

Q & As on Sedation and Anesthesia Permits and Inspections

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Questions for the VA Board of Dentistry Regarding Sedation and Anesthesia Permits and Inspections Submitted by the Virginia Dental Association

ANSWERS Added by Sandra K. Reen, Executive Director, Virginia Board of Dentistry

1. Once the Board has received an application and paperwork for a sedation permit, how long does it take for the dentist to receive the permit (assuming all requested material is supplied, etc.)?

ANSWER: Generally speaking, complete applications which document that an applicant meets the requirements for the selected type of permit are processed and the permit is issued within five business days. If the documents received raise questions about an applicant's qualifications, action on the application will be delayed until the questions are resolved.

2. If a dentist's permit application is denied due to a clerical mistake or error on the application, what are the measures that the dentist can take to rectify the application?

ANSWER: Submit the correct information with a written explanation of the error.

3. Who reviews the permit applications and has the authority to approve or deny them?

ANSWER: The executive director of the Board of Dentistry (the Board) is authorized to grant permits when it is evident that the applicant meets the requirements. When the executive director determines that an application is incomplete and when it is not evident that the applicant is qualified, she will notify the applicant of the presenting issue and request additional information and/or request an investigation of the applicant's qualifications and the truthfulness of the information provided in the application. In either case, once the executive director has the needed information, she might grant the permit or notify the applicant that she is unable to grant it because the applicant's eligibility is in question because of the presenting issue. The notice advises the applicant that the application can only be considered further by submitting a request for an informal conference with a Special Conference Committee of the Board. Only a Special Conference Committee through an informal conference or the Board through a formal hearing has the authority to deny an application.

4. If a dentist decides to no longer administer conscious/moderate and deep sedation after obtaining a permit, is he/she still required to complete the survey and will he/she be subject to an office inspection? (For example, a dentist obtains a permit on April 1, 2014 and stops administering sedation/anesthesia on August 1, 2014). Many members would like some clarification and guidance on cancelling permits should they decide to no longer administer sedation/anesthesia.

ANSWER: There is no provision of law which authorizes the Board to accept surrender of a license without making the surrender public information. In order for the Board to accept surrender of an active permit, the holder will need to agree to enter into a consent order in which he/she voluntarily surrenders the permit. This consent order would be a public record with the Board and would be available to the public online. The alternative to surrender is that the permit holder can let his/her permit expire on March 31, 2015 or any subsequent renewal date.

5. Can dentists suspend their permits temporarily should they go on leave for any reason?

ANSWER: No, a permit will remain in active status until it expires or the Board accepts surrender

and records the permit as null and void.

6. Why has the Board decided that the inspections must be unannounced and not scheduled?

ANSWER: The Department of Health Profession's policy of conducting unannounced inspections was affirmed by the Director of the Department to the Board of Veterinary Medicine in the 1990's and most recently by the current Director to the Board of Pharmacy. Here is the excerpt from the minutes of the Board of Pharmacy's June 4, 2014 meeting:

Dr. Brown discussed with the Board his decision regarding the request from the March 26, 2014 board meeting for inspectors to give pharmacies a 24-hour notice for routine inspections. He acknowledged that this was not a small decision and that he had researched the matter. During his research of several other state agencies, he learned that none conduct announced inspections. Dr. Brown commented that providing notice, even short notice, may compromise the inspector's ability to identify non-compliance with certain requirements. Additionally, providing longer notice does not appear to offer a more efficient inspection process as it is unlikely that additional staff will be routinely scheduled for the 3 months in which an inspection could randomly be performed. Dr. Brown stated that the goal of an inspection program is not to catch someone doing something they shouldn't, but to create a culture of compliance. He stated that communication is important for ensuring the licensees know what to expect during an inspection and that we may need to create a better system of communication and utilize the assistance of the associations for solutions.

7. In the Board's minutes from their June 13th meeting it is stated that "Ms. Yeatts explained that unannounced inspections are a statewide policy in keeping with the state's interest in promoting a culture of compliance." Who set this statewide policy?

ANSWER: The quote from the draft minutes noted above is another person's summary of Ms. Yeatt's remarks. Ms. Yeatts advised that it is correct to say that unannounced inspections are the policy of this and other agencies in Virginia.

8. What was the name of the committee that initially established the inspection guidelines and made the decision to do unannounced inspections?

ANSWER: The Regulatory/Legislative Committee reviewed and developed the draft guidance document and draft inspection form which were prepared and presented by the Board's executive director. The Board decided to do unannounced inspections at its June 13, 2014 meeting.

9. If an inspector shows up to an office and the dentist and staff are busy treating a patient, will the inspector wait for the treatment to be completed so as not to be disruptive to the care? Isn't there concern that this would interfere with patient care?

ANSWER: The Department of Health Professions' inspectors who will be conducting the dental office inspections for permit holders routinely do unannounced inspections for the health regulatory boards. The inspector will:

- arrive at the practice and let the receptionist know who he/she is, provide identification, and ask to speak to the permit holder or the office manager,
- introduce himself/herself to the permit holder and/or office manager, get information on the permit holder's scheduled activities and explain how the inspection will proceed,
- request guidance on where to locate the needed types of information in the practice,

- coordinate the inspection activities with the permit holder and/or office manager to minimize disruption of patient care,
- complete the inspection, and
- review preliminary results with the permit holder and/or office manager before leaving.

The inspectors are experienced professionals who will work to prevent or minimize patient disruption.

