Adverse impact notification sent to Joint Commission on Administrative Rules, House Committee on Appropriations, and Senate Committee on Finance (COV § 2.2-4007.04.C): Yes ☒ Not Needed ☐

If/when this economic impact analysis (EIA) is published in the *Virginia Register of Regulations*, notification will be sent to each member of the General Assembly (COV § 2.2-4007.04.B).

Virginia Department of Planning and Budget

Economic Impact Analysis

12 VAC 30-120 – Regulations Governing the Practice of Medicine, Osteopathy, Podiatry and Chiropractic
Department of Health Professions
Town Hall Action/Stage: 4272/7315
October 14, 2015

Summary of the Proposed Amendments to Regulation

In response to a petition for rulemaking from the Medical Society of Virginia, the Board of Medicine (Board) proposes to amend its requirements for office-based anesthesia to: 1) define the administration of 300 milligrams or more of lidocaine (or equivalent doses of local anesthetics) as moderate sedation that is subject to the requirements of this regulation, 2) limit the duration of a procedure that include sedation that falls under the requirements of this regulation to last no longer than four hours if the anesthesia is not administered by an anesthesiologist or a certified registered nurse anesthetist or eight hours if anesthesia is administered by one of these entities and 3) define "reasonable proximity" for the safe transfer of patients to a hospital in case of an emergency as "accessible within 30 minutes of the office". The Board also proposes several clarifying changes that will likely not affect costs.

Result of Analysis

There is insufficient information to ascertain whether benefits will outweigh costs for one proposed substantive change. Benefits likely outweigh costs for all proposed clarifying changes and the two other proposed substantive changes.

Estimated Economic Impact

Current regulation applies to "the administration of moderate sedation/conscience sedation, deep sedation, general anesthesia or regional anesthesia consisting of a major conductive block" in an office setting. On the recommendation of the Medical Society of Virginia, and particularly plastic surgeons that are part of that group, the Board proposes to also require that any procedure that involves the administration of 300 milligrams or more of lidocaine (or equivalent doses of local anesthesia) be subject to this regulation. This would mean that doctors who choose to use lidocaine or other local anesthetics in the described dosages as a part of an office surgery or procedure would newly have to follow all the requirements laid out in this regulation including: ensuring a pre-anesthetic check-up is performed, developing an anesthesia plan and having written protocols for office-based anesthesia, procedure selection and patient evaluation. Doctor's offices where such procedures are performed would also newly be required to be within reasonable proximity of a licensed general hospital capable of providing necessary emergency services (within 30 minutes' drive, according to the proposed regulation).

This new requirement will likely increase costs (or decrease revenue) for doctors who perform office-based procedures or surgeries under lidocaine or other local anesthetics; these doctor's will either incur additional bookkeeping and other time costs for any procedure that requires these local anesthetics, have to stop performing those procedures if they know or suspect that the patient will require 300 milligrams or more of lidocaine (or equivalent for other local anesthetics) or will have to switch to other, presumably less optimal, forms of anesthesia. Specifically, doctors will definitely incur additional costs that accrue on a per patient basis (such as time spent either performing pre-anesthesia checkups or ensuring that such checkups have been performed) but will only incur time and other costs for writing and keeping required protocols if they only perform in-office surgeries that are currently exempt from this regulation but will not be exempt under the proposed regulation. Doctors who now only perform surgery and procedures requiring minor, local or topical anesthesia and whose offices are more than 30 minutes from a hospital would either have to move offices, switch to using other, presumably less optimal, anesthesia or stop performing the surgeries they now offer altogether. Affected patients will likely also incur costs on account of pre-anesthesia checkup requirements as well as other requirements that would extend the time and doctor resources required to care for them.

Research indicates that lidocaine is given in doses that vary according to the weight of the patient. Specifically, Drugs.com[1] reports that the usual adult dose for lidocaine used as a local anesthetic "varies with procedure, degree of anesthesia needed, vascularity of tissue, duration of anesthesia required and physical condition of (the) patient" but can go up to a maximum dosage of 4.5 milligrams per kilogram of weight not more than every two hours. The website for the University of Iowa Healthcare System[2] reports that the maximum safe dosage of lidocaine without epinephrine for pediatric patients is 4 milligrams per kilogram of weight. This means that for adults, any procedure involving administration of the maximum safe dosage of lidocaine for patients weighing more than approximately 147 lbs.[3] would automatically fall under the more stringent rules for moderate or deep sedation or general anesthesia even if that patient is in excellent general health and would otherwise not need the heightened scrutiny and care plans required under this regulation.

In addition to disproportionately affecting patients that weigh more than 147 pounds, this requirement may have a disproportionate adverse impact on patients that live in rural parts of Virginia that do not have a local hospital within 30 minutes. Patients that now can have minor procedures or surgeries involving lidocaine (300 milligrams of more) in a local doctor's office would, under the proposed requirement, have to incur travel expenses, and possibly higher medical costs to have that procedure or surgery done either at a hospital or at a non-local doctor's office that is close enough to a hospital to meet the requirements of this regulation. All of these potential costs would have to be measured against the possible benefits to patients of limiting the absolute amount of lidocaine that can be used in a procedure without enhanced requirements kicking in. There is currently insufficient information on the magnitude of potential benefits that may accrue on account of this change to ascertain whether benefits will outweigh costs.

