



Economic Impact Analysis Virginia Department of Planning and Budget

18 VAC 60-20 – Regulations Governing Dental Practice
Department of Health Professions
March 21, 2013

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 526 (Senate Bill 1146) of the 2011 Acts of the Assembly, the Board of Dentistry proposes to establish a permit program for dentists who provide or administer conscious/moderate sedation or deep sedation/general anesthesia in a dental office.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Pursuant to Chapter 526 (Senate Bill 1146) of the 2011 Acts of the Assembly, the Board of Dentistry (the Board) proposes to establish a permit program for dentists who provide or administer conscious/moderate sedation or deep sedation/general anesthesia in a dental office.

Sedation and anesthesia are provided by dentists to reduce patient anxiety about undergoing dental treatment and to eliminate pain during the procedure. According to the Department of Health Professions (DHP), the use of sedation and anesthesia in dental practices has increased significantly and the offer of “sedation dentistry” is frequently used in advertising to attract patients in recent years. The use of controlled substances in dentistry brings with it the risks of adverse reactions and even death.

Since 2007, the Board has received 10 reports of patients needing emergency or follow-up care after receiving dental treatment under sedation or anesthesia. While seven of these incidents were minor in nature, three were highly publicized critical incidents involving children. Each of those three incidents resulted in the death of a child. Through its investigation, the Board has learned that children under the age of 12 are particularly susceptible to having extreme

adverse reactions to sedation and anesthesia. The Board also found that the treating dentists failed to properly monitor and record vital signs and pulse oximetry readings. In at least one of these cases, excessive medication was administered, the sedatives were administered by unlicensed personnel and the parents were left alone with their unmonitored children following administration of the pre-operative medications. Additionally, the Board found that Virginia is currently one of only four states that do not require dentists to obtain permits to administer sedation and anesthesia in a dental practice.

Also, the Board has received three petitions for rulemaking advocating for regulatory changes in the area of sedation and anesthesia (one in 2008 and two in 2009) and numerous public comments made at Board meetings asking the Board to update and strengthen its regulations for administration. Two of the petitions for rulemaking specifically advocate that dentists be required to prove they have the training required to administer sedation and anesthesia through a registration or permit process and further encourage periodic inspection of dental practices using sedation and anesthesia. When these petitions were considered, the Board was advised by legal counsel that legislative authority was needed before permits could be required.

Current regulations have required dentists to have appropriate training, trained auxiliary personnel and patient monitoring equipment in order to administer sedation and anesthesia. Dentists have been also required to report adverse patient reactions to such administration. However, based on the pre-emergency legal authority of the Board, compliance with these requirements to ensure patient safety was only checked by the Board after a complaint or an adverse reaction report is received.

As a result, in 2011, legislation was introduced at the request of DHP and the Board to establish a permit program for administration of sedation and anesthesia in dentistry. The legislation required that the Board promulgate emergency regulations which became effective September 14, 2012.

The proposed regulations will permanently replace emergency regulations currently in effect. The proposed regulations do not introduce any new education or training requirements for administration of sedation and anesthesia in a dental practice. They, however, require a dentist to obtain a permit to practice sedation or anesthesia dentistry. The Board proposes to establish a

\$100 annual permit fee for both types of permits. A \$35 late fee is also proposed which is consistent with fee structures of other regulated professions. It is not known at this time whether these fees will be sufficient to cover the Board's administrative expenses associated with issuance of permits, inspections, and taking corrective actions.

The emergency regulations require all dentists who administer moderate sedation/conscious sedation or deep sedation/general anesthesia in dental offices to obtain a permit by March, 2013. Dentists who were "self-certified" (no formal education or training required) prior to January 1989 will be allowed to hold a temporary permit until September 14, 2014 to allow adequate time to obtain the appropriate qualifications for administration of conscious/moderate sedation. As of March 18, 2013 there were 132 moderate/conscious and 18 deep sedation/general anesthesia permits issued. Many additional permit applications are expected to be received by DHP before the deadline. However, the Board has no estimate of the number of permits that will be issued before the end of March, 2013.

In addition, the proposed regulations require certain equipment to be able to administer sedation or anesthesia. The additional emergency equipment that must be available in the areas where patients are sedated and recover from sedation or anesthesia include a defibrillator, an electrocardiographic monitor (EKG)¹, a suction apparatus, a temperature measuring device, a throat pack, and a precordial or pretracheal stethoscope. The cost of this equipment represents additional compliance costs to the dentists wishing to administer sedation and anesthesia in their office. According to DHP, an EKG machine and a stethoscope are the most expensive equipment costing approximately \$2,000 and \$700, respectively.

The emergency regulations required an EKG machine for any type of moderate sedation while these permanent proposed regulations do not require an EKG machine for moderate sedation administered in a single dose by an enteral method. Thus, a number of dentists may have already acquired an EKG machine due to the equipment requirements set out in the emergency regulations that may not be required to have it under the proposed permanent regulations. While these dentists have already incurred the additional compliance costs, some of them may chose to sell their EKG machines to recover some of their original purchase costs.

¹ EKG is not required for moderate sedation administered in a single dose by an enteral method.

The main expected benefit of the proposed permit program is to strengthen compliance with the existing requirements. Sedation and anesthesia permits are expected to advance patient safety by enabling proactive oversight by the Board through periodic inspections. The permits will enable the Board to implement a periodic inspection program of the practices where sedation and anesthesia are administered to verify that 1) the treating dentist has the necessary education and training to safely administer controlled substances and to perform life saving interventions when adverse reactions occur, 2) required patient monitoring and safety equipment is present, is maintained in working order, and that personnel are properly trained in its use, and 3) auxiliary personnel have the required training and are assigned duties within the parameters established in the regulations.

Given the significant risk of death due to errors in administration of sedation and anesthesia and follow up care, to the extent that the permit program will reduce this risk, the proposed amendments should create a net benefit.

Businesses and Entities Affected

The proposed regulations will specifically affect dentists who wish to administer sedation and anesthesia in their offices. As of March 18, 2013 there are 132 moderate/conscious and 18 deep sedation/general anesthesia permits issued. Many additional permit applications are expected to be received by DHP before the deadline. However, the Board has no estimate of the number of permits that will be issued before the end of March, 2013.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

The proposed regulations will require dentists wishing to administer sedation and anesthesia in their offices to pay for the permit fee and purchase necessary equipment if they do not currently have it. Added compliance costs may discourage sedation and anesthesia dentistry by a small margin and reduce supply of sedation and anesthesia dentistry services. However, this possible change in supply is not likely to cause a significant reduction in employment.

Effects on the Use and Value of Private Property

Added compliance costs due to the permit fees and the required equipment would negatively affect profitability of dentists administering sedation and anesthesia in their offices and consequently their asset values.

Small Businesses: Costs and Other Effects

There are 3,049 dental offices in Virginia. All of these dental practices are small businesses. The proposed changes will add to their compliance costs in terms of the permit fees and cost of the required equipment if they wish to use sedation and anesthesia in their practice.

Small Businesses: Alternative Method that Minimizes Adverse Impact

There is no known alternative method that minimizes the adverse impact on small businesses while accomplishing the same goals.

Real Estate Development Costs

No impact on real estate development costs is expected.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, Section 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of

achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.