conduct periodic on-site inspections of any of the 4,617 dentists licensed and actively practicing in North Carolina.

The Board may perform on-site inspections in response to complaints against a dentist. However, these inspections are for cause and do not occur at regular intervals.

As a result, some dental facilities may never be inspected again after the initial permitting evaluation.

Without periodic inspections, substandard practices could go undetected for extended periods. For example, without periodic inspections of dental facilities that provide minimal conscious sedation services, potential noncompliance issues such as the following could go undetected:¹⁴

- Dentists using insufficient auxiliary personnel without documented annual basic life support training for each procedure performed.
- Patients administered minimal conscious sedation not properly evaluated for medical health risks prior to the start of any sedative procedure.
- Equipment not adequately evaluated and maintained for proper operation.
- Dentists administering sedative agents in a manner that is not within the standard of care.
- Dentists, personnel and facilities are not prepared to treat emergencies that may arise from the administration of minimal conscious sedation and/or do not have the ability to provide positive pressure ventilation with 100% oxygen with an age appropriate device.

The North Carolina Administrative Code (NCAC) authorizes the Board to conduct periodic inspections. It states:

“Incident to the renewal of an anesthesia or sedation permit, for cause or **routinely at reasonable time intervals in order to ensure compliance**, the Board may require an on-site inspection of the dentist's facility, equipment, personnel and procedures.”¹⁵ (*Emphasis Added*)

However, the Board currently does not have procedures in place to perform anesthesia or sedation inspections after the initial permitting inspection.

¹⁴ 21 NCAC 16Q .0402(c-g)

¹⁵ 21 NCAC 16Q .0503

Best practices require regulatory agencies to systematically inspect regulated entities. Specifically, The National State Auditors Association's "Best Practices in Carrying out a State Regulatory Program" states,

"The agency should develop a systematic process for monitoring regulated people's/entities' activities to ensure that they are following applicable requirements and that the public is adequately protected."

Additionally, the National State Auditors Association states that regulatory agencies should "set up a schedule for periodically inspecting regulated people/entities" that:

- Is frequent enough to provide reasonable safeguards to the public;
- Is risk-based¹⁶ if possible; and
- Complies with any legal/regulatory requirements.

Board Does Not Verify That Dentists Complete Continuing Education Hours for Sedation Services

The Board does not verify that continuing education hours for sedation services reported by dentists are valid.

Because continuing education hours are not verified, dentists could potentially provide sedation services without having obtained the continuing education required to protect public health and safety.

Dentists are required to report the number of continuing education hours earned each year to show that they have obtained at least the minimum hours required by the North Carolina Administrative Code.

For example, dentists who hold a minimal conscious sedation permit must complete annual basic life support training and obtain six hours of continuing education every two years in one or more of the following areas:

- Pediatric or adult sedation;
- Medical emergencies;
- Monitoring sedation and the use of monitoring equipment;
- Pharmacology of drugs and agents used in sedation;
- Physical evaluation, risk assessment, or behavioral management;

¹⁶ Best practices recommend that inspections be risk-based to divert resources to the areas that are most in need of oversight. A risk-based inspection process would involve assessing which facilities have the greatest risk of non-compliance and inspecting those facilities more often while inspecting low-risk facilities less often.

- Audit advanced cardiac life support/pediatric advanced life support courses;
- Airway management.

Best practices require regulatory agencies to ensure that practitioners meet requirements before they are allowed to practice in the regulated industry.

The National State Auditors Association's "Best Practices in Carrying Out a State Regulatory Program" states,

"As part of a good licensing/permitting process, the agency would be expected to take reasonable steps for the initial application and subsequent renewals to ensure that the **applicant meets all current requirements.**"
(Emphasis Added)

RECOMMENDATIONS

The Board should reconsider its policy of issuing temporary anesthesia and sedation permits prior to an inspection of the dental facilities.

The Board should set up a risk-based schedule for inspecting dentists and dental facilities.

The Board should develop standardized checklists, guides, or other documents covering the areas of compliance/requirements to be checked during the inspection and the level of reporting involved.

The Board should verify continuing education hours that dentist report when renewing anesthesia and sedation permits.

NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS

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BOBBY D. WHITE, Chief Operations Officer

13 February 2015

The Honorable Beth A. Wood, CPA
 State Auditor
 Office of the State Auditor
 2 South Salisbury Street
 20601 Mail Service Center
 Raleigh, NC 27699-060

Dear Ms. Wood:

The North Carolina State Board of Dental Examiners (the Board) accepts the recommendations of the Office of State Auditor (OSA) and believes the areas identified for improvement will increase the Board's effectiveness in protecting public health.

It should be noted that beginning in the spring of 2014 the Board held three public hearings and convened a special advisory committee to review and improve sedation regulations. This committee has developed recommendations and will be proposing rules that address two of the concerns raised independently by the OSA, i.e., discontinuing the use of the temporary anesthesia permit and verification of anesthesia related continuing education.

The third recommendation of the OSA – that the Board conduct periodic site evaluations of dentists with sedation permits – will require a significant shifting or development of resources. However, the Board is committed to implementing this recommendation as quickly as possible.

The Board appreciates the time, effort, and professionalism of your staff in conducting this audit. Our Board is confident this process will improve our ability to ensure that the practice of dentistry merit and receive the confidence of the public.

Sincerely,

A handwritten signature in black ink, appearing to read "Bobby D. White".

Bobby D. White
 Chief Operations Officer

The North Carolina Board of Dental Examiners issues six types of anesthesia and sedation permits. They are:

1. Anesthesia Permit
2. Moderate Conscious Sedation Permit
3. Moderate Pediatric Conscious Sedation Permit
4. Limited Moderate Conscious Sedation Permit
5. Limited Moderate Pediatric Conscious Sedation Permit
6. Minimal Conscious Sedation Permit

The North Carolina Administrative Code (NCAC) provides the following definitions:¹⁷

General anesthesia – the intended controlled state of a depressed level of consciousness that is produced by pharmacologic agents and accompanied by a partial or complete loss of protective reflexes, including the ability to maintain an airway and respond purposefully to physical stimulation or verbal commands.

Moderate conscious sedation – conscious sedation characterized by a drug induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years or older, by oral, nasal, rectal or parenteral routes of administration of multiple pharmacological agents, in multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate conscious sedation is provided for behavior control.

Moderate pediatric conscious sedation – conscious sedation characterized by a drug induced depression of consciousness, during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients under 13 years of age, by oral, nasal, rectal or parenteral routes of administration of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period, including the time of treatment, possibly in combination with nitrous oxide. Moderate pediatric conscious sedation is provided for behavior control.

Moderate conscious sedation limited to oral routes and nitrous oxide inhalation – conscious sedation characterized by a drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation, provided to patients 13 years or older, by oral routes of administration and nitrous oxide inhalation, of single or multiple pharmacological agents, in single or multiple doses, within a 24 hour period. Moderate conscious sedation limited to oral routes and nitrous oxide inhalation is provided for behavior control.

¹⁷ 21 NCAC 16Q .0101

Minimal conscious sedation – conscious sedation characterized by a minimally depressed level of consciousness, in which patient retains the ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command, provided to patients 13 years or older, by oral or rectal routes of administration of a single pharmacological agent, in one or more doses, not to exceed the manufacturer's maximum recommended dose, at the time of treatment, possibly in combination with nitrous oxide. Minimal conscious sedation is provided for behavioral management.

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This audit required 848 audit hours at an approximate cost of \$64,448.