The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Community Affairs

BILL:	SB 380
INTRODUCER:	Senator Garcia and others
SUBJECT:	Protection from Surgical Smoke
DATE:	March 14, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Favorable**
2.	Hackett	Ryon	CA	**Pre-meeting**
3.			RC	

I. Summary:

SB 380 requires hospitals and ambulatory surgical centers to, by January 1, 2024, adopt and implement policies that require the use of a smoke evacuation system during any surgical procedure that is likely to generate surgical smoke.

The bill provides an effective date of July 1, 2023.

II. Present Situation:

Surgical Smoke

Surgical smoke is produced by the thermal destruction of tissue by use of lasers or electrosurgical devices.[1] Surgical smoke has been shown to contain toxic gases, vapors and particulates, viable and non-viable cellular material, viruses, and bacteria.[2]

Potential known health effects from the exposure to surgical smoke include eye, nose, and throat irritation; headache; cough; nasal congestion; and asthma and asthma-like symptoms, but little is known about the health effects from chronic exposure to surgical smoke.[3] Other risks include the transmission of viruses through surgical smoke, for example the transmission of Human Papillomavirus (HPV) through surgical smoke from lasers has been documented,[4] and some

[1] The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, *Health and Safety Practices Survey of Healthcare Workers*, last updated March 30, 2017, available at https://www.cdc.gov/niosh/topics/healthcarehsps/smoke.html (last visited March 2, 2023).
[2] *Id.*
[3] *Id.*
[4] *Id.*

researchers have suggested that surgical smoke may act as a vector for cancerous cells that may be inhaled.[5]

According to the Occupational Safety and Health Administration (OSHA), recognized controls and work practices for surgical smoke include:

- Using portable local smoke evacuators and room suction systems with in-line filters.
- Keeping the smoke evacuator or room suction hose nozzle inlet within two inches of the surgical site to effectively capture airborne contaminants.
- Having a smoke evacuator available for every operating room where plume is generated.
- Evacuating all smoke, no matter how much is generated.
- Keeping the smoke evacuator "ON" (activated) at all times when airborne particles are produced during all surgical or other procedures.
- Considering all tubing, filters, and absorbers as infectious waste and dispose of them appropriately.
- Using new tubing before each procedure and replace the smoke evacuator filter as recommended by the manufacturer.
- Inspecting smoke evacuator systems regularly to ensure proper functioning.[6]

While OSHA recognizes potential risk factors and remedial measures, it has not as of yet adopted regulations specific to surgical smoke.[7]

Additionally, the Joint Commission, a major accrediting non-profit organization for hospitals and ambulatory surgical centers, recommends the following actions to protect patients and staff from the dangers of surgical smoke:

- Implement standard procedures for the removal of surgical smoke and plume through the use of engineering controls, such as smoke evacuators and high filtration masks.
- Use specific insufflators for patients undergoing laparoscopic procedures.
- During laser procedures, use standard precautions to prevent exposure to the aerosolized blood, blood by-products and pathogens contained in surgical smoke plumes.
- Establish, review, and make available policies and procedures for surgical smoke safety and control.
- Provide surgical team members with initial and ongoing education and competency verification on surgical smoke safety, including the organization's policies and procedures.
- Conduct periodic training exercises to assess surgical smoke precautions and consistent evacuation for the surgical suite or procedural area."[8]

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[5] United States Department of Labor, Occupational Safety and Health Administration, *Surgical Suite >> Smoke Plume*, available at https://www.osha.gov/etools/hospitals/surgical-suite/smoke-plume, (last visited March 9, 2023).
[6] *Id*.
[7] United States Department of Labor, Occupational Safety and Health Administration, *Laser/Electrosurgery Plume*, available at https://www.osha.gov/laser-electrosurgery-plume/standards (last visited Mar. 9, 2023).
[8] The Joint Commission, *Quick Safety Issue 56: Alleviating the Dangers of Surgical Smoke*, available at https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-56/quick-safety-issue-56/ (last visited March 9, 2023).

