

Hammond, Abigail M

From: John Bitting <John.Bitting@b2dmarketing.com>
Sent: Friday, March 11, 2016 1:03 PM
To: Hammond, Abigail M
Cc: DrDave77@aol.com; cschweitzer@ec.rr.com; dionner@ecu.edu
Subject: RE: 21 NCAC 16Q

Importance: High

Dear Ms. Hammond and the RRC,

On behalf of the 79 North Carolina DOCS members and the 100 minimal and 102 limited moderate sedation permit holders all of whom are similarly situated, please accept this formal objection to the changes to 21 NCAC 16Q, et seq that have been proposed by the North Carolina State Board of Dental Examiners.

The proposed rules seek to eliminate the minimal sedation and limited moderate sedation permits entirely without any gradual phase-out nor a grandfather provision.

The proposed rules would limit anxiolysis to a single dose of the MRD of a single sedative or nitrous oxide, not both, unless the dentist has an intravenous moderate sedation permit. This would be by far the most restrictive dental sedation rule in the country. Every other state allows a dentist to combine at least the MRD of a single with nitrous in order to achieve anxiolysis or minimal sedation (depending on how the state defines those levels of sedation). No one has satisfactorily explained why on earth intravenous (IV) training is necessary in order to give a small amount of oral sedative in combination with nitrous.

There were at least two tragic dental sedation deaths. One of those was IV sedation! The other one was an oral sedation case where the dentist sedated a patient who was not a candidate for oral sedation (sleep apnea) and also had a bad reaction to the sedative in a previous appointment. Thus the dentist shouldn't have tried to sedate the patient second time. Why is the board punishing the 202 permit holders for the negligence of one dentist?

It has been suggested that these changes will bring dental sedation more in line with the medical side. If that was true, then (1) they might as well eliminate nitrous in dentistry because medicine doesn't use it, and (2) they might as well eliminate the single-operator anesthetist since medicine doesn't use that model.

The only thing these overly restrictive rules will accomplish is a severe drop in access to care. Fearful patients will avoid the dentist altogether instead of paying more to the select few IV sedation dentists...and oral surgeons don't provide general and restorative dentistry. If the dental patients of North Carolina knew what was being done under the conspicuously suspicious guise of "safety," *they would demand the RRC reject this proposal and send it back to the board with instructions to balance safety and efficacy.*

For these reasons, I/we respectfully request that the RRC do just that. Thank you for your time and consideration.

Sincerely,

John P. Bitting, Esq.
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From: Hammond, Abigail M [abigail.hammond@oah.nc.gov]
Sent: Friday, March 11, 2016 9:24 AM
To: John Bitting
Subject: RE: 21 NCAC 16Q

Good afternoon,

There has been discussion by the Rules Review Commission about the staff staying within the timelines set by the Commission's rules. Do you have written comments prepared that you could provide today?

Thank you,
Abby

From: John Bitting [mailto:John.Bitting@b2dmarketing.com]
Sent: Friday, March 11, 2016 12:17 PM
To: Hammond, Abigail M <abigail.hammond@oah.nc.gov>
Subject: RE: 21 NCAC 16Q

Just written objection, but looks like they were due this past Tuesday 3/8 before 5pm your time. Thank you.

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From: Hammond, Abigail M [abigail.hammond@oah.nc.gov]
Sent: Friday, March 11, 2016 9:09 AM
To: John Bitting
Subject: RE: 21 NCAC 16Q

Good afternoon,

For the March 17, 2016 RRC meeting, I just wanted to clarify. Do you want to have a written comment before the Rules Review Commission for their review? The rules pertaining to written comments and requests to speak are provided on the agenda:

<http://www.ncoah.com/rules/rrc/meetings/Agendas/March%202016/MeetingAgenda.html>

Please see 26 NCAC 05 .0103 and 26 NCAC 05 .0105. After looking at those rules, please let me know if you have any requiring questions or concerns.

Thank you,
Abby

*Abigail M. Hammond
Counsel to the Rules Review Commission
Office of Administrative Hearings
Direct Dial: (919) 431-3076*

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From: John Bitting [<mailto:John.Bitting@b2dmarketing.com>]
Sent: Friday, March 11, 2016 11:52 AM
To: Hammond, Abigail M <abigail.hammond@oah.nc.gov>
Subject: RE: 21 NCAC 16Q

Abigail,

Is there still time to register objections to 21 NCAC 16Q in time for the 3/17 rules commission meeting?

