February 6, 2016

Attn: Abigail Hammonds
Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6700

Dear Ms. Hammonds and the Rules Review Commission

I commend the NC State Board of Dental Examiners on attempting to improve safety for the dental patients of North Carolina. Providing safe and effective sedation for our patients is of utmost importance. Rules that increase safety and provide high level standards for practitioners are necessary. Some of the recent proposed changes to the sedation rules will not increase safety and will provide an unnecessary burden to patients and practitioners who have been providing safe sedation for decades. Additionally, some necessary safety standards are not present in the new proposal. In light of some unnecessary rules as well as omitted safety protocols, I write this letter as a formal objection to the latest version of the rules that have been submitted to the Rules Review Commission regarding sedation.

1. 21 NCAC 16Q .0302 item 7 states two BLS certified auxiliaries shall be present at all times during the procedure. This requirement is unnecessary for moderate conscious sedation. This will not increase safety or lower risk of morbidity and mortality. For example under the new rules, a healthy patient taking 5mg of Valium along with the administration of N20 falls under the moderate conscious sedation rules. Having two auxillaries in the room during the procedure is unnecessary and unreasonable. There is no evidence that an additional monitor will reduce risk and it will ultimately lower access to care by increasing patient cost.

2. Under the nitrous oxide section "Non-Delegable Functions" it states that induction of nitrous oxide is not permitted by any auxiliary - this task is limited to doctors, RNs and anesthesiologists. This is a good rule and provides safety to patients. However, it is inconstant and dangerous that no such section of "Non-Delegable Functions" exists for the administration of sedative drugs used in conscious sedation or general anesthesia. Omitting specific instructions about who may administer drugs for higher level sedation permits allows untrained individuals to physically push these drugs. If nitrous oxide requires these limitations, shouldn't the administration of drugs with greater risk have similar specific limitations?

3. The new rules require a physician consultation for all ASA III patients for conscious sedation permit holders. However, no consultation is necessary if you are a general anesthesia permit holder. If there is a potential risk to a patient in providing sedation, this risk should be equally explored by all practitioners.

Although it is my understanding that an advisory panel was used to develop these recommended changes, it is my opinion that not enough consideration has been given to patient access or the variety of training standards that different practitioners hold. It is also my opinion that some of the proposal is a reaction to tragic incidences that have occurred in this state. Changes are necessary to improve safety. However, making recommendations that are not evidence based or validated with safety statistics will ultimately reduce access to care for our patients and increase sedation costs to patients unnecessarily.

Thank you for your time and consideration.

Regards,

Steven M. Van Scoyoc, DDS, MS
Diplomate of the American Board of Periodontology

240 Davis Street
Suite A
Southern Pines, NC 28387
(910)-692-6270

Hammond, Abigail M

From: Scott Gould <sgould@capefearperio.com>
Sent: Monday, February 08, 2016 4:06 PM
To: Hammond, Abigail M
Subject: attn: Abigail Hammond - Formal Objection to Proposed Dental Sedation Rule Changes

Dear Board Members and/or NC lawmakers,

I would like to start by saying that I truly appreciate your service to our profession and to the state of NC. I have read through the most recent proposed sedation rule changes.

I understand the rationale for a few of the proposed changes and I appreciate the need for the board to protect the public.

I would like to make a formal objection to the latest version of the rules that have been submitted to the Rules Review Commission regarding Sedation. Specifically I would like to make the following objections and proposals:

1) Instead of mandating that the sedation permit holder have annual ACLS, I would propose offering the option of either annual ACLS **or** annual BLS and an approved airway management course.

2) In my opinion, the requirement of having an additional staff member in the room will serve no purpose. This will undoubtedly increase the cost of the procedures for the patients due to the additional staff members required to comply with the rule. Additionally, it will ultimately result in reduced access for care for patients, since many permit holders will likely discontinue sedation practices in light of the unnecessary changes. The increased costs which will be passed along to our patients will likely be too much for many patients to afford. My objection to the additional staff member is undoubtedly my most vehement objection. This is a poorly thought out proposal and there is no evidence that it will make the experience any safer for patients. This rule, is not in the best interest of the public.