Smoke Evacuation Systems

Smoke evacuators are devices which contain a suction unit (i.e. a vacuum), filter, hose, and inlet nozzle. They are designed, as recommended by the Center for Disease Control, to capture air from where the nozzle is targeted and filter the air through a High Efficiency Particulate Air (HEPA) filter. [9] These systems may be stationary, with permanent construction requirements, or handheld portable systems with disposable filters, hand pieces, and hoses. While costs for these products range greatly, with installation of a stationary system far more costly than more common handheld systems, recurring costs associated with disposable parts for handheld systems are frequently cited at roughly $19 per surgery, and total recurring costs including filter replacement between $8,000 and $10,000 annually depending on frequency of use.[10]

As of 2021, 21 states had considered legislation requiring smoke evacuator usage during surgery.[11] At least 10 states[12] have passed laws requiring that operating rooms are made free of surgical smoke.[13]

III. Effect of Proposed Changes:

SB 380 creates s. 395.1013, F.S., to require that hospitals and ambulatory surgical centers (ASC)[14] adopt and implement policies that require the use of a smoke evacuation system during any surgical procedures that is likely to generate surgical smoke.

The bill defines:

- "Smoke evacuation system" to mean equipment that effectively captures, filters, and eliminates surgical smoke at the site of origin before the smoke makes contact with the eyes or respiratory tract of occupants in the room; and
- "Surgical smoke" to mean the gaseous byproduct produced by energy-generating devices such as lasers and electrosurgical devices. The term includes, but is not limited to, surgical

[9] Centers for Disease Control, *Control of Smoke from Laser/Electrical Surgical Procedures*, available at https://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html (last visited Mar. 9, 2023).
[10] *See* Relias Media, *OR Teams Often Exposed to Toxic Chemicals in Surgical Smoke*, Mar. 1, 2021, available at https://www.reliasmedia.com/articles/147530-or-teams-often-exposed-to-toxic-chemicals-in-surgical-smoke#:~:text=The%20estimated%20cost%20of%20using,for%20the%20standard%20electrosurgical%20pencil. (last visited Mar. 10, 2023), Ohio Legislative Service Commission, *SB 161 Fiscal Note & Local Impact Statement*, available at https://www.legislature.ohio.gov/download?key=17773&format=pdf (last visited Mar. 10, 2023); Kreuger, Steven, et al., *The Effect of a Surgical Smoke Evacuation System on Surgical Site Infections of the Spine*, available at https://www.oatext.com/pdf/CMID-3-132.pdf (last visited Mar. 10, 2023); Utah State Legislature, *S.B. 105 Surgical Smoke Evacuation System Requirements Fiscal Note*, available at https://le.utah.gov/~2020/bills/static/SB0105.html (last visited Mar. 10, 2023).
[11] The Joint Commission, *Surgical Smoke Legislation Gaining Traction Across the Country*, Jun. 9, 2021, available at https://www.jointcommission.org/resources/news-and-multimedia/blogs/leading-hospital-improvement/2021/06/surgical-smoke-legislation-gaining-traction-across-the-country/ (last visited Mar. 9, 2023).
[12] Arizona, Colorado, Connecticut, Georgia, Illinois, Kentucky, New York, Oregon, Rhode Island, and Washington.
[13] AORN, *Surgical Smoke-Free OR*, available at https://www.aorn.org/get-involved/government-affairs/policy-agenda/surgical-smoke-free-or (Mar. 9, 2023).
[14] The bill uses the term "licensed facilities," which is defined as hospitals or ambulatory surgical centers (ASCs) licensed under ch. 315, F.S. An ASC is further defined as a facility separate from a hospital, the primary purpose of which is to provide elective surgical care with less than 24 hours' inpatient time, not including facilities which perform abortions or dentistry. Section 395.002(3), F.S.

plume, smoke plume, bio-aerosols, laser-generated airborne contaminants, and lung-damaging dust.

The bill requires hospitals and ASCs to adopt and implement the required policies by January 1, 2024.

The bill provides an effective date of July 1, 2023.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 380 may have a negative fiscal impact on hospitals and ASCs if the hospital or ASC is required to purchase and maintain equipment in order to meet the requirements of the bill.

C. Government Sector Impact:

To the extent that hospitals and ASCs are funded or operated by governmental entities, this bill may similarly have a negative government sector impact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 395.1013 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.