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From: Hammond, Abigail M [abigail.hammond@oah.nc.gov]
Sent: Monday, February 22, 2016 2:23 PM
To: John Bitting
Subject: Re: 21 NCAC 16Q

Thursday, March 17th.

From: John Bitting <John.Bitting@b2dmarketing.com>
Sent: Monday, February 22, 2016 4:58:05 PM

To: Hammond, Abigail M
Subject: RE: 21 NCAC 16Q

Abigail,

Thank you for this quick response. What is the date of the March meeting? I couldn't find it on the NCOAH site.

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From: Hammond, Abigail M [abigail.hammond@oah.nc.gov]
Sent: Monday, February 22, 2016 1:29 PM
To: John Bitting
Subject: RE: 21 NCAC 16Q

Good afternoon,

Thank you for the email below. Please note that the rules were not reviewed at this month's Rules Review Commission meeting, but should be before the Commission at the March meeting. Here is the Board of Dental Examiners request:

<http://www.ncoah.com/rules/rrc/meetings/Agendas/February%202016/Dental%20Board%20req%20for%20extension.pdf>

And here is the agenda for last week's meeting:

<http://www.ncoah.com/rules/rrc/meetings/Agendas/February%202016/MeetingAgenda.html>

If you have any procedural questions about the review of these rules, please let me know.

Thank you,
Abby Hammond

Abigail M. Hammond
Counsel to the Rules Review Commission
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From: John Bitting [<mailto:John.Bitting@b2dmarketing.com>]
Sent: Monday, February 22, 2016 4:20 PM
To: Hammond, Abigail M <abigail.hammond@oah.nc.gov>
Subject: 21 NCAC 16Q

Abigail,

What is the status after last week's meeting of the new dentistry sedation rules? Approved or sent back to the board? Any substantive changes? If so, what is the effective date?

Thank you.

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Hammond, Abigail M

From: DrDave77@aol.com
Sent: Friday, March 11, 2016 12:34 PM
To: Hammond, Abigail M
Cc: John@DOCSeducation.com
Subject: Fwd: Opposition to proposed change in sedation regulations

Please find below an email which I submitted to the NC State Board of Dental Examiners opposing the changes in sedation regulations. When I reviewed the comments to this regulation on your web site I discovered that my email is not among those included. If possible, could you add my email to the comments since they were submitted well in advance of the submission requirements for your meeting?

Thank you,
David Mayberry

From: DrDave77@aol.com
To: bwhite@ncdentalboard.org
CC: John@DOCSeducation.com
Sent: 8/4/2015 9:43:33 A.M. Eastern Standard Time
Subj: Opposition to proposed change in sedation regulations

August 3, 2015

David J. Mayberry, DDS, PA
1539 East Innes Street
Salisbury, NC 28146

Attention: Bobby White (bwhite@ncdentalboard.org)

I am first and foremost writing to express my strong opposition to the proposed changes in the oral conscious sedation permit requirements in North Carolina. The history of sedation regulation by the NC State Board of Dental Examiners gives me confidence that the Board will take its obligation seriously to protect the general public, as well as its obligation to allow dentists to provide care in a manner that best benefits the patient.

I have provided oral conscious sedation since 2006 in my office without incident. When I began offering oral conscious sedation in 2006, after a thorough training course from the Dental Organization for Conscious Sedation (DOCS), I was told by the NC State Board of Dental Examiners that they did not even have an application for an oral sedation permit and they would let me know when a permit would be required. After much discussion by the Board, hearings, and extensive input from the dental community including many of the practitioners who were providing conscious sedation, the Board developed a permitting process and licensing requirements that were both fair to the dentists and provided protection for the patients. In doing so, the Board rightfully resisted pressure from those who were advocating regulations similar to those that are proposed today. In the spring of 2008 the NC State Board began the process of instituting an application and permitting procedure. Since that time there has been no incident of an adverse outcome from oral sedation provided in compliance with the

regulations established by the Board. Certainly, if nothing else, this is evidence that the regulations currently in place are working to effectively protect the citizens of North Carolina.

Unfortunately, due to two recent sedation related deaths in NC, the current sedation regulations have been called into question and drastic changes to the process proposed, including the elimination of any oral sedation permit. The reality is that these deaths were not the result of inadequate regulations, nor were they the result of inadequate training. One of the deaths was an IV Sedation patient where the Board ruled the dentist failed to properly dose the patient and failed to recognize and manage a medical emergency when it occurred. Obviously, eliminating the oral sedation permit would not have had an effect on this situation.

The other was an oral sedation patient where the Board ruled the dentist failed to recognize the patient was not a good candidate for oral sedation, ignored warnings from her assistant concerning the patient's condition, and also failed to manage a medical emergency. Neither of these deaths resulted from inadequate training, but were the result of the dentists ignoring the protocols they were taught and a subsequent failure to adequately monitor their patients and to handle medical emergencies.

It is my understanding that the regulations currently under consideration would require a 90 hour IV training program in order to provide any type of in office sedation. After searching for such programs, I can find none that fit this requirement other than general practice residency programs in general anesthesia. Adoption of this requirement would make it virtually impossible for my highly apprehensive patients to receive dental care, and definitely make it impossible for them to receive care in my office where they have come to feel comfortable and safe. The availability of dentistry to this population would be severely reduced and likely limited to a hospital setting with a significant increase in cost and I expect resulting in a large number of patients dropping out of care. Even with the burdensome training that is being proposed, there is no guarantee that a practitioner will follow the guidelines and protocols they are taught. To me, the proposals currently being considered are analogous to an individual driver ignoring the posted speed limit resulting in an accident and death and the DMV deciding to cancel everyone's drivers license in the state and requiring drivers to take 90 hours of drivers training before they can get their license back.

As a dentist who has safely provided oral conscious sedation since before the current guidelines were put into place, and who participated in the conversation that resulted in the current regulations, I strongly urge the Board to thoughtfully consider what they are trying to accomplish. If the goal is the protection of the patient, while at the same time giving the patient reasonable access to care, then the evidence supports continuing the current regulations. If the Board feels there is evidence to support the need for additional training, then I would suggest focusing on options that might be more effective in addressing those concerns without resorting to the "nuclear option. At this point I have seen no evidence to support the benefit of changing the training requirements from 24 hours to 90 hours for oral sedation.

I am further concerned that the proposed NC regulations differ greatly from the current ADA Guidelines, approved in 2012, for the Use of Sedation and General Anesthesia by Dentists as well as the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. The current ADA guidelines are nearly perfectly aligned with the current regulations in North Carolina. I am aware that the ADA has called for comments on revisions to their guidelines, but these have yet to be considered and are being met with considerable resistance.

Here are some specific concerns I have about the new guidelines. A sedation permit is not required to administer nitrous oxide without any other drugs for the purpose of anxiolysis but is required if administered in combination with any other drug. What if the patient has an Rx for Valium or Xanax?

Would this mean that a patient who routinely takes Xanax for sleep every night would not be eligible for Nitrous Oxide for their dental appointment the next day.

In the proposed guidelines anxiolysis is defined as the pharmacological reduction of anxiety through the administration of a single dose of any anti-anxiety drug within a 24 hour period. This would mean that the anti-anxiety regimen I was taught in dental school, and have used safely for 35 years, of prescribing a patient Valium to take the night before a dental appointment and a second dose an hour or two before dental treatment would no longer be allowed and would also rule out any possibility of the use of Nitrous Oxide and oral medications without the new IV sedation permit. Even the new proposed ADA guidelines still allow for minimal conscious sedation and would allow a combination inhalation-enteral sedation with only a requirement of a 16 hour course and certainly two BLS certified assistants are not required.

I have followed explicitly every requirement of the NC Board of Dental Examiners to earn my sedation permit and in some areas exceeded the requirements. This includes regular training for my staff with monthly medical emergency mock drills, training for my staff in monitoring sedated patients, the purchase of equipment that cost several thousands of dollars including electronic equipment with audible alarms and an AED, maintaining emergency drugs and equipment as required, an initial facility inspection, providing annual BLS training for all of my staff including not just my dental assistants and dental hygienists but even my receptionist, exceeding the annual CE requirements every year, written emergency protocols, and maintaining a current ACLS certification which was not required.

It is my hope that the NC Board of Dental Examiners will use a common sense and an evidence based approach to evaluate the new proposed regulations. I am convinced that such an evaluation will determine that there is no evidence that drastically changing the current regulations will result in a safer environment for patients, but instead will result in significant financial hardships and inadequate care for our anxious patients.

Sincerely,

David J. Mayberry, DDS

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