3) I also object to the end tidal CO2 monitoring requirement. Many sedated patients breathe through their mouth during the entire procedure. The monitoring will be ineffective and the alarms will consistently sound during procedures due to patients breathing through their mouths. This will likely result in most doctors removing the monitoring equipment despite the rule. Please do not make this a part of the rule changes. It makes very little sense.

4) Lastly, my understanding is that the itinerant requirements are more restrictive for moderate sedation permit holders than they are for oral surgeons. I'm a periodontist and I should point out have never had a single adverse event from sedation in my office in the past 11 years of practice. Many patients require sedation for scaling and root planning and I will often have side by side (itinerant) sedation cases going on at once. Please do not make itinerant requirements more restrictive. This will be unfortunate for so many of our anxious sc/rp cases.

I appreciate your consideration of the above objections. Sincerely, Scott Gould

M. Scott Gould, DDS, MS
Diplomate of the American Board of Periodontology
219 Station Road, Suite #102
Wilmington, NC 28405
(o) 910.686.4644
(f) 910.686.4340
(m) 910.274.4800
www.capefearperio.com

Matthew D. Ficca, D.M.D., M.S.D.

Diplomate, American Board of Periodontology
Practice Limited to Periodontics & Dental Implants

3325 Springbank Lane, Suite 140, Charlotte, NC 28226
Tel # 704-544-2224 Fax # 704-544-2259

Dear Rules Review Commission of the North Carolina General Assembly, Board Members, and Colleagues:

I am writing to file a formal objection to the latest version of the rules that have been submitted to the Rules Review Commission regarding Sedation.

Patient safety should always be a priority, along with comfort, quality, and access to care. Some of the proposed rules, proposed with the best intentions, pose a concern to these priorities.

The proposed changes in doctor training and preparedness to handle emergencies all represent positive changes to help ensure the priorities of patient care.

My first concern is with the proposal for making mandatory a third assistant solely for the purpose of monitoring sedation. A third person in the operatory overcrowds the workspace and potentially defers the monitoring responsibility to a third person rather than the doctor, promoting complacency and a potential detriment to patient safety. Emphasis should be placed on monitoring and accompanying patient at all times with appropriately trained personnel. Focus should be on increasing the quality of monitoring and response not increasing the quantity. More assistants does not equate to increased patient safety or satisfaction.

The second concern the required use of end tidal CO2 monitoring in an open monitoring system. Closed system ETCO2 monitoring, as in intubation breathing and general anesthesia, has been proven to be faster and more effective than P02 monitoring. However open system ETCO2 monitoring, as in conscious sedation through a canula, has been reported to be less effective, present a high incidence of false alarms. Also, according to recent literature from Am J Gastroenterology 2016, it does not improve patient safety or satisfaction.

Thank you for your efforts and time dedicated to these and other matters on our behalf. Our patients' best interests are always our priority.

Sincerely,

Matthew D. Ficca, DMD, MSD
Diplomate, American Board of Periodontology

Hammond, Abigail M

From: Ron Nason <ronnason@gastonperio.com>
Sent: Monday, February 08, 2016 7:27 PM
To: Hammond, Abigail M
Subject: NCSP Objection to Proposed Sedation Rule Changes

Dear Rules Review Committee,

As President of the North Carolina Society of Periodontists, I'd like to declare our collective opposition to the proposed sedation rule changes in their current form. I will not specifically reiterate the reasons why, as they have already been clearly stated by our colleagues Dr. Crosland, Dr. Byerly, Dr. Pierce, Dr. Kadona and others in the NC Dental Board's comment section on the website. The Periodontist of this State have an excellent record of safety with the delivery of sedation to our patients. This is attributed to the excellent training received in our residency programs, our commitment to quality continuing education and genuine concern for providing the best treatment to our patients. If these current changes become law, many of our patients will be denied access to care because of increased cost or the unavailability of the sedation that they have become accustomed too.
We all agree that some change needs to occur to insure the citizens of North Carolina have access to safe dental care. The NCSP respectably feels that this issue needs to be explored further as it relates to the moderate sedation license and the Periodontists of this State. I know that your task has been overwhelming and appreciate the work that you have done so far. We are simply asking as a longstanding dental specialty in this State for more consideration to be given before this becomes law. Please contact me for further discussion on this topic.