10. Who will be doing the inspections and what are the qualifications of the inspectors?

ANSWER: The Department of Health Professions' inspectors and investigators will be conducting the dental office inspections. They are sworn officers of the Commonwealth charged with enforcing the laws applicable to health professions, and the rules and regulations of the 13 health regulatory boards in the Department of Health Professions pursuant to §54.1-2506 of the Code of Virginia. The required qualifications for these positions include:

- experience in conducting inspections or investigations,
- coursework in health, criminal justice, paralegal or an equivalent combination of education and experience,
- comprehensive knowledge, skills and abilities related to inspection and/or investigative techniques to include interviewing, data collection and the analysis of complex records and reports, and
- excellent verbal and written communication skills, including impartiality and objectivity.

The strongly preferred qualifications for these positions include:

- licensure or certification as a health care practitioner,
- graduation from an accredited health care program, and
- experience working as a health care professional and/or regulatory or law enforcement professional.

11. Is there consideration for contracting with an outside organization of clinicians with training in anesthesia to conduct the inspections similar to how the oral & maxillofacial surgeons are inspected by their association?

ANSWER: Not currently because the Board uses the resources of the Department of Health Professions to meet this staffing need. The Board, as one of the 13 health regulatory boards in the Department, shares in the use of the full-time, trained professional inspectors and investigators who are employed for the sole purpose of conducting inspections and investigations for the boards.

12. Were these regulations and the approach of permits and inspections a result of **fatalities** occurring in Virginia dental offices where sedation was administered?

ANSWER: The Board began exploring a proactive approach in regulating sedation practices as a result of investigations of numerous cases addressing fatalities, adverse reactions, as well as egregious practices related to sedation and the treatment of patients while under sedation. The Board learned that Virginia was one of only a handful of states which did not require permits and conduct some form of inspection of sedation practices. The Board decided it wanted to implement an inspection program of offices where sedation is practiced. The Board has long standing authority, granted by §54.1-2703 of the Code of Virginia, to inspect dental practices. It also has long standing regulatory requirements for the administration of sedation and anesthesia. The authority to issue permits was obtained so that the Board could identify the locations where sedation is administered and to verify the educational qualifications of the dentists administering sedation. The regulatory requirements for administration were expanded effective September 14, 2012 to address:

- the requirements for permits,
- the findings that resulted from the investigations as addressed above, and

- the national standards of professional organizations including the American Dental Association and the American Academy of Pediatric Dentistry.

The final regulations issued on May 7, 2014 included clarifying changes to the requirements which have been in effect since September 14, 2012.

13. If these inspections are only for offices doing sedation and anesthesia, why do these inspections include many other aspects of our offices (i.e. Record keeping, office cleanliness, OSHA , etc.)?

ANSWER: The purpose of the periodic inspections is to verify that permit holders are appropriately prepared, staffed and equipped to sedate patients and to treat patients who are under sedation in compliance with the protections accorded to patients in the Regulations Governing the Practice of Dentistry and the laws applicable to health professionals. Patients being treated under conscious/moderate sedation, deep sedation and general anesthesia are the patients who are the most vulnerable to serious harm if all the safety and record keeping requirements associated with their sedation and dental treatment are not met.

14. How does the inspection of items such as lab slips, etc. protect a patient in regards to sedation and anesthesia?

ANSWER: The Board's interest extends beyond assessing the readiness of a permit holder to administer sedation and anesthesia to include the readiness of the permit holder to safely and competently treat patients who are sedated. The recordkeeping requirements, including lab slips, and the other requirements which apply to all dental treatment do apply and must be in place when such treatment includes sedation and anesthesia.

15. In the Board's minutes from their June 13th meeting it states that "Ms. Reen said that the Board's interests and inspection resources are different from those of AAOMS, which is a membership organization." In the AAOMS Office Anesthesia Evaluation Manual it states that their program "was designed to assure that each practicing AAOMS member maintains a properly equipped office and was prepared to use accepted techniques for managing emergencies and complications of anesthesia in the treatment of the OMS patient in the office or outpatient setting." Please explain how the Board's interests are different from AAOMS's purposes of their examinations.

ANSWER: The purpose of the Board's periodic inspections is to verify that permit holders are appropriately prepared, staffed and equipped to sedate patients and to treat patients who are under sedation in compliance with the protections accorded to patients in the Regulations Governing the Practice of Dentistry and the laws applicable to health professionals. Patients being treated under conscious/moderate sedation, deep sedation and general anesthesia are the patients who are the most vulnerable to serious harm if all the safety and record keeping requirements associated with their sedation and dental treatment are not met.

16. In regards to the inspection form, since ephedrine is a Schedule V drug, must it be securely locked when not in use even if it is used in a drug emergency kit? It needs to be readily accessible for emergencies. If it needs to be locked up, then it will not be readily accessible for emergencies. Do records of purchase and administration need to be kept the same as schedule II-IV drugs?

ANSWER: The Virginia Board of Pharmacy advised that ephedrine is not a scheduled drug. Since it is not a scheduled drug, ephedrine is not subject to the requirements for maintenance of

scheduled drugs. Permit holders should follow the safety precautions provided with any over the counter drug maintained in his or her practice.

17. The Board lists emergency preparedness by the dental hygienist along with proper training as a criterion to be evaluated on their office inspection form. Will the Board be advising permit holders on emergency scenarios in advance of the inspection?

ANSWER: The inspectors will be checking for the written basic emergency procedures which are required for dental hygienists to practice under general supervision and for the administration of sedation. In response to comments made by oral and maxillofacial surgeons, the Board is exploring the feasibility of incorporating a testing component on emergency preparedness based on the scenario model used and advocated for by the Virginia Society of Oral and Maxillofacial Surgeons. Adding this component is in the early stages of consideration so it is not possible to predict if or when the Board might add such a component.

18. There are several items on the inspection form list that are not defined in the regulations. Will there be further guidance documents to indicate the following?

ANSWER: The items of concern were not identified to enable a response.