Current regulation does not set a limit on the duration of in-office surgeries using moderate sedation/conscience sedation, deep sedation, general anesthesia or regional anesthesia consisting of a major conductive blocks but only requires that such surgeries be "of a duration and degree of complexity that will permit the patient to recover and be discharged from the

[1] http://www.drugs.com/dosage/lidocaine.html
[2] https://wiki.uiowa.edu/display/protocols/Maximum+Recommended+Doses+and+Duration+of+Local+Anesthetics

[3] 300/4.5= 66.6666666667 kilograms which is just shy of 147 pounds

facility in less than 24 hours". The Board now proposes to specify that surgeries occurring under the auspices of this regulation may last no longer than four hours if the anesthesia is not administered by an anesthesiologist or a certified registered nurse anesthetist or eight hours if anesthesia is administered by one of these entities. Because research indicates[4] that the odds of a whole host of potential side effects and adverse outcomes increase as the length of time spent under anesthesia increases, patients will likely benefit from this restriction. Patient benefits will likely outweigh any costs doctors incur for not being able to perform surgeries over four (or eight) hours in their offices.

Current regulation requires that doctors who perform in-office surgery using moderate sedation/conscience sedation, deep sedation, general anesthesia or regional anesthesia consisting of a major conductive blocks be able to transfer their patients to a hospital in "reasonable proximity" to their office. The Board now proposes to specify that reasonable proximity is within 30 minutes of the doctor's office. Although the actual specified time is new, it is likely that the Board already enforced this provision using the same or similar time limits. In any case, all affected entities in both the regulated and regulating community will likely benefit from the additional certainty that this change will bring.

Businesses and Entities Affected

Board staff reports that these changes will potentially affect all Board licensed doctors of medicine, osteopathy and podiatry that perform surgeries in their offices as well as all of these doctors' patients.

Localities Particularly Affected

Rural communities that are not in close proximity to a hospital will be disproportionately affected by these proposed changes.

Projected Impact on Employment

These proposed changes may moderately decrease employment in doctor's offices that currently are not subject to these regulations but will become subject to them on account of the proposed changes.

[4] See, for instance, "Duration of General Anesthesia and Surgical Outcome": Yoho, Robert, et. al. (http://www.dryoho.com/dr-yoho/clinical/duration_anesthesia.pdf). This study notes that research found the odds of patient death, post-operative nausea and vomiting, venous thromboemboli, post-operative surgical site S. aureus infection, post-operative core hypothermia and cardiopulmonary complication increased either as time under anesthesia increased or in surgeries over a certain duration (in this study, either two or three hours).

Effects on the Use and Value of Private Property

The value of some medical, osteopathic or podiatric practices may decrease if they incur costs on account of these proposed changes.

Real Estate Development Costs

These proposed changes will likely not affect real estate development costs.

Small Businesses:

Definition

Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects

Small business doctors will likely incur additional costs that accrue on a per patient basis (such as time spent either performing pre-anesthesia checkups or ensuring that such checkups have been performed) but will only incur time and other costs for writing and keeping required protocols if they only perform in-office surgeries that are currently exempt from this regulation but will not be exempt under the proposed regulation. Doctors who now only perform surgery and procedures requiring minor, local or topical anesthesia and whose offices are more than 30 minutes from a hospital would either have to move offices, switch to using other, presumably less optimal, anesthesia or stop performing the surgeries they now offer altogether.

Alternative Method that Minimizes Adverse Impact

Doctor's and their patients would incur fewer costs if lidocaine standards were written so that any imposed limit on the amount of lidocaine is evidence based and varies directly with the weight of the patient as that appears to be the way lidocaine is administered.

Adverse Impacts:

Businesses:

Doctors who own their practices will likely incur additional costs that accrue on a per patient basis (such as time spent either performing pre-anesthesia checkups or

ensuring that such checkups have been performed) but will only incur time and other costs for writing and keeping required protocols if they only perform in-office surgeries that are currently exempt from this regulation but will not be exempt under the proposed regulation. Doctors who now only perform surgery and procedures requiring minor, local or topical anesthesia and whose offices are more than 30 minutes from a hospital would either have to move offices, switch to using other, presumably less optimal, anesthesia or stop performing the surgeries they now offer altogether.

Localities:

Rural localities that currently do not have a hospital in close proximity (as defined by this proposed regulation) may see a disproportionate adverse impact on the availability of minor out-patient surgical services offered.

Other Entities:

The proposed changing categorization of lidocaine in doses at or over 300 milligrams (or like amounts of other local anesthetics) may have a disproportionate adverse impact on patients that live in rural parts of Virginia that do not have a local hospital within 30 minutes. Patients that now can have minor procedures or surgeries involving lidocaine (300 milligrams of more) in a local doctor's office would, under the proposed requirement, have to incur travel expenses and possibly higher medical costs to have that procedure or surgery done either at a hospital or at a non-local doctor's office that is close enough to a hospital to meet the requirements of this regulation..

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order Number 17 (2014). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(C): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

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