Sincerely and respectfully,

Dr Ronald H Nason Jr.

President NCSP

1601-D East Garrison Blvd
Gastonia, NC 28056

Subject: NCSP Objection to Proposed Sedation Rule Changes
Date: Monday, February 8, 2016 at 7:14:42 PM Eastern Standard Time
From: Ron Nason
To: abigail.hammond@oah.nc.gov

Dear Rules Review Committee,

As President of the North Carolina Society of Periodontists, I'd like to declare our collective opposition to the proposed sedation rule changes in their current form. I will not specifically reiterate the reasons why, as they have already been clearly stated by our colleagues Dr. Crosland, Dr. Byerly, Dr. Pierce, Dr. Kadona and others in the NC Dental Board's comment section on the website. The Periodontist of this State have an excellent record of safety with the delivery of sedation to our patients. This is attributed to the excellent training received in our residency programs, our commitment to quality continuing education and genuine concern for providing the best treatment to our patients. If these current changes become law, many of our patients will be denied access to care because of increased cost or the unavailability of the sedation that they have become accustomed too.
We all agree that some change needs to occur to insure the citizens of North Carolina have access to safe dental care. The NCSP respectably feels that this issue needs to be explored further as it relates to the moderate sedation license and the Periodontists of this State. I know that your task has been overwhelming and appreciate the work that you have done so far. We are simply asking as a longstanding dental specialty in this State for more consideration to be given before this becomes law. Please contact me for further discussion on this topic.

Sincerely and respectfully,

Dr Ronald H Nason Jr.

President NCSP

1601-D East Garrison Blvd
Gastonia, NC 28056
704-866-8281

704-866-8281

Bradley N. Adkins, DDS
2319 Grace Avenue
New Bern, NC 28562
252.633.2876
252.634.9980 fax

ADKINS
DENTISTRY
— DDS, PLLC —

February 11, 2016

Attn: Abigail Hammond (abigail.hammond@oah.nc.gov)

CC: Carolin Bakewell (carolin.bakewell@gmail.com)

Bobby White (bwhite@ncdentalboard.org)

Dear Rules Review Commission:

I would like to take this moment to file a formal objection to the "latest version of the rules that have been submitted to the Rules Review Commission regarding Sedation" as seen on the Board home page (http://www.ncdentalboard.org/). I find the proposed rules to be excessively limiting, and believe it will lead to diminished access of care for our State's citizens.

Many individuals neglect their dental needs and general health due to severe anxiety, which is not surprising, given the somewhat invasive nature of dentistry on conscious patients. Pharmacologic intervention has been well documented to mitigate these anxieties and allow for safe treatment of these patients in the dental office setting.

Our office maintains a license for, and trains for, moderate conscious sedation. We find that for a large majority of our conscious sedation cases, that we can attain a desired level of comfort with very light sedation, most frequently staying below the maximum recommended doses for unsupervised home use with a single pharmacologic agent, sometimes supplemented with nitrous oxide/oxygen. I believe that a majority of anxiety cases can effectively be managed this way.

As I read the proposed rules, this minimal sedation is now being lumped under moderate sedation, which will have several negative effects.

First, it will limit the number of providers willing to treat these cases due to stricter licensing requirements. I find it difficult to believe that a dental professional needs to complete a residency in IV sedation to provide, in a supervised office setting, the same pharmacologic intervention that a primary care physician could write for unsupervised home use. Does this also mean that a non-sedation licensed dentist cannot treat patients who are taking these same medications on a daily basis by order of their physician?

Secondly, it will increase the costs to the patients seeking to have any pharmacologic intervention to reduce anxiety. While I maintain thousands of dollars of monitoring equipment, and use it dilligently, I find it difficult to believe that the added expense of capnography for every light sedation case is justifiable, relative to other means of monitoring respiration. I personally prefer use of a precordial stethoscope to monitor respiration. I am not discounting the benefits of capnography, but find it to be redundant and excessive for the majority of light sedation cases (I trained with capnography in my residency), and believe it will create additional expenses which will be passed on to the patients, further limiting their access to dental care.

I applaud the Board and those involved with the Sedation rules proposals for looking to improve the safety and welfare of our citizens, but believe that the rules as proposed may have negative unintended consequences for many of our citizens needing dental care. I believe the only proper changes are those that have abundant evidence to support them.

Please verify receipt of this letter by email.

Sincerely,

Bradley N. Adkins DDS

Bradley N. Adkins DDS

COASTAL DENTISTRY
Drs. Smith, Schweitzer & Nelson
General Dentistry & Orthodontics

Cliff R. Schweitzer, DDS
405 N. 35th Street
Morehead City, NC 28557

February 12, 2016

Re: Formal Objection to latest version of rules regarding sedation.

Abigail Hammond
Rules Review Commission
abigail.hammond@oah.nc.gov

Dear Ms. Hammond,

The intent of this letter is to file a formal objection to the latest version of the rules that have been submitted to the Rules Review Commission regarding sedation.

If passed, these rules will have a negative impact on the citizens of North Carolina, especially in regards to access to care.

Moderate sedation by oral routes has proven to be an effective and safe means to help achieve oral health for those patients with true dental phobias.

Please send verification of receipt of this request by email or other means.

Thank you,

Cliff R. Schweitzer, DDS

Forsyth
Periodontal
associates

Periodontics & Dental Implants
W. Mark Suttle, DDS, MS, PA
Trent C. Pierce, DMD, MSD
Diplomates, American Board of Periodontology

February 9, 2016

Rules Review Commission
Attn: Abigail Hammond
Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-7600

To Whom It May Concern:

I am writing to express a formal objection to the latest version of the rules that have been submitted to the Rules Review Commission regarding conscious sedation administered by dentists in North Carolina. Given the recent adverse occurrences that have occurred in this state I do understand that some changes to the sedation rules are needed.

I am most concerned about the rule requiring a 2nd dental assistant in the operatory at all times to monitor the patient. With regards to monitoring in my practice, the patient is continuously monitored via the pulse oximeter/vital signs monitor which generates a printed summary when finished. However, a 2nd designated dental assistant is responsible for coming to the operatory every five minutes to manually record vital signs, check to make sure the IV line is still going and dripping at the correct interval, and to check the patient overall. If my partner and I are both performing procedures until IV sedation then essentially this assistant is floating between the two operatories at all times.

If the new rules pass as written, then it create a significant manpower burden on our practice. For a two-doctor practice such as mine, and with both doctors performing IV sedation, we would be required to hire at least one or more additional assistants. This would lead to increased overhead and ultimately increased sedation fees for the patient, thus affecting many patients' access to care.

I appreciate your attention to the matter above, and please do not hesitate to contact me if you have any questions.

Sincerely,

W. Mark Suttle, DDS, MS
Diplomate, American Board of Periodontology

2870 Lyndhurst Avenue ■ Winston-Salem, NC 27103
336-765-9224 ■ 336-765-2340 fax ■ www.forsythperio.com

Kuhn Dental
ASSOCIATES
Implant, Sedation, Cosmetic & General Dentistry

David R. Kuhn, DMD • Mandy Kuhn Grimshaw, DDS • D. Ritt Kuhn, DMD

February 8, 2016

North Carolina State Board of Dental Examiners
2000 Perimeter Park Drive, Suite 160
Morrisville, NC 27560

Dear North Carolina State Board of Dental Examiners:

I commend the board on attempting to improve safety for the dental patients of North Carolina. Providing safe and effective sedation for our patients is of utmost importance. Some of the recent proposed changes to the sedation rules will not increase safety and will provide an unnecessary burden to patients and practitioners who have been providing safe sedation for decades.

As a moderate sedation permit holder, I formally object to the proposed Sedation Rule changes. It will result in limited access to care. The sedation patients will not seek care elsewhere if we as practitioners can no longer provide adequate sedation. Just coming into a dental office is very difficult for the high fear patient.

I request that this objection be provided to the NC Rules Committee and also request an email receipt when you receive this letter (drgrimshaw@kuhndentist.com). Thank you for your time and consideration.

Regards,

D. Ritt Kuhn, DMD
Kuhn Dental Associates
AKG:rny

Kuhn Dental
ASSOCIATES
Implant, Sedation, Cosmetic & General Dentistry

David R. Kuhn, DMD • Mandy Kuhn Grimshaw, DDS • D. Ritt Kuhn, DMD

February 8, 2016

North Carolina State Board of Dental Examiners
2000 Perimeter Park Drive, Suite 160
Morrisville, NC 27560

Dear North Carolina State Board of Dental Examiners:

I commend the board on attempting to improve safety for the dental patients of North Carolina. Providing safe and effective sedation for our patients is of utmost importance. Some of the recent proposed changes to the sedation rules will not increase safety and will provide an unnecessary burden to patients and practitioners who have been providing safe sedation for decades.

As a minimal sedation permit holder, I formally object to the proposed Sedation Rule changes. It will result in limited access to care. The sedation patients will not seek care elsewhere if we as practitioners can no longer provide adequate sedation. Just coming into a dental office is very difficult for the high fear patient.

I request that this objection be provided to the NC Rules Committee and also request an email receipt when you receive this letter (drgrimshaw@kuhndentist.com). Thank you for your time and consideration.

Regards,

Amanda K. Grimshaw

Amanda Kuhn Grimshaw, D.D.S.
Kuhn Dental Associates
AKG:rny

Phone (910) 692-4450 • (800) 682-4191 • Fax (910) 692-3919 • www.KuhnDentist.com
1902 N. Sandhills Boulevard, Suite H • Aberdeen, North Carolina 28315

Subject:	[No Subject]
From:	sueandneill (sueandneill@yahoo.com)
To:	Sueandneill@yahoo.com;
Date:	Sunday, February 7, 2016 1:04 PM

Dear North Carolina Board members,

I would like to file an objection to the latest version of the rules that have been submitted regarding sedation. Although I do not perform IV sedation I do occasionally have anxious patients benefit from diazepam and there are many requests to use nitrous oxide to relax. These patients are certainly fully conscious and respond to any questions and even can get up during treatment and use the restroom if needed, all under their own energy.

To present roadblocks and hurdles to the dental professionals of our great state, I feel, will drastically decrease the ability and desire to treat any anxious / nervous patients requesting the above modalities of relaxation. They will not follow through with treatment offered as barricades will have been put up to all of their individual dentists. The good citizens of our state will procrastinate and eventually flood local hospital emergency rooms increasing costs to localities and the state in general. If the suggestions pass your review, dental health for many, many lovely and deserving people will be compromised. What a shame.

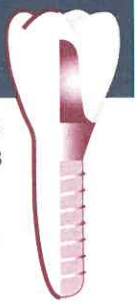
I thought the North Carolina dental community was striving to increase access to care. This will thwart our good efforts and trickle down as a disservice to the North Carolinian population who desperately need our services. We are "shooting ourselves in the foot" (and mouth). We are undoing all the good we have been working towards and already accomplished. I do not understand why. Please explain this to me. Thank you for your time.

Respectfully,

Neil Lutins, DDS
P.S. Please verify to me if you would, that you received and read this. Again, I thank you.

Email: SueandneiLL@ yahoo.com
Fax: 336-275-2078

Periodontics & Implants
Dr. J. Michael Ruff
823 Elm St., Suite 220
Fayetteville, NC 28303
(910) 483-4867
1-800-672-4986
www.implantsandperio.net



February 9, 2016

North Carolina Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6700

Re: Sedation rules changes that have been sent to Rules Review Commission

Dear Sir or Madam:

By this letter, I file a formal objection to the latest version of rules changes on sedation that have been submitted to the Rules Review Commission. I am all for the safe management of phobic dental patients who are in need of treatment and are extremely anxious; however, I believe the proposed rules changes will result in significantly fewer providers offering sedation in a dental office. Another problem is increased cost for the patient. Some may find the need to have their care in an out-patient surgical facility which could be a barrier to them having needed dental treatment.

Sincerely,

J. Michael Ruff

J. Michael Ruff, D. D. S.

JMR